



Institutional Review Board
Standard Operating Procedures
March 2021

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HRP-001 Definitions

1 PURPOSE

1.1 This policy establishes the definitions followed by the human research protection program.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Pre-2018 Requirements: For purposes of this section, the pre-2018 Requirements means this subpart as published in the 2016 edition of the Code of Federal Regulations.

3.2 2018 Requirements: For purposes of this section, the 2018 Requirements means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date of 45 CFR 46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

3.3 Research subject to pre-2018 requirements will not be transitioned to 2018 Requirements.

3.3.1 The pre2018 Requirements shall apply to the following research,

3.3.1.1 Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019

3.3.1.2 Research for which IRB review was waived pursuant to 46.101(i) of the pre-2018 Requirements before January 21, 2019 and

3.3.1.3 Research for which a determination was made that the research was exempt under 46.101(b) of the pre-2018 Requirements before January 21, 2019.

3.4 Access: means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource for the purpose of using, transmitting, or receiving private identifiable information.

3.5 Administer or administration: the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means. (Pharmacy.la.gov)

3.6 Adverse Event (AE): For Veterans Administration (VA) research any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research.

3.7 An AE in research can be any unfavorable or unintended event, including abnormal laboratory findings, symptom or disease, or death associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation and does not necessarily have to be caused by any identifiable aspect of the research.

3.8 Agent: An individual who is an employee is considered to be an agent of LSUHSC-S if the individual is performing institutionally designated activities or exercising institutionally delegated authority or responsibility. This would include, among others, students or volunteers when interacting with human participants for classroom activities that qualify as human research; employees when conducting research with participants or when using or controlling human participant records; and any individual conducting research with participants at LSUHSC-S facilities or for whom LSUHSC-S has responsibility.

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3.8.1 An individual who is not an employee is considered an agent of the organization for purposes of engagement in Human Research when that individual has been specifically authorized to conduct research on behalf of the organization. Examples of individuals who would not be considered agents would be employees when conducting human research while on sabbatical through a separate institution; or employees when conducting research for another entity while acting in a consulting role that is not assigned by LSUHSC-S. However, if data derived from consulting work could reasonably be expected to be used later for university related purposes, the employee would be considered an agent. When an LSUHSC-S researcher conducts a consenting process, he/she is then engaged which makes LSUHSC-S engaged.

3.8.2 Legal counsel has the ultimate authority to determine whether someone is acting as an agent of the organization.

3.9 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.

3.10 Approval Period (Interval): The time period between the first day of IRB approval (Start Date) of a protocol and the last day (End Date) of IRB approval of a protocol.

3.11 Assent: A child's affirmative agreement to participate in research. Mere failure to object is not the same as assent.

3.12 Assurance of Compliance (Human Subjects) or Federalwide Assurance: A legally binding written document that commits an institution to complying with the Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects.

3.13 Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

3.14 Biologic: Any therapeutic serum, toxin, anti-toxin, or analogous microbial drug applicable to the prevention, treatment or cure of disease or injuring.

3.15 Case Report (also called Limited Case Series): A description of the clinical characteristics or treatment(s) provided to a single patient or a small group of patients that share a common condition, which did not involve activities defined as research. (A series of 3 or more case reports requires IRB review).

3.16 Case Report Form (CRF): A printed, optical or electronic document designed to record all the protocol-required information to be reported to the clinical trials sponsor or entered into the research database for each clinical trial participant.

3.17 Certification: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

3.18 Children: Children means under the following:

3.18.1 DHHS and FDA: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

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3.18.2 Louisiana Law: Child means a person under eighteen years of age who, prior to juvenile proceedings, has not been judicially emancipated under Civil Code Article 385 or emancipated by marriage under Civil Code Articles 379 through 384.

3.19 Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.20 Collaborative Study: A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

3.21 Coded Samples: Biological samples that are identified by a code or link to the subjects' identities rather than by a direct identifier such as a name or medical record number. These samples may also be called "linked."

3.22 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:

3.22.1 Involvement in the design, conduct, or reporting of the research.

3.22.2 Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly traded, diversified mutual funds.

3.22.3 Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.

3.22.4 Proprietary interest including, but not limited to, a patent, trademark, copyright, or licensing agreement.

3.22.5 Board or executive relationship, regardless of compensation.

3.22.6 Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

3.22.7 Any other reason for which the individual believes that he or she cannot be independent.

3.23 Continuing Non-Compliance: A pattern of Non-Compliance that shows multiple or repeated instances of noncompliance, particularly after written notice from the IRB that the investigator must take action to correct noncompliance. The multiple or repeated instances of noncompliance may occur on one protocol or on more than one protocol and may occur simultaneously or over a period.

3.23.1 For Veterans Administration (VA) research Continuing Non-Compliance includes a persistent failure to adhere to the legal and policy requirements governing Human Research.

3.24 Corrective Action: An action usually required of the Principal Investigator, which is necessary to reduce the risk to the subjects and/or prevent a recurrence of the reported protocol deviation/violation or other non-compliance. Examples of corrective actions include revision of the protocol and/or consent form, re-consent of subjects, further training of study staff, or formal notification to the appropriate government oversight agencies.

3.25 Department or agency head: means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

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- 3.26 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.
- 3.27 Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
- 3.28 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.
- 3.29 Federal department or agency: refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).
- 3.30 Finding of Non-Compliance: Non-Compliance in fact.
- 3.31 Human Research: Any activity that either:¹
- 3.31.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
 - 3.31.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.
- 3.32 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:
- 3.32.1 Intervention: Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
 - 3.32.2 Interaction: Communication or interpersonal contact between investigator and subject.
 - 3.32.3 Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
 - 3.32.4 Identifiable Private Information: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
 - 3.32.5 Identifiable Biospecimen: A biospecimen for which the identity or the subject is or may be readily ascertained by the investigator or associated with the biospecimen.
- 3.33 Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.
- 3.34 HUD: A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in no more than 8,000 individuals in the United

¹ The terms "Human Subject Research," "Research Involving Human Subjects," "Clinical Research," "Clinical Investigation," "Clinical Study" and similar phrases are considered to be synonyms for the term Human Research.

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States per year. HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in emergencies where the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient. Although the use of a HUD within treatment does not constitute research, the FDA requires IRB approval to be obtained before a HUD can be used in a facility.

3.35 Immediate Family: Spouse, domestic partner; and dependent children.

3.36 Institution: means any public or private entity, or department or agency (including federal, state, and other agencies).

3.37 Institutional Official/ Organizational Official (IO/OO):

3.37.1 Institutional Official (IO): Term utilized by DHHS.

3.37.1.1 The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA)². The IO is often the Vice President for Research.

3.37.2 Organizational Official (OO): Term utilized by AAHRPP.

3.37.2.1 An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, and should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human participants, the responsibilities of an organizational official, and the responsibilities of the IRB or EC and researchers and research staff in protecting research participants. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity³.

3.38 Institutional Profile: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative Studies or Multi-Site Studies.

3.39 Investigation: A searching inquiry for facts; detailed or careful examination.

3.40 Investigator: An individual who conducts a clinical investigation, or other type of research under whose immediate direction a test article or experiment is administered or dispensed to, or used involving, a human subject. In the event of an investigation conducted by a team of individuals, the principal investigator is responsible leader of that team.

3.41 IRB: means an institutional review board established in accord with and for the purposes expressed in this policy.

² <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html>

³ AAHRPP Evaluation Instrument (2018-10-15); <http://www.aahrpp.org/apply/web-document-library/domain-i-organization>

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- 3.42 IRB approval: the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.
- 3.43 Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- 3.43.1 If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
- 3.43.2 See "SOP: LARs, Children, and Guardians (HRP-013)" for who may serve as a Legally Authorized Representative at this institution.
- 3.44 Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.⁴
- 3.44.1 For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- 3.44.2 When following Department of Defense regulations, the definition of minimal risk based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).
- 3.45 Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.
- 3.46 Non-Committee Review: Any of the following:
- 3.46.1 Determination of whether an activity is Human Research.
- 3.46.2 Determination of whether Human Research is exempt from regulation.
- 3.46.3 Reviews of non-exempt research using the expedited procedure.
- 3.46.4 Determinations of which subjects can continue in expired research.
- 3.46.5 Concurrence of IRB Chair or designee for non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) or non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.
- 3.47 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.

⁴ The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

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3.47.1 In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements

3.47.2 In the case of Veterans Administration (VA) research, Non-Compliance is any failure to adhere to the requirements for conducting VA research covered by the VHA Handbook.

3.48 Participating Site (pSite): An institution that participates in a Single IRB (sIRB) Study.

3.49 Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

3.49.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.

3.50 Public health authority: means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a 5 person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

3.51 Related to the Research: A financial interest is Related to the Research when the interest is in:

3.51.1 A sponsor of the research

3.51.2 A competitor of the sponsor of the research

3.51.3 A product or service being tested or

3.51.4 A competitor of the product or service being tested

3.52 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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3.53 Research as Defined by FDA: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

3.53.1 Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug during medical practice

3.53.2 Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device OR

3.53.3 Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

3.54 Restricted: Applies to investigators who are delinquent in meeting IRB requirements.

3.55 Serious Non-Compliance: Non-Compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; significantly decreases potential benefits; or compromises the integrity of the Human Research protection Program (HRPP).

3.55.1 For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.55.2 For Veterans Administration (VA) research Serious Non-Compliance is any failure to adhere to requirements for conducting Human Research that may reasonably be regarded as:

3.55.2.1 Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

3.55.2.2 Substantively compromising a Veterans Administration (VA) facility's human research protection programs (HRPP).

3.56 Single IRB (sIRB) Study: A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.

3.57 Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

3.57.1 For Veterans Administration (VA) research, Suspension of IRB Approval:

3.57.1.1 Refers to a temporary interruption in selected research activities (e.g., new enrollments or specific interventions) due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action was taken by an investigator, facility official, research review committee, or external entity.

3.57.1.2 Does not refer to interruptions in research for other reasons, including the expiration of project approval periods.

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3.58 Systematic: Having or involving a system, method, or plan

3.59 Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

3.59.1 For Veterans Administration (VA) research, Termination of IRB Approval:

3.59.1.1 Refers to a permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action was taken by an investigator, facility official, research review committee, or external entity.

3.59.1.2 Does not refer to interruptions in research for other reasons, including the expiration of project approval periods.

3.60 Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.

3.60.1 For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions:

3.60.1.1 Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

3.60.1.2 Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

3.60.1.3 Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has occurred.

3.60.2 For Veterans Administration (VA) research:

3.60.2.1 Unanticipated Problem Involving Risks to Subjects or Others would include any serious problem or local serious adverse event (SAE) that is both unanticipated and related to the research.

3.60.2.2 The term “serious problem” include a problem in human research or research information security that may reasonably be regarded as:

3.60.2.2.1 Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or

3.60.2.2.2 Substantively compromising a Veterans Administration (VA) facility’s human research protection program (HRPP) or research information security program.

3.60.2.3 The term “serious adverse event” refers to an untoward occurrence in human research that results in death, a life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, congenital abnormality, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such outcome.

3.60.2.4 The terms “unanticipated” and “unexpected” refer to an event or problem in human research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol documents and the characteristics of the study population.

3.60.2.5 The term “related” means the problem may reasonably be regarded as caused by, or probably caused by, the research.

3.61 Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

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4 RESPONSIBILITIES

- 4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.
- 4.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

5 PROCEDURE

- 5.1 None

6 MATERIALS

- 6.1 SOP: LARs, Children, and Guardians (HRP-013)

7 REFERENCES

- 7.1 45 CFR 46
- 7.2 21 CFR 50.3; 21 CFR 56.102; 21 CFR 312.3; 21 CFR 812.2(a); 21 CFR 812.3(p)
- 7.3 [VHA Handbook 1058.01; VHA Directive 1058, dated March 28, 2017](#)
- 7.4 AAHRPP I.1.A.; I.1.B.; I.1.F.

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HRP-002 Education

1 PURPOSE

- 1.1 This policy establishes the procedure for educating Louisiana State University Health Sciences Center at Shreveport (LSUHSC-S) Institutional Review Board (IRB) members, IRB staff, investigators, and site research staff to ensure adequate training in human research protection and qualifications and credentialing of all staff.
- 1.2 The policy begins when the individual becomes an IRB member or is engaged in LSUHSC-S human subjects research.
- 1.3 The guidance ends when the individual's involvement with LSUHSC-S human subjects research ceases.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The LSUHSC-S HRPP offers comprehensive human research protection education to the LSUHSC-S research community and affiliate organizations.
- 3.2 Education is offered in many areas of research, including ethical standards, LSUHSC-S policies and procedures, and applicable federal, state, and local law. The foundation of ethical training at LSUHSC-S is the Belmont Report, which is made available through the IRB website and the Collaborative Institutional Training Initiative (CITI) website.
- 3.3 IRB members, IRB staff, investigators, and all site research staff involved in the design, conduct, or reporting of research are required to complete initial education and training on human subject protection and refresher courses, as applicable.
 - 3.3.1 Investigators should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications through up-to-date curriculum vitae, CITI training certificates and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
 - 3.3.1.1 Principal Investigator: This Institution will allow a faculty or senior staff to serve as the Principal Investigator on a research project involving human subjects in their field of expertise. Adjunct and Gratis faculty members are approved by the IRB chair IO or designee on a case by case basis in consultation with HRPP Counsel and Human Resources.
 - 3.3.1.2 Student Investigators: This Institution allows students and/or medical residents and fellows to act as Principal Investigators in specific human subject research as follows: investigator initiated retrospective review of data, documents or specimens and minimal risk survey research. They are required to obtain a Faculty Advisor for guidance. The Faculty Advisor is required to be listed as part of the research personnel (staff) of the study and to complete human subject research online training courses. Students, medical residents, or fellows may not serve as the principal investigator for any research that is determined to be greater than minimal risk.
 - 3.3.2 IRB approval will not be granted for proposed research in which members of the research team have not completed the required human research protections training.

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3.3.3 Initial training and education requirements and refresher updates including timeframes is specified for IRB members, IRB staff, and site research staff.

3.4 All educational requirements by all site research staff must be met for IRB study approval (initial and continuation).

3.4.1 If site research staff education requirements are not fulfilled, the study is not approved until all site research staff meets requirements.

3.5 Monitoring of education requirements of IRB members, IRB staff, and all site research staff is performed regularly as applicable to the role.

4 RESPONSIBILITIES

4.1 IRB staff performs these procedures.

4.2 IRB members, IRB staff, and all site research staff must fulfill the required training and information requirements set forth in this guidance.

4.3 Investigators ensure that site research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.

4.4 IRB staff monitors investigator and site research staff education requirements during the initial IRB review process and during the continuation request process.

5 PROCEDURE

5.1 Education Planning

5.1.1 Before the beginning of a new IRB Year (July 1), the IRB reviews and updates this IRB education guidance as needed.

5.1.2 The IRB incorporates input received from IRB members, IRB staff, and investigators and from monitoring and evaluation activities. Trends in research at LSUHSC-S are considered and new federal, state, or local regulations (or published guidance) are integrated. Compliance activities (e.g., internal, and external audits) also provide input into the education plan.

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5.2 Required Initial and Continuing Training:

5.2.1 Institutional Official Required Training:

Institutional Official Required Training		
	Course	Timeline
Initial Courses	CITI IRB Members Basic	Within 30 days of appointment
	CITI Conflict of Interest	Within 30 days of appointment
	CITI Good Clinical Practice	Within 30 days of appointment
	CITI Health Information Privacy & Security	Within 30 days of appointment
	CITI Institutional/Signatory Official: Human Subject Research	Within 30 days of appointment
	Undue Foreign Influence: Risks and Mitigations	Within 30 days of appointment
Refresher Courses	CITI IRB Members Refresher	Every 3 years
	CITI Conflict of Interest	Every 4 years or upon change
	Undue Foreign Influence: Risks and Mitigations	Every 3 years

5.2.2 IRB Members Required Training:

IRB Members Required Training		
	Course	Timeline
Initial Courses	CITI IRB Members Basic	Within 45 days of appointment
	CITI Conflict of Interest	Within 45 days of appointment
	CITI Good Clinical Practice	Within 45 days of appointment
	CITI Health Information Privacy & Security	Within 45 days of appointment
	IRB Member Orientation	Prior to Voting and Review Assignments
	Undue Foreign Influence: Risks and Mitigations	Within 45 days of appointment
Refresher Courses	CITI IRB Members Refresher	Every 3 years
	CITI Conflict of Interest	Every 4 years or upon change
	Undue Foreign Influence: Risks and Mitigations	Every 3 years

5.2.3 IRB Staff Required Training:

IRB Staff Required Training		
	Course	Timeline
Initial Courses	CITI Biomedical Research Basic	Within 14 days of appointment
	CITI Conflict of Interest	Within 14 days of appointment
	CITI Good Clinical Practice	Within 14 days of appointment
	CITI Health Information Privacy & Security	Within 14 days of appointment
	Clinical Trial Billing Compliance (Required for CTMT Team only)	Within 14 days of appointment
	Undue Foreign Influence: Risks and Mitigations	Within 14 days of appointment

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Refresher Courses	CITI Biomedical Refresher	Every 3 years
	CITI Conflict of Interest	Every 4 years or upon change
	Undue Foreign Influence: Risks and Mitigations	Every 3 years

5.2.4 Investigator and Site Research Staff Required Training:

Investigator and Site Research Staff Required Training		
	Course	Timeline
Initial Courses	CITI Biomedical Research Basic	Prior to IRB Submission
	CITI Conflict of Interest	Prior to IRB Submission
	CITI Good Clinical Practice	Prior to IRB Submission
	CITI Health Information Privacy & Security	Prior to IRB Submission
	Undue Foreign Influence: Risks and Mitigations	Prior to IRB Submission
Refresher Courses	CITI Biomedical Refresher	Every 3 years
	CITI Conflict of Interest	Every 4 years or upon change
	Undue Foreign Influence: Risks and Mitigations	Every 3 years

Investigator and Research Staff involved in Non-Clinical Studies (Surveys, Qualitative, Educational, Record Reviews) Required Training		
	Course	Timeline
Initial Courses	CITI Biomedical Research Basic or CITI Social and Behavioral Research Basic	Prior to IRB Submission
	CITI Conflict of Interest	Prior to IRB Submission
	CITI Health Information Privacy & Security	Prior to IRB Submission
	Undue Foreign Influence: Risks and Mitigations	Prior to IRB Submission
Refresher Courses	CITI Biomedical or Social & Behavioral Refresher	Every 3 years
	CITI Conflict of Interest	Every 4 years or upon change
	Undue Foreign Influence: Risks and Mitigations	Every 3 years

5.2.5 New LSUHSC-S employees may use previously completed CITI human subject protections training from their prior institution if within the applicable timeframe.

5.2.5.1 There may be additional protocol-specific educational requirements or certification required for investigators and site research staff based on additional regulations (e.g., [Department of Defense \[DoD\]](#) or sponsor requirements, due to the complexity and risk of the research).

5.3 Training and Education Records:

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5.3.1 All IRB-required education records and appropriate certificates of completion are maintained by the investigator. Individual investigators maintain their own training records and provide to the IRB as required.

5.3.2 IRB staff will be given access to the CITI online education certificates of completion for all individuals covered by this policy.

5.4 Each investigator will complete the minimum required, mandatory, CITI education module - "Conflict of Interest mini-course" and then register in SHIELDS to complete their COI disclosure and submit study application in IRB SHIELDS.

5.4.1.1 The IRB staff will verify completion of other mandatory CITI education required as per the type of the protocol submitted by the investigator to the IRB. If they submit a "Not Human Subject Research" protocol (such as QI/case series), they would not be required to complete the other CITI modules (such as Biomedical, GCP, HIPS, Social and Behavioral or Undue Foreign Influence: Risks and Mitigations), unless the IRB determines that their project is "Human Subject Research". The IRB staff will notify the investigator if his CITI education is incomplete.

5.5 Ongoing education will be provided to IRB members at convened meetings. Additionally, the educational information will be distributed to all members through email.

5.6 LSUHSC-S faculty or employees that are also IRB members will complete a COI disclosure through the electronic system in addition to the other requirements specified in SOP: Conflicting Interest of IRB Members (HRP-050) and Worksheet: IRB Member and Consultant COI (HRP-325).

6 MATERIALS

6.1 SOP: Conflicting Interest of IRB Members (HRP-050)

6.2 Worksheet: IRB Member and Consultant COI (HRP-325)

7 REFERENCES

7.1 AAHRPP I.1.E.

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HRP-003 HRPP Organization

1 PURPOSE

- 1.1 LSUHSC-S ensures that the Human Research Protection Program (HRPP) has resources sufficient to protect the rights and welfare of research participants for the research activities that the Organization conducts or oversees.
- 1.2 This procedure establishes the process that allow the Institutional Review Board (IRB) to function independently of other organizational entities in protecting research participants.
- 1.3 This procedure establishes the process to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of a mission statement; ethical principles; policies and supporting SOPs; and various individuals and committees such as: the IO, the Vice Chancellor for Research, the Assistant Vice Chancellor for Research Management, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Bio-safety Committee, Radiation Safety Committee, Pharmacy and Therapeutics Committee, Radioactive Drug Research Committee, Conflict of Interest Committee), investigators, IRB staff, HRPP staff, Clinical Trials Office (CTO) including research staff, health and safety staff (e.g., Hospital Safety Officer Research Compliance Specialist, Privacy Officer) and research pharmacy staff. The objective of this system is to assist the Institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research. The following officials, administrative units and individuals have primary responsibilities for implementing the HRPP:
 - 3.2 Chancellor: The Chancellor is responsible for the overall operations at LSUHSC-S. The Chancellor may retain the responsibilities of IO, or may delegate the ultimate responsibility and authority of the HRPP.
 - 3.3 Institutional Official (IO): The ultimate responsibility of the HRPP resides with the Vice Chancellor for Research who serves as the Institutional Official (IO). The IO is responsible for ensuring that the Institution's HRPP has the resources and support necessary to comply with all Institutional policies and with applicable Federal regulations and guidelines that govern human subject research. The IO is legally authorized to represent the Institution and is the signatory of the FWA, and assumes the obligations of the FWA.
 - 3.4 Assistant Vice Chancellor for Research Management: The Assistant Vice Chancellor for Research Management (AVCRM) reports to the Vice Chancellor for Research and is responsible for the duties below. These duties, or portions thereof, may be delegated to a responsible party as deemed appropriate by the AVCRM, the Vice Chancellor for Research or the IO.
 - 3.4.1 Developing, managing and evaluating policies and procedures that ensure compliance with all state, federal, and local regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protections and overseeing all aspects of the HRPP program.
 - 3.4.2 Advising the Institutional Official (IO) on key matters regarding research at the Institution.
 - 3.4.3 Implementing the institution's HRPP policy.
 - 3.4.4 Submitting, implementing and maintaining an approved FWA through the Institutional Official (IO) and the Department of Health and Human Services Office of Human Research Protections (OHRP)

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- 3.4.5 Providing information to the IO regarding the needs and resources required for the HRPP operation.
- 3.4.6 Serving as the primary contact at LSUHSC-S for the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies.
- 3.4.7 Assisting the investigators in their efforts to carry out the Institution's research mission.
- 3.4.8 Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate for the purpose of managing risk in the HRPP.

3.5 HRPP Staff

- 3.5.1 Institutional Official (IO) designee is responsible for:
 - 3.5.1.1 Advising the Institutional Official (IO) on key matters regarding research at the Institution.
 - 3.5.1.2 Implementing the institution's HRPP policy.
 - 3.5.1.3 Assisting the investigators in their efforts to carry out the Institution's research mission.
 - 3.5.1.4 Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate for the purpose of managing risk in the HRPP.
- 3.5.2 IRB Director: reports directly to the AVCRM and indirectly to the IO.
 - 3.5.2.1 Advises the AVCRM on day to day operations of the IRB.
 - 3.5.2.2 Ensuring constructive communication concerning HRPP, IRB and Clinical Trial Office(CTO) matters among the officials of the Institution, investigators, clinical care staff, and human subjects as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
 - 3.5.2.3 Assist the AVCRM in developing, managing and evaluating policies and procedures that ensure compliance with all state, federal, and local regulations governing research. This includes monitoring changes in regulations and policies that relate to human research protections and overseeing all aspects of the HRPP program.
 - 3.5.2.4 Assisting investigators in their efforts to carry out the Institution's research mission.
 - 3.5.2.5 Developing and implementing needed improvements and ensuring follow-up of actions, as appropriate, for the purpose of managing risk in the research program.
 - 3.5.2.6 Developing training requirements as required and as appropriate for investigators, subcommittee members and research staff, and ensuring that training is completed on a timely basis.
- 3.5.3 HRPP Educator & Participant Outreach Coordinator: The HRPP Educator & Participant Outreach Coordinator is responsible for:
 - 3.5.3.1 Developing, coordinating, and implementing the LSUHSC-S comprehensive education program for the protection of human participants in research, GCP, investigator responsibilities, IRB and regulatory reporting.
 - 3.5.3.2 Assuring that all components of the education program are in strict compliance with federal and state regulations and Institutional policies governing human research.
 - 3.5.3.3 Assists the IRB Director and/or AVCRM in determining that all initial and biannual certification requirements have been met by all members of the IRB and IRB staff; Investigators and research staff; and students engaged in research involving human subjects.
 - 3.5.3.4 The development and implementation of educational materials (manuals for faculty, staff, and investigators; newsletters; web updates; announcements).
 - 3.5.3.5 The development and implementation of outreach resources and educational materials for research participants, prospective research participants and community members. 6. Participating in the periodic evaluation of community outreach activities. This Coordinator is supervised by the IRB Director and evaluated annually as per Institutional policy.
- 3.5.4 HRPP Quality Assurance/Quality Improvement Coordinators (QA/QI Coordinators): The HRPP Quality Assurance/Quality Improvement Coordinators oversee and ensure that research conducted at the Institution is

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in compliance with research regulations applicable to human subjects. In this capacity, the QA/QI Coordinators are responsible for

3.5.4.1 developing and implementing policies and procedures to ensure compliance with research regulations and requirements;

3.5.4.2 conducting training and education regarding research compliance topics; and (3) conducting audits and monitoring research activity.

3.5.4.3 The QA/QI Coordinators serve as ex-officio guests of the IRB to provide information regarding routine or for cause audits, monitoring activities, compliance deviations and violations and assist with corrective measure(s). The HRPP Quality Assurance/Quality Improvement Coordinators evaluate and implement measures to improve Human Research Protections in compliance with organizational policies and procedures.

3.5.4.4 When Protocol Exceptions and Deviations are deemed to be serious or continuing, (as defined in Section 10 of this manual), the IRB Director (or designee) shall report the Exception or Deviation to the QA Coordinator for review. The coordinator will review/monitor the information and investigate, as needed, and report to the IRB recommendations for a corrective action plan.

3.5.4.5 The QA Coordinators review and investigate all credible complaints and Allegations of Non Compliance that are submitted to the IRB or that have been brought to their attention, and will make a report, as appropriate, to the IRB with recommendation for a corrective action plan.

3.6 Institutional Review Board

3.6.1 LSUHSC-S IRB has one IRB, appointed by the Institutional Official. The IO retains the authority to create or dissolve IRBs. Members of the IRBs are also appointed by the IO. The IRB is one of five (5) LSUHSC-S Research Assurance Committees. The IRB prospectively and retrospectively reviews and makes decisions concerning all human research conducted at its facilities or by its employees or agents, or under its auspices. The IRB is responsible protecting the rights and welfare of human research subjects involved in research conducted under the auspices of the Institution. It discharges this duty by complying with the requirements of the Common Rule and other applicable federal regulations, state regulations, the FWA; and institutional policies. (See Section 2 for a detailed discussion of the nature, role and duties of the IRB).

3.6.2 The LSUHSC-S IRB serves as the IRB of record for LSUHSC-S; **Overton Brooks VA Medical Center; Overton Brooks Research Corporation**; Biomedical Research Foundation-Northwest LA; Ochsner Health System and any other IRB affiliated sites through agreements.

3.7 Counsel for the HRPP

3.7.1 The Institution's Office of Legal Affairs and Organizational Integrity provides advice to the HRPP, the IO and the Institutional Agents, PIs, Investigators, and research staff with respect to laws, regulations, and requirements applicable to Human Subjects Research. This includes interpretation and application of Federal, State and local laws where research is conducted. Counsel is responsible for addressing all of the legal issues arising out of the activities of LSUHSC-S. A representative of the Office of Legal Affairs and Organizational Integrity is available for consultation on issues regarding human subject research and participant protection.

3.8 Department Chair

3.8.1 The Department Chair is responsible for ensuring that the Principal Investigator (PI) is qualified by training and experience to conduct the proposed research. In addition, Department Chairs are responsible for ensuring that the PI has sufficient resources and facilities to conduct the proposed research. Such resources include but are not necessarily limited to personnel, space, equipment, and time. For each proposal submitted to the LSUHSC-S IRB for approval, the Department Chair must certify that they accept responsibility for assuring

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adherence to the federal and state regulations and institutional policies governing the protection of human subject's research, including applicable institutional credentialing requirements. The Department Chair is required to review all proposals before they are submitted to the IRB for review. The signature of the Department Chair indicates that the study is found to be scientifically sound and can reasonably be expected to answer the proposed question.

3.9 The Principal Investigator (PI)

3.9.1 The Principal Investigator bears the ultimate responsibility for the protection of human subjects who participate in research. The PI is expected to abide by the highest ethical standards for developing a protocol that incorporates the principles of the Belmont Report. He/she is expected to conduct research in accordance with the IRB approved research protocol and to oversee all aspects of the research by providing supervision of support staff, including oversight of the informed consent process. All subjects must provide their informed consent and the investigator must establish and maintain an open line of communication with all research subjects within his/her responsibility. In addition to complying with all the policies and standards of the governing regulatory bodies, the investigator must comply with institutional and administrative requirements for conducting research. The PI is responsible for ensuring that all research staff are appropriately qualified and complete all required training prior to initiating research. When investigational drugs or devices are used, the investigator is responsible for providing written procedures for their storage, security, dispensing and disposal. The PI is ultimately responsible for ensuring that no subject is enrolled before IRB approval is issued and any related sponsor agreement is fully executed. This Institution will allow a faculty or senior staff to serve as the Principal Investigator on a research project involving human subjects in their field of expertise. Adjunct and Gravis faculty members are approved by the IRB chair IO or designee on a case by case basis in consultation with HRPP Counsel and Human Resources.

3.9.2 Investigators are expected to:

- 3.9.2.1 Protect the rights and welfare of prospective subjects
- 3.9.2.2 Assume overall administrative responsibilities for all aspects of each IRB-approved research study, conducting the research according to the IRB-approved protocol, maintaining appropriate oversight of the research study and supervision of the research staff, appropriately delegating research responsibilities
- 3.9.2.3 Assure all key personnel under his/her supervision are adequately trained and supervised in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based including mandatory institutional CITI training
- 3.9.2.4 Assure that research duties are delegated to individuals who are qualified to perform the assigned tasks and informing research staff of any pertinent changes during the course of the study.
- 3.9.2.5 Develop and conduct a research plan that is in accordance with the ethical principles in the Belmont Report.
- 3.9.2.6 Develop a research plan that is scientifically sound and in accordance with the standards of their discipline
- 3.9.2.7 Studies should be in a design that minimizes risks to participants \
- 3.9.2.8 Follow Good Clinical Practice (GCP) guidelines when conducting any study that meets the definition of human subjects' research and involves
 - 3.9.2.8.1 FDA regulated approved or unapproved drugs, devices or biologics or any other FDA regulated product; or
 - 3.9.2.8.2 where the sponsor or funding agency requires the use of GCP guidelines
- 3.9.2.9 Ensure that pertinent laws, regulations, and institutional procedures and guidelines are observed by participating investigators and research staff. Investigators must be knowledgeable about and

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comply with requirements of Common Rule and other federal research laws and regulations, applicable state law, LSUHSC-S FWA, and institutional policies and procedures for protection of human subjects

3.9.2.10 Maintain contact with the sponsor, the monitoring entity if applicable, and receive reports from the sponsor

3.9.2.11 Ensure that every investigator discloses any potential conflict of interest

3.9.2.12 Cooperate with evaluations, inspections, and audits performed by authorized internal oversight authorities, such as the IRB, as well as external reviews (e.g., sponsor or government agency such as FDA)

3.9.2.13 Maintain adequate and accurate records in accordance with 21 CFR 312.62, making those records available for inspection in accordance with 21 CFR 312.68

3.9.2.14 Make a reasonable effort to ascertain the reason for a participant withdrawal from a clinical trial while fully respecting the participant's rights, although the participant is not obliged to give his or her reasons for withdrawing from a clinical trial.

3.9.2.15 The researcher informs the subject's primary physician about the subject's participation in the clinical trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.

3.9.2.16 The researcher will provide evidence of his or her qualifications through up- to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, the regulatory authority.

3.9.2.17 The researcher is familiar with the appropriate use of the investigational, as described in the protocol, in the current investigator brochure, in the product information, and in other information sources provided by the sponsor.

3.9.2.18 A qualified physician (or dentist when appropriate), who is a researcher or a coresearcher for the clinical trial, is responsible for all clinical trial related medical (or dental) decisions.

3.9.2.19 During and following a subject's participation in a clinical trial, the researcher ensures that adequate medical care is provided to a subject for any adverse events, including significant laboratory values, related to the clinical trial.

3.9.2.20 The researcher ensures the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor.

3.9.2.21 The researcher permits monitoring and auditing by the sponsor and inspection by the appropriate regulatory authority.

3.9.2.22 Investigators are expected to comply with IRB

3.10 The Office of Sponsored Programs and Technology Transfer (OSPTT)

3.10.1 The OSPTT reviews grants and contracts involving human subjects. OSPTT works with departments to secure and document departmental commitments. OSPTT acts as the authorized official and single point of contact for grant applications and awards. When a grant involves human subject research, the grant information will be shared with the IRB.

3.10.2 OSPTT processes determine compliance with state, federal, and institutional policies prior to accepting awards. Federal regulations and institutional commitments can change between time of application and the time of the award. The institution reserves the right to accept or reject awards based on reported levels of financial commitment. This institutional review ensures that all terms of award are in compliance with institutional policies.

3.11 When the grant includes human research activities that will be conducted by investigators who are not employees or agents of LSUHSC-S, an agreement or subcontract is executed between LSUHSC-S and the collaborating institution. All agreements and subcontracts are reviewed by the Office of Legal Affairs and Organizational Integrity or LSU Compliance or Assistant Vice Chancellor of Research Management. The agreement

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or subcontract includes the requirement for the collaborating institution to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval. The collaborating institution must also ensure that key personnel involved in human subjects' research are in compliance with other appropriate federal agencies policy on education in the protection of human subjects and provide documentation of education of key personnel to LSUHSC-S.

3.12 Research Pharmacy

3.12.1 All test articles including investigational drugs, devices, biologics and combination products used in human participants research are stored, handled, and dispensed in compliance with regulations or requirements of the FDA, The Joint Commission, Federal and State Boards of Pharmacy, other applicable organizations and in accordance with applicable Hospital, Medical Center and Institutional policies and guidelines.

3.12.2 *Investigators conducting investigational drug research at Overton Brooks VA Medical Center are responsible for following the VA Research and Investigational Drug Policies and Procedures.*

3.12.3 The Research Pharmacy provides services to achieve safe and responsible handling of medications. The main purpose is to maintain control and accountability of medication use in research subjects in order to provide maximum benefit and safety for those participating in research protocols. Pharmacy staff also serve as collaborators in the planning of research protocols to ensure feasibility of implementation.

3.12.4 Ancillary Units Involved in Research All units involved in research may include but are not limited to Lab, Cardiopulmonary, Radiology, Pharmacy, Nursing, Social Services and Others.

3.13 Protocol Specific Coordination

3.13.1 For research conducted under the auspices of the LSUHSC-S IRB, protocol-specific coordination must take place. The Principal Investigator must identify services to be provided by ancillary units within the Ochsner Health System that are above standard of care. These services will require reimbursement to the hospital. Each department/unit that is to provide the service must be identified in the IRB Initial Application Form and appropriate signatures must be obtained on the Cost Analysis (CA) before IRB approval can be made and services obtained. A copy of the Cost Analysis is located in the document library of the electronic IRB data system (Shields) along with the necessary IRB forms.

3.13.2 The Cost Analysis document must be submitted with every proposal. The CA requires PIs to indicate the Institutional support required for the research. The cost analysis process serves to: 1. identify Medicare Qualifying Trials; 2. identify costs to the institution for conducting the research; 3. provide documentation of specific details for services and procedures from the provider of services in collaboration with LSU Health Shreveport in performing clinical research; and 4. identify and document the funding source for all research procedures.

3.13.3 The CA document details the services, procedures, use of the research pharmacy, use of equipment, procedures to be billed to insurance and professional services needed, if any, and the associated costs. The Investigator Financial Attestation page, completed by the PI, will designate the cost of research covered by either the study sponsor budget or departmental funds. A finalized Cost Analysis will be provided to the institution and/or the applicable Professional Billing Service for billing purposes related to the study by the Clinical Trials Management Team. HRPP will provide notice of IRB approval to LSU Compliance and to UH Compliance in order that Compliance may complete a final sign off and approval of the document.

3.14 Relationship between Components

3.14.1 The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction

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over all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects' regulations.

3.14.2 The Institutional Official's Advisory Committee will meet to ensure a dialogue is maintained between the various entities at the Institution. Membership is determined by the Institutional Official, but will include the AVCRM, Office of Legal Affairs and Organizational Integrity, representation from the IRB, among others. The committee will act in an advisory capacity to the IO, monitoring the effectiveness of existing compliance programs, developing new or revised policies as changes in requirements occur, and disseminating updated compliance information to the research community.

3.14.3 Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the Institution. However, those officials may NOT approve research involving Human Subjects if it has been disapproved by the IRB.

4 MATERIALS

4.1 None

5 REFERENCES

5.1 AAHRPP I.1.B.; I.1.C.; I.1.D.; I.1.F.; I.1.G.; I.2.; I.7.B.; I.8.B.; I.8.C.; I.8.D.; I.8.E.; III.1.; III.2.

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HRP-004 Outreach and Community Involvement

1 PURPOSE

- 1.1 This guidance establishes the procedure for enhancing understanding of human research with participants, potential participants, and their communities and conducting outreach activities for increased involvement to human research participants and their communities.
- 1.2 This guidance begins when a human subjects' research study is initiated at LSU Health Shreveport.
- 1.3 This guidance ends when the outcome of the human subjects' research is disseminated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The HRPP ensures the availability of information and resources to improve community awareness and involvement with research at LSUHSC-S to comply with the ethical principal of respect for persons participating in research and maximize their involvement in the research process, including proactive outreach activities.

4 RESPONSIBILITIES

- 4.1 The IO is responsible for ensuring the respect for human participants and their awareness of and involvement in LSUHSC-S research protocols.
- 4.2 Site investigators are responsible for day-to-day assurance of compliance with all aspects of the HRPP, including participant awareness and outreach activities.
- 4.3 Investigators involved in human research protocols are responsible for maintaining respectful interactions with participants, involving research participants at every stage, enhancing appropriate safeguards, answering questions in a complete and sensitive manner, and participating in outreach and educational activities for participants and their communities.

5 PROCEDURES:

- 5.1 Informed consent form/s (ICF) associated with research activities are to be reviewed and approved by the LSUHSC-S Institutional Review Board (IRB) to ensure that procedures are in place to facilitate the ability of research participants to ask questions, express concerns, or voice complaints to the IRB, or investigator.
- 5.2 LSUHSC-S enhances the understanding of human research with participants, potential participants, and communities, as appropriate, using a variety of methods. These include, among others:
 - 5.2.1 Regular communications.
 - 5.2.2 General and specialized research communications available on the institutional website.
 - 5.2.3 Internal resources for investigators to share with the research community on the HRPP website.
 - 5.2.4 Individual and group meetings and presentations.
 - 5.2.5 Hosted events, such as workshops, seminars, and training courses.
- 5.3 To involve and inform current and future research participants, in accordance with the Belmont principle of Respect for Persons, IRB maintains a "Research Participants" page on the LSUHSC-S/HRPP website. This page provides resources for current and future research participants, including:
 - 5.3.1 The opportunity to submit concerns, questions or comments, and receive feedback.

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- 5.3.2 Participant Brochure. See BROCHURE: Should I Take Part in Research? (HRP-104).
- 5.3.3 Links to government websites where research information may be obtained (e.g., OHRP, FDA, NIH).

5.4 For LSUHSC-S investigator-initiated research, investigators incorporate community input as appropriate in the design (including reducing invasiveness), implementation, and dissemination of research. Based on the type of research, investigators may employ one or more of the following methods, among others:

- 5.4.1 Planned community sessions
- 5.4.2 Community advisory groups
- 5.4.3 Participant advocates
- 5.4.4 Partnerships with community-based organizations
- 5.4.5 Community-based participant research design methodologies

5.5 Investigators make available information regarding a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives or their community to discuss concerns, raise questions, obtain information, complaint about the research, or ask questions about rights as a research participant, or provided input on the design of future studies.

- 5.5.1 This information is available to all persons who are going to participate in the human research protocol.
- 5.5.2 Contact information for reporting complaints or concerns is provided in the informed consent, participant brochure, and the LSUHSC-S/IRB website.
- 5.5.3 Research participants are invited via the LSUHSC-S/IRB website to contact the HRPP or IRB staff to provide feedback and/or obtain information about human subjects' research and LSUHSC-S HRPP activities.

5.6 Any form of participant communication received by the HRPP or investigator will be acknowledged and forwarded to the appropriate individual within the organization for handling and follow-up. While a prompt resolution is expected, the timeframe is dependent on the complexity of the complaint or concern.

5.7 Feedback from investigators and other research community members, the consent process, formal and informal evaluations, and audits are used as input for improvements to the LSUHSCS's HRPP program plan, including community awareness and outreach activities.

5.8 The HRPP periodically evaluates its community involvement activities and makes changes, when appropriate, to improve outreach methods; adjust content and materials; and collaborate and educate others on updating such activities.

5.8.1 These evaluations take place in an informal, ongoing manner. HRPP staff will report both positive and negative feedback regarding community awareness and outreach activities to the Assistant Vice Chancellor for Research Management or designee, who tracks the input and recommends changes to improve community involvement.

5.8.2 The Assistant Vice Chancellor for Research Management or designee summarizes the feedback annually to formally evaluate its outreach activities and determine:

- 5.8.2.1 The specific community outreach activities being used; and
- 5.8.2.2 Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these.

6 MATERIALS

6.1 BROCHURE: Should I Take Part in Research? (HRP-104)

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7 REFERENCES

7.1 AAHRPP I.4.B.; I.4.C.

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HRP-005 HRPP Quality Assurance/Quality Improvement Program

1 PURPOSE

1.1 This Standard Operating Procedure defines the Human Research Protection Program (HRPP) Quality Assurance/Quality Improvement function at LSU Health Shreveport.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 AUTHORITY AND SCOPE

3.1 The LSUHSC-S Human Research Protection Program (HRPP) QA/QI Program is under the general direction of the Assistant Vice Chancellor for Research Management and the IRB. The HRPP QA/QI Program includes the following:

3.1.1 Post Approval Monitoring: Conducted based upon selection of the, QA/QI Auditor or at the request of the IRB, Institutional Official or designee. Circumstances where Post Approval Monitoring may occur include, but are not limited to:

3.1.1.1 Monthly selection of active human research studies with enrolled participants;

3.1.1.2 Investigator Initiated Studies (minimal risk and greater than minimal risk);

3.1.1.3 Investigator/Sponsor Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies;

3.1.1.4 Re-assessment of studies previously reviewed to evaluate adherence to corrective action plans and ongoing compliance;

3.1.1.5 Studies assessed by the IRB to include a high degree of risk (adverse events, protocol deviations, type of study, or vulnerable populations); or

3.1.1.6 New, or inexperienced investigator or research staff.

3.1.2 Directed or For-Cause Review: Conducted at the request of IRB, IRB Chair, IRB Director, Institutional Official or designee. Circumstances where a For-Cause Review may occur include, but are not limited to:

3.1.2.1 As part of an ongoing corrective action;

3.1.2.2 To support a review associated with an RNI or IRB's assessment of potential noncompliance including failure to follow the approved protocol, and/or;

3.1.2.3 When there are concerns regarding whether the rights and welfare of participants enrolled in research are adequately protected.

3.1.2.4 When there are concerns about the validity or integrity of the data collected.

3.1.3 Voluntary Reviews: Conducted upon request of Principal Investigator to support self -assessment and improvement efforts by Investigator and Study Team.

3.1.3.1 The investigator may also use Checklist: Investigator Quality Improvement Assessment (HRP-430) to conduct a voluntary self-assessment.

3.1.4 IRB Minutes Review: Conducted quarterly to assure compliance and support the operations of the IRB.

3.1.5 Human Research Protection Program Quality Improvement: Conducted quarterly to track and improve overall satisfaction and institutional compliance with human research protection program requirements.

3.1.6 Non-Institution Institutional Audits and Compliance Reviews

3.1.6.1 External directed (for-cause audits), post-approval monitoring, and voluntary reviews will be conducted at non-LSUHSC-S Institutional sites, where the Institution's IRB serves as the IRB of Record, to assess compliance with federal, state, and local law, research subject safety, and IRB requirements. Directed audits are implemented in response to identified concerns that require an IRB determination. These reviews may include items listed above.

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3.1.6.2 VA Research: Beginning in FY 2009 Veteran Health Administration (VHA) research facilities must conduct audits of informed consent documents for all research studies annually and audits of regulatory documents are performed every three years.

4 RESPONSIBILITIES

4.1 The Quality Assessment/Improvement Team (QA/QI Auditor) is responsible for ensuring these procedures are carried out.

5 PROCEDURE

5.1 Post Approval Monitoring:

5.1.1 Selection and Scheduling:

5.1.1.1 The QA/QI Auditor selects studies as follows:

5.1.1.1.1 From a list of active studies selects from 1-4 each month.

5.1.1.1.2 Through request by the IRB, IRB Chair, IRB Director, Institutional Official or designee, to assess general programmatic compliance with regulatory and institutional requirements based upon specified study characteristics.

5.1.1.2 The QA/QI Auditor contacts the Principal Investigator and Study Coordinator in writing (email) to:

5.1.1.3 Schedule the review in a timely manner;

5.1.1.4 Provide an overview of the scope, process and required workspace needed for the review; and

5.1.1.5 Provide a copy of the Quality Improvement Review Checklist to be used as a general guide for review to the Investigator and Study Coordinator.

5.1.2 Review Procedures:

5.1.2.1 In advance of the review visit, the QA/QI auditor reviews the protocol information on file with the IRB;

5.1.2.2 On the day of the review, the QA/QI auditor will meet with the Investigator and designated study staff at the open and close of the review if possible. The investigator will arrange for a private work area for the conduct of the review. At a minimum, designated study staff should make themselves available for documentation retrieval, answer any questions or provide clarification as may be needed;

5.1.2.3 The investigator will provide the following study files (as applicable) for the QA/QI auditor's review:

5.1.2.3.1 All study related regulatory documents;

5.1.2.3.2 Subject screening/enrollment log;

5.1.2.3.3 Case report forms;

5.1.2.3.4 Source documents;

5.1.2.3.5 Informed consents, assents and HIPAA for all enrolled and screened participants

5.1.2.3.6 Study drug accountability logs (to be reviewed in the Research Pharmacy, as applicable);

5.1.2.3.7 Device accountability logs (as applicable);

5.1.2.3.8 Lab logs (as applicable);

5.1.2.3.9 Other documents/files as requested that support the study administration;

5.1.2.4 Research records are expected to be maintained by study team in a review-ready state at all times. Study team will have an opportunity to locate and provide materials or documentation not present in the files at time of review, but the initial absence of material or documentation will be noted in the findings.

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5.1.3 Findings

5.1.3.1 Finding types may include, but are not limited to:

5.1.3.1.1 No further action necessary;

5.1.3.1.2 Minor administrative issue(s) with best practice or additional education recommendation for corrective action;

5.1.3.1.3 Finding that meets the definition of 'Reportable New Information' with best practice or additional education recommendation for corrective action.

5.1.3.1.4 Major finding indicating potential harm or imminent risk of harm to participants' safety and well-being. These findings will be reported immediately by QA/QI auditor to the HRPP Director and IRB Chair and when necessary to Institutional Official or designee.

5.1.3.1.5 Potential misconduct will also be reported to the Research Integrity Officer in accordance with the LSUHSC-S Policy and Procedures for Dealing with Allegations of Research Fraud.

5.1.4 Documentation and Distribution of Findings

5.1.4.1 The QA/QI auditor will document observations, findings and any concerns.

5.1.4.2 At the conclusion of the review, the QA/QI auditor verbally debriefs the investigator and/or designated study team members regarding findings, applicable recommendations and next steps.

5.1.4.3 The QA/QI auditor generates a written report of findings and recommendations. The written report of findings is shared with the principal investigator, HRPP, IRB Chair and Compliance Committee.

5.1.4.4 The QA/QI auditor submits a copy of the written report into the electronic IRB submission system (Shields) and references all applicable research through the Reportable New Information activity.

5.1.4.5 The investigator is asked to review the written report and provide a response and a corrective action when necessary.

5.1.4.6 In the event the Investigator disagrees with the findings of fact or wishes to provide clarification, the Investigator may provide the rebuttal and/or clarifications, in writing. The provided information and any corrective action plan will be submitted into the electronic IRB submission system (Shields).

5.1.4.7 The investigator is also asked to submit each incident of Reportable New Information found through the audit that has not already been reported to the IRB.

5.1.4.8 Follow-up reviews may be scheduled to confirm ongoing adherence to corrective action recommendation and continued compliance.

5.2 Directed or For Cause Review

5.2.1 Selection and Scheduling

5.2.1.1 The IRB Chair, IRB Director, Institutional Official or designee ("Requestor") may request a directed or for-cause review.

5.2.1.2 The Requestor will notify the HRPP QA/QI auditor of the investigator that is to have a directed or for-cause review. An official notification will be sent to the investigator with a cc to their department chair person. This notice will include the scope, timing, scheduling process and next steps.

5.2.1.3 Unless directed to contact investigator sooner, the QA/QI auditor will contact the investigator by the next business day following receipt of the audit request to schedule the review and will work with investigator and study team to schedule review within the timeline established by the requestor.

5.2.1.3.1 If scheduling and/or completion of audit will not be possible within the established timeframe due to circumstances beyond the investigator's control, the QA/QI auditor will notify the Requestor and request additional guidance.

5.2.1.3.2 As research records are expected to be maintained in an audit-ready state at all times, time needed for record preparation is not an acceptable reason to request delay.

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5.2.2 Review Procedures

5.2.2.1 Review procedures will follow those outlined in 5.1.2, above.

5.2.3 Documentation and Distribution of Findings

5.2.3.1 The report and associated findings are shared with the Requestor, HRPP Director, IRB Chair and the Compliance Committee. The findings are also cc'd to the Investigator and their department chair person.

5.2.3.2 Remainder of Documentation and Distribution of Findings procedures will follow those as outlined in 5.1.4, above.

5.3 Voluntary Reviews

5.3.1 The HRPP makes the Investigator Self-Assessment (HRP-430) available to investigators and study teams;

5.3.2 The Principal Investigator, or study team member with Principal Investigator's support, may conduct a self-assessment or ask for a voluntary review/assistive review by the QA/QI team.

5.3.2.1 The review procedures will follow those outlined in 5.1.2, above.

5.4 IRB Minutes Reviews

5.4.1 The QA/QI auditor or designee reviews the IRB minutes for compliance with HRP-043 IRB Meeting Minutes.

5.4.2 The QA/QI auditor or designee uses the Checklist: Minutes Quality Improvement Assessment (HRP-431) to guide and document the review;

5.4.3 The QA/QI auditor or designee prepares a report of findings, if any, and forwards to the IRB Director and Staff.

5.4.4 The IRB Director or designee develops a corrective action plan if necessary or provides clarification to findings, and communicates the findings and any corrective action plan as appropriate.

5.5 Human Research Protection Program Quality Improvement

5.5.1 Routine Monitoring Trends Assessment

5.5.1.1 On an annual basis or more often if requested by the HRPP Director, Institutional Official or designee, the QA/QI team will provide a report of general trends and findings from the audits to the Institutional Official, HRPP Director, IRB Director, IRB Chair and others as necessary.

5.5.1.2 The QA/QI team and individuals listed in 5.5.1.1 will review the findings and develop corrective and education action plans as necessary.

5.5.1.3 The QA/QI team will monitor the impact of the corrective and education plans on findings and will report outcomes to the individuals listed in 5.5.1.1.

6 MATERIALS

6.1 Checklist: Investigator Quality Improvement Assessment (HRP-430)

6.2 Checklist: Minutes Quality Improvement Assessment (HRP-431)

6.3 HRP-043 IRB Meeting Minutes

6.4 Policy and Procedures for Dealing with Allegations of Research Fraud.

7 REFERENCES

7.1 45 CFR 46.103(b)(5); 45 CFR 46.109(e)

7.2 21 CFR 56.108(b); 21 CFR 56.109(f)

7.3 AAHRPP I.5.

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HRP-006 Research Covered by the HRPP

1 PURPOSE

- 1.1 This Standard Operating Procedure defines research covered by LSUHSC-S.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 LSUHSC-S conducts or oversees biomedical, social science and behavioral research. Human subject research is covered as stated in the Federalwide Assurance for LSUHSC-S and any affiliated organization. All research engaged in at LSU Health Shreveport is covered by the HRPP. The LSUHSC-S HRPP covers all research involving human subjects that is under the auspices of the Institution regardless of funding. The research may be externally funded, funded from LSUHSC-S sources, or conducted without direct funding. An activity is covered by the HRPP when:

- 3.1.1 It is considered human subject research as defined in any one of the following:

- 3.1.1.1 FDA regulations
- 3.1.1.2 DHHS regulations or other Common Rule regulations
- 3.1.1.3 VA regulations (VA Handbook 1200.5) or
- 3.1.1.4 Any other applicable state or local regulations, e.g. Louisiana regulations and

- 3.1.2 LSUHSC-S (or its employees or agents) is engaged research - as defined by being involved in one or more of the following activities:

- 3.1.2.1 Receiving an HHS award for research
- 3.1.2.2 Intervening with participants for research purposes (invasive or noninvasive)
- 3.1.2.3 Manipulating the environment
- 3.1.2.4 Interacting with participants for research purposes
- 3.1.2.5 Obtaining identifiable private information or identified biological specimens from any source for research purposes, according to the OHRP guidance Engagement of Institutions in Human Subjects Research. <http://www.hhs.gov/ohrp/policy/engage08.html>.

- 3.2 Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility, including students, faculty, staff, employees or visiting scholars.

- 3.3 LSU Health Shreveport research affiliate organizations are Biomedical Research Foundation of Northwest Louisiana and Ochsner Health System.

- 3.4 VA Research - Classified research involving human subjects cannot be approved by a VA IRB or R&D Committee or performed at a VA facility, including space leased to, and used by VA.

4 RESPONSIBILITIES

- 4.1 The investigators are responsible for ensuring these procedures are carried out.

5 PROCEDURE

- 5.1 Sponsored Research

- 5.1.1 The HRPP, in collaboration with the LSU Health Shreveport Office of Legal Affairs and Organizational Integrity, is responsible for ensuring that negotiations between LSU Health Shreveport and Sponsors relative to Clinical Investigations that will take place under the purview of LSUHSC-S IRB follow all relevant Federal and State

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laws, rules and regulations and Institutional policies and procedures. The PI cannot commence research and/or otherwise enroll subjects until the IRB has approved the study and, to the extent that the activity is sponsored, a fully executed sponsor agreement is in place between the Sponsor and the Institution.

5.1.2 The Contract Coordinators of the HRPP and AVCRM in collaboration with the Office of Legal Affairs and Organizational Integrity negotiate all contracts for clinical trial research involving human subjects to be conducted at LSU Health Shreveport. Contracts will not be approved by the Chancellor or designee until all institutional requirements have been satisfied. It is both LSU Health Shreveport and the Sponsor's obligation to protect human research participants. All Clinical Trial Agreements (CTA) and Confidential Disclosure Agreements (CDA) must be reviewed and approved by the institution prior to execution.

5.1.3 Definitions

5.1.3.1 Self-Sponsored ("Investigator-Initiated," "Investigator-Sponsored," or "Un-sponsored") - refers to a situation in which the individual Investigator is a LSUHSC-S Investigator and is conducting research without an extra mural sponsor. This happens in such cases as when the PI is the holder of the IND or IDE and therefore assumes the duties of the Sponsor of the clinical Investigator under the applicable FDA regulations.

5.1.3.2 Sponsor - Sponsor means the company, institution, individual donor, or organization responsible for the initiation, management or financing of a research study. Sponsor is responsible for registering the clinical investigation and submitting clinical trial information to the Clinical Trial Registry Data Bank (www.clinicaltrials.gov).

5.1.3.3 Sponsored research - Sponsored research means research funded by external entities through a grant or contract that involves a specified statement of work (e.g., the research proposal) with a related transfer of value to the sponsor, including clinical trials involving investigational drugs, devices or biologics.

5.1.4 Office of Legal Affairs and Organizational Integrity Review

5.1.4.1 The AVCRM and Office of Legal Affairs and Organizational Integrity are designated as institutional representative and are responsible for securing authorized signatures on agreements with Sponsors. They serve as the intermediary between a Sponsor and the PI for purposes of negotiation, budget changes, modifications to an agreement, agreement date extensions, and other administrative matters. In consultation with the PI and/or OSPTT for grants, AVCRM, the Contract Coordinators of HRPP and the Office of Legal Affairs and Organizational Integrity review the clinical trial agreement terms and conditions and the budget before obtaining authorized signatures. They are responsible for ensuring Institutional compliance with the terms and conditions of the agreement, as well as any applicable Federal, State, and Institutional regulations and guidelines. Under special circumstances, electronic signatures/digital signatures may be allowed in lieu of traditional "wet ink" or "handwritten" signatures. An example of such a special circumstance would be the COVID-19 pandemic, which has unexpectedly required institutional and sponsor staff to operate in a remote work environment. This abrupt change has increased the importance of relying on electronic signatures/digital signatures. As per the ESIGN ACT, the electronic signature (or e-signature) can be any "electronic sound, symbol or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record."

5.1.4.2 Elements of Contracts

5.1.4.2.1 Applicable Law - A statement should be included in the standard template or any proposed contract stating all work performed by the Institution under the agreement shall be conducted in accordance with the terms of the Protocol, and consistent with applicable laws and the Institution's policies and procedures.

5.1.4.2.2 HIPAA/Protected Health Information (PHI) - Protecting and maintaining the integrity of patient's protected health information is required of the Institution. LSU Health Shreveport is

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and will always comply with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). A statement reflecting HIPAA compliance should be included in any proposed contract and is in the standard LSUHSC-S template. A statement should also be included by the sponsor on how they will treat LSU Health Shreveport patient’s protected health information. PHI shall only be disclosed to individuals who agree to the terms of the Agreement and who reasonably require such information for the performance of the agreement. PHI should be kept confidential and not be released for any purpose other than authorized by the patient in the Consent document or HIPAA authorization or enumerated in the Agreement.

5.1.4.2.3 Informed Consent/HIPAA Authorization - A statement should be included in the contract stating that a sponsor and IRB approved informed consent form and HIPAA authorization form will be obtained from each study participant, or their legal representative, prior to participation in the Study.

5.1.4.2.4 Indemnification - Studies with pharmaceutical sponsors must provide indemnification coverage and defense of LSU Health Shreveport for performing the study, including its trustees, officers, agents, faculty, and employees for all claims arising from the Institution’s conduct of the study that are not due to negligence or willful misconduct on Institution’s part. The indemnification terms, must at a minimum, cover claims arising from study subject injury or illness caused by the product or protocol and the Institution’s proper conduct of the protocol. Because we are an Institute of the State of Louisiana, the Attorney General of the state shall represent the state and all departments and agencies of state government in all litigation arising out of or involving tort or contract. Language in the contract should state the following:

5.1.4.2.4.1 “Subject to the statutory duties of the Attorney General of the State of Louisiana, Sponsor, as Indemnitor, shall have the right to select counsel and has sole control over the disposition of such claim or suit, provided, however, that the Sponsor shall sign no settlement of Institution’s behalf without first receiving written input from the Institution, and the right to settle any such claim at Sponsor’s sole expense provided that any settlement will not include admission of liability on the Indemnities without their prior written consent.”

5.1.4.2.5 Subject Injury - Prior to the start of any clinical research involving human research participants, arrangements for medical care for research-related injuries are defined within the contract, including who will provide such care and who will be responsible for paying for the care. Also defined is who will determine whether the injury or illness is related to the study drug/procedure. LSU Health Shreveport in conjunction with the Ochsner Health System will provide the medical treatment and care for any illness or injury caused as a result of study drug/study device. Investigator will determine, either by himself, or in consultation with the Sponsor/CRO, if the injury or illness was a direct result of the study drug/study device. LSU Health Shreveport does not expect the Sponsor to pay for subject injury claims if the injury or illness is due to (i) the negligence or malfeasance of the Institution or Investigator (ii) the failure of the Investigator to follow the Protocol, good clinical practices, any applicable laws or regulations, or any IRB approved written instructions by the Sponsor concerning the study. The Patient Informed Consent form should reflect the contract language.

5.1.4.2.6 Insurance: Insurance terms of the Sponsor should be stated in the contract. Sponsor should ensure that it maintains enough insurance to cover any indemnification obligations, product liability or subject injury claims relating to the Agreement. The minimum per occurrence amount and the annual aggregate amount will depend on the risk level of the study. For lower risk studies, the amounts should be \$2,000,000 per occurrence and \$5,000,000 annual aggregate; the higher the risk level for the study, the higher the insurance amounts should be. For evidence of insurance coverage, a certificate of insurance (COI) is requested for each study and the contract will not be sent for final review until the COI has been obtained. LSU Health Shreveport (employees, while acting on behalf of the State of Louisiana) is covered by the Office of Risk Management, State of Louisiana Self-Insurance Fund for general liability

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insurance with limits of \$5,000,000 per occurrence, professional liability insurance with limits of \$5,000,000 per occurrence subject to LA R.S. 40:1237 et seq., and Worker's Compensation Insurance with limits of \$5,000,000. A certificate of insurance is available to Sponsors/CRO's upon request.

5.1.4.2.7 Travel Language: In order for PI and study coordinator staff to travel, LSU Health Shreveport travel language must be included in the clinical trial agreement. The language must reflect that any required travel must (i) either be paid directly to or (ii) on behalf of the travelers. This language must be agreed upon prior to PI and/or coordinator traveling (the entire contract does not have to be agreed upon at this time, just the travel language).

5.1.4.2.8 Safety Concerns/Data and Safety Monitoring Reports: LSU Health Shreveport has an obligation to protect the human subjects participating in human subjects research. In order to help protect subjects, LSU Health Shreveport will need the assistance of the Sponsor/CRO. It is stipulated in the clinical trial agreement that the Sponsor/CRO shall immediately/promptly send reports of any findings of serious or continuing non-compliance detected during the monitoring process to the Institution's HRPP/Organization or Researcher that could: (i) affect the safety of participants (ii) affect the participants willingness to continue study participation (iii) influence the conduct of the study and (iv) alter the IRB's approval to continue the study. Some findings are risks that were not anticipated at the time the study was designed. Participants, past and present, should be notified of these results. The Sponsor/CRO should agree to notify the Investigator and/or the Institution's Human Research Protection Program, who then, will communicate these findings to the participants and IRB as warranted. The Sponsor should be given a time frame after the closure of the study during which they will report such findings to the Institution/Human Research Protection Program. Contracts or other funding agreements require the Sponsor/CRO to send data and safety monitoring plans and reports to the Organization or Researcher who then provides them to the IRB for review within five (5) days of receipt. The contract or funding agreement must specify the time frame for providing routine and urgent data and safety monitoring reports to the Organization.

5.1.4.2.9 Publications: Sponsor recognizes that the results of the Project must be publishable, and agrees that researcher(s) engaged in the Project shall be permitted to present at symposia, international, national, or regional professional meetings and to publish in journals, theses, or dissertations, or otherwise publish through means of their choosing, methods and results of the Project. Sponsor shall be furnished copies of any proposed publication or presentation at least sixty (60) days in advance of the submission of such proposed publication or presentation to a journal, editor, or other third party and shall have the right to review the documents and make suggestions for appropriate changes. Upon request from the Sponsor, the Institution agrees to delete from publication presentation any "confidential information" owned or provided by the Sponsor. LSU Health Shreveport shall be given the rights to publish data as a result of the study. The Sponsor shall recognize under the Institution's policy that the results of the study must be publishable and agrees that the Principal Investigator engaged in the study shall be permitted to present and publish these results. The Principal Investigator shall furnish a copy of the proposed publication or presentation to the Sponsor for review and comment; the Sponsor will then approve the presentation or publication or request additional time/information at which the Principal Investigator will comply. Each pharmaceutical company has its own stipulations for publication rights.

5.1.4.2.10 IRB Fee Schedule: A fee schedule has been developed for the LSU Health Sciences Center – Shreveport Institutional Review Board for Human Research (IRB) for review and approval of study documents. This fee schedule will be reflected either in the body of the contract or in the study budget worksheet.

5.1.4.2.11 Pharmacy Fee Schedule: A fee schedule has been developed for the Research Pharmacy for study drug maintenance. This fee schedule will need to be reflected either in the body of the contract or in the study budget worksheet.

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5.1.4.2.12 Clinical Trial Billing Compliance Fee Scheduled: A fee schedule has been developed for the Clinical Trial Billing Compliance function. This fee schedule will be reflected in either the body of the contract or in the study budget worksheet.

5.1.4.3 Clinical Trial Agreement/Informed Consent Form Review

5.1.4.3.1 Language contained in the Informed Consent Form Document (ICFD) that is completed for Sponsor initiated Clinical Trials shall not contradict the language negotiated in the Clinical Trial Agreement. Certain elements in the ICFD must reflect contract language. These include: (i) Subject Injury language; (ii) Protected Health Information language (PHI); and (iii) Subject Reimbursement for time and travel. It is the responsibility of the Study Coordinator/Regulatory Coordinator to ensure that these elements are reflected in the ICFD. The outlined process is listed below:

5.1.4.3.1.1 Once negotiations for the Clinical Trial Agreement have begun with the Sponsor, if the Regulatory/Study Coordinator does not have a copy of the sponsor ICFD, the Contract Coordinators of the HRPP will provide the sponsor draft ICFD to them.

5.1.4.3.1.2 The Regulatory/Study Coordinator will send the sponsor draft ICFD containing LSUHSC-S required edits to the Contracts Coordinators for review of the following: (i) Subject Injury; (ii) Protected Health Information (PHI); and (iii) Subject Reimbursement. In most cases, the sponsor ICFD will need to be changed to reflect the language proposed for the Clinical Trial Agreement.

5.1.4.3.1.3 An email is sent by the Contract Coordinators of the HRPP to the Regulatory/Study Coordinator outlining the draft ICFD language and the proposed contract language. Sections in the draft ICFD language that are not acceptable to the Institution are highlighted or bolded. The Regulatory/Study Coordinator is instructed to use the proposed contract language for the ICFD (making it read in 5th grade language). It is the department's responsibility to incorporate the changes in the ICF.

5.2 Clinical Trial Agreement Includes Protections for Research Participants

5.2.1 In LSU Health Shreveport sponsored research, LSUHSC-S addresses the protections of research participants by:

5.2.1.1 Including in the standard contract templates a provision that the sponsor acknowledges and understands that the LSUHSC-S HRPP is applicable to all human subject research.

5.2.1.2 Asking for the inclusion of such a provision in any proposed contract that does not use the LSUHSC-S standard template.

5.2.1.3 Including in the cover letter accepting and acknowledging the grant an equivalent statement regarding the HRPP in grants to LSUHSC-S.

5.2.1.4 Ensuring that relevant policies and procedures are made available to sponsors, researchers, research staff, research participants, and the Institutional Review Board(s) as appropriate. Additionally, the IRB will review the proposed consent form and delete any provision that requires a participant to waive or appear to waive any legal rights (i.e., exculpatory provisions).

5.2.2 Communications from Sponsors Affecting IRB Oversight

5.2.2.1 In LSU Health Shreveport sponsored research contracts, LSU Health Shreveport address communication with the sponsors regarding information and findings related to the protocol obtained by the sponsor which could affect the safety of participants or influence the conduct of the study. LSU Health Shreveport requires Sponsors or its agents to report findings of serious or continuous non-compliance detected during the monitoring process that could affect the safety of participants or influence the conduct of the study. This is accomplished by:

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5.2.2.1.1 Including in standard contract templates a provision that the sponsor will notify the Institution or the IRB of:

5.2.2.1.1.1 Non-compliance with the protocol or applicable laws, particularly those laws related to participants, that could impact the safety or welfare of the participants or Serious adverse events that have been reported to the FDA or other governmental agency in relation to the protocol at LSU Health Shreveport or any other site

5.2.2.1.1.2 Unanticipated problems in the protocol at LSUHSC-S or any other site that could relate to risks to participating participants, and

5.2.2.1.1.3 Circumstances that could affect participant's willingness to continue to participate in the protocol or the IRB's continuing approval of the protocol.

5.2.2.1.2 Ask for the inclusion of such a provision in any proposed contract that does not use their standard template.

5.2.2.1.3 The Institution should receive copies of the monitoring reports that contain findings that could affect the safety of participants or influence the conduct of the study. These finding will be made available to the IRB.

5.2.2.1.4 As outlined in the Institutional SOPs researchers must promptly (within five (5) days) report to the IRB any information that could affect the safety of participants or influence the conduct of the study.

5.2.3 Data and Safety Monitoring (DSM) in Sponsored Agreements

5.2.3.1 For sponsored research, LSU Health Shreveport agreements specify that, as appropriate:

5.2.3.1.1 Provisions are made for monitoring study data which could affect the safety of participants

5.2.3.1.2 The results of this monitoring are reported to the researcher (PI) so that:

5.2.3.1.2.1 Routine monitoring reports will be submitted to the IRB in accordance with Institutional Policy

5.2.3.1.2.2 Urgent reports-Events and Information which require Prompt Reporting to the IRB are submitted according to the Institutional policy outline in Section 8 13.8 Publication of Research Results

5.2.4 LSU Health Shreveport establishes the importance of disseminating research findings. LSU Health Shreveport shall be given the rights to publish data as a result of the study. The sponsor shall recognize under the Institution's policy that the results of the study may be publishable and agrees that the PI or engaged in the study shall be permitted to present and publish these results at a mutually agreed upon time. The PI shall furnish a copy of the proposed publication or presentation to the Sponsor for review and comment; the Sponsor will then approve the presentation or publication or request additional time/information at which the PI will comply. Each pharmaceutical company has its own stipulations for publication rights but agrees to provide a copy of the manuscript once accepted for publication.

5.2.4.1 For Sponsored research, LSU Health Shreveport implements this policy in agreements concerning sponsored research by:

5.2.4.1.1 Including in its standard template a provision that provides the investigator with a right to publish the research results.

5.2.4.1.2 Revising any provision in any proposed contract that limits an investigator's right to publish research results in a manner that is inconsistent with the policy.

5.2.5 Communicating Study Findings/Results to Participants

5.2.5.1 For Sponsored research, LSU Health Shreveport address communication with sponsors regarding the impact of research results on participant health and safety by:

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5.2.5.1.1 Including in their standard contract templates a provision that the sponsor will develop a plan of communication with the PI that is acceptable with the IRB when new findings or results of the protocol might impact the willingness of subjects to continue to participate in the protocol or directly affect their current or future safety or medical care.

5.2.5.1.2 Ask for the inclusion of such a provision in any proposed contract that does not use the LSU Health Shreveport standard template.

5.2.6 Investigators will obtain a copy of the final manuscript from the sponsor and communicate study results to participants in lay language as applicable

5.3 International Research/Transnational Research

5.3.1 The purpose of this policy is to establish guidelines for LSU Health Shreveport or affiliates when conducting human subject research, for which one or all of the sites or participants, are located outside the United States (U.S.), regardless of funding.

5.3.2 LSU Health Shreveport transnational research requirements are consistent with the ethical principles set forth in its HRPP and strive to meet equivalent levels of participant protections for research conducted within the United States. For federally funded research, the regulations of the sponsoring agency apply and the required protections must be provided. This policy is to ensure all human subject research, regardless of whether the research is subject to U.S. federal regulations, will be guided by one of the following statements of ethical principles:

5.3.2.1 The Belmont Report

5.3.2.2 Nuremberg Code

5.3.2.3 The World Medical Association's Declaration of Helsinki

5.3.2.4 Other appropriate international ethical standards recognized by the U.S. Federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects, known as the Common Rule.

5.3.3 The LSUHSC-S IRB will review the research in accordance with the applicable Department of Health and Human Services (DHHS) regulations at 45 CFR 46, and the FDA regulations at 21 CFR 50,56,312,600,612, 812 and International Conference on Harmonization (ICH) Guidelines to the extent ICH encompassed in FDA and OHRP regulations. Recognizing the continued growth of international research, the Office of Human Research Protections (OHRP) has developed an International Compilation of Human Subject Research Protections. OHRP provides this compilation of regulations and guidelines that govern human subject research in other countries, as well as standards from a number of international and regional organizations to support researchers in the conduction of human subject research outside the U.S. The Compilation provides direct web links to each country's key Organizations and laws whenever available. LSUHSC-S HRPP directs researchers to these guidelines and requires their compliance while conducting transnational research.

5.3.4 The document noted below provides an overview of what ethical standards different countries follow and what offices you may need local approval from. To use the compilation, go to page 3 of the document and then click the country of interest.

5.3.4.1 See: OHRP <https://archive.hhs.gov/ohrp/international/HSPCompilation.pdf>

5.3.4.2 For VA research: VA Handbook 1200.05(1) Requirements for the Protection of Human Subjects in Research, 10P9 - Research and Development Conflicts arising between federal or national law and other applicable laws are referred to the LSUHSC-S Department of Legal Affairs and Organizational Integrity In House Counsel for guidance and resolution.

5.4 Principal Investigator Responsibilities for International Research

5.4.1 All LSUHSC-S policies and procedures that are applied to research conducted in the U.S. are also applied to research conducted in other countries as appropriate. In addition, Principal Investigators (PI) should ensure

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that participants outside the U.S. have equivalent protections that participants would be afforded to participants in the U.S.

5.4.2 The PI must obtain LSUHSC-S IRB approval in addition to approval from the local Ethics Committee, should one exist in the host country, in which the research is conducted. If an Ethics Committee or other similar review committee does not exist, then a letter of support from a community leader must be obtained and submitted to the LSUHSC-S IRB. The PI will obtain the letter of support from the facility at which the research is conducted, if applicable.

5.4.3 Investigators are required to be knowledgeable about and comply with local laws while conducting their research and take into account the local customs and cultural context. Care must be taken to ensure that the cultural norms of the host country are respected and that the participants will not suffer adverse consequences from participation, such as being subjected to retaliation from local authorities or local community. The investigator should also consult with researchers familiar with the culture differences of transnational research and become knowledgeable in the different customs, habits, and practices of international study subjects.

5.4.4 Principal Investigators must assist their colleagues from the host country in obtaining a Federalwide Assurance (FWA) if the research is federally funded and requires that the transnational institution receive an approved FWA from the Office of Human Research Protections (OHRP).

5.4.5 Listed below are additional elements the investigator should address prior to IRB review and approval:

5.4.5.1 The qualifications of collaborator(s) at each site.

5.4.5.2 Provide the names and dates of completion of the CITI module on conducting research in an international setting for investigators.

5.4.5.3 Is the investigator providing equivalent protections to US regulations and if federally funded, include the FWA number for each research site.

5.4.5.4 Investigator must be knowledgeable of local laws and cultural context in all locations where research is conducted.

5.4.5.5 Cultural differences that influence study design and the consent process. • The rationale for conducting the study with an international population.

5.4.5.6 Investigator must comply with local laws and adhering to local cultural norms (e.g., customs, socio-economic, political, cultural factors, language and literacy).

5.4.5.7 Research methods appropriately minimize the risks to research participants at the selected sites.

5.4.5.8 Are there any state department warnings that would prohibit travel? Think about potential risks to the research team. Check early and before leaving the US as political or environmental conditions can change at any time.

5.4.5.9 Be sure to allow enough time for additional logistics related to travel (passport, Visas, Immunizations, permits to transport goods into or out of the country).

5.4.5.10 Investigator to consider if biological specimens can be brought back into the US. While designing your protocol you may contact LSUHSC-S Safety Office for guidance.

5.4.5.11 Meaningful Informed Consent- understand and weigh the implications for cultural differences when trying to obtain informed consent, the informed consent process should be based on local cultural norms and laws, quality of translation, local collaborators to assist in explanation

5.4.5.12 Who will translate documents for LSUHSC-S and host country review? • Is there funding to cover the costs of translations?

5.4.5.13 Translator certification will be required for the IRB review.

5.4.5.14 English translated documents must be provided to the IRB for IRB review.

5.4.5.15 Will a translator be required on-site?

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5.4.5.16 Have risks been minimized based on the methods implemented? Low risk in the U.S. does not mean low risk in host country. Asking certain questions may be offensive or responses could place the participant at risk.

5.4.5.17 Does the host country have provisions for research –related injuries? If clinical studies are conducted, available health care may be minimal or non-existent.

5.4.5.18 What is considered Identifiable Data in the U.S. may differ in the host country. Do not collect any data or specimens without knowing the rules. IP addresses are considered identifiable in European countries.

5.4.5.19 Have you obtained the appropriate approvals in the host country to conduct research?

5.4.5.20 Submit your IRB application to the IRB for IRB review and approval at least 8 to 10 weeks in advance of your planned departure.

5.4.5.21 Determine if written agreements are required. Contact the Department of Legal Affairs & Organizational Integrity Contract Coordinator for guidance as needed.

5.4.5.22 HIPAA is a U.S. regulation that does not apply in other countries.

5.4.5.23 Obtain a description of the host country's ethics review and oversight mechanism for participant protection.

5.4.5.24 All federally funded studies must have Federalwide Assurance (FWA) before the study can begin.

5.4.6 When following VA regulations, International Research includes VA-approved research conducted at international sites not within the United States, its territories, or Commonwealths; and includes research where human tissues are sent outside the United States. For VA purposes, International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e. the PI for the study as a whole is not a VA investigator)." The researcher must provide the IRB documentation that the facility director has approved any international research involving the VA.

5.4.6.1 Overton Brooks VA Medical Center does not participate in international research.

5.5 IRB Responsibilities for International Research

5.5.1 LSUHSC-S's IRB review of transnational research adheres to the same policies applied to domestic (US) research, when appropriate. The IRB must have knowledge of the local research context. This level of knowledge is in part based upon the level of risk presented by the research. Additional legal or cultural expertise may be consulted by the IRB during its review, and the IRB will make those determinations required by the laws of the countries in which the research is conducted. This knowledge may also be gained from involving legal or cultural expertise as a consultant to the IRB during its review of the research. In addition, the IRB requires documentation that the host country is aware of the research and has agreed for the research to be conducted in that country. When necessary, the IRB will communicate with the host country's Ethics Committee or similar review committee should one exist.

5.5.2 The IRB must review the Informed Consent document which must be translated into the language understandable by the subjects for accuracy and approval. The translated document must be certified or back-translated and major discrepancies with the English version must be addressed. In some circumstances it may be inappropriate to document consent by using the standard written and signed informed consent document. There also may be different laws regarding determination as to who may serve as a Legally Authorized Representative (LAR) which the IRB must take into account.

5.5.3 If subjects participating in transnational research will be compensated for their participation in the research, the IRB must ensure that the amount to be provided to subjects is appropriate and reflective of the standard of living in the country in which the research is being conducted as to not unduly influence subjects to participate.

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5.5.4 The IRB is responsible for monitoring the research as with all other human subject research under its purview. Any problems encountered with the research should be communicated to the study sponsor, relevant regulatory bodies, and all reviewing IRBs and Ethic Committees as appropriate. Research that is federally funded and FDA regulated must comply with both DHHS and FDA regulations.

5.5.5 When researchers conduct studies in other countries, the IRB that reviews such research will confirm the following when reviewing and approving transnational research

5.5.5.1 The IRB must have the appropriate expertise and knowledge of the country(ies) either through the IRB membership or consultants.

5.5.5.2 The IRB must be knowledgeable about the local laws, regulations, codes, and guidance that govern such research in addition to the cultural context in which the research is conducted. The IRB requires the PI to provide information about the laws and cultural context of other countries in which the research is being conducted.

5.5.5.3 The PI must ensure that all of the research procedures described in the IRB application will be conducted at the foreign site for review by the IRB committee and the committee in the host country.

5.5.5.4 The PI must provide the qualifications of all of the researchers in the IRB application. The IRB will confirm the qualifications of the researchers and research staff for conducting research in that country.

5.5.5.5 When there is a local IRB in the host country where the research is conducted, the researcher and IRBs must agree prior to approval on a process for ensuring that initial review, continuing review, review of modifications, post-approval monitoring, handling of complaints, non-compliance and unanticipated problems involving risks to subjects or others are conducted. Depending upon the risk level and other factors, the IRB would consider the following options: LSUHSC-S can enter into agreements with the other IRB requiring the other IRB to report problems and complaints or the researcher can describe a process for reporting problems and complaints.

5.5.5.6 The IRB must approve the plan provided by the PI regarding informed consent process and document and other language issues

5.5.5.7 Coordination and communication with local IRBs or EC when appropriate

5.5.5.8 All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate.

5.5.5.9 The IRB should ensure that equivalent protections are provided to research in other countries. The IRB should make determinations and decisions based on laws and knowledge of the country in which the research will be conducted. **When following VA regulations and guidance in transnational research the IRB ensures the following:**

5.5.5.9.1 **Permission must be obtained from the chief research and development officer or designee, prior to initiating any VA-approved international research.**

5.5.5.9.2 **The VA facility director must approve any request for permission to conduct international research prior to forwarding it to the chief research and development officer.**

5.5.5.9.3 All international sites must hold an international Federalwide Assurance, and the research, and the research must be approved by the IRB or Ethics Committee of the participating sites listed on the international Federalwide Assurance.

5.6 Approvals Required Before International Human Subject Research Commences

5.6.1 IRB approval is required before research activities may commence. In addition to approval from the IRB, depending on the funding source, either contract finalization or departmental approval is required before research involving human participants can commence, as follows:

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5.6.1.1 Externally funded research (industry-sponsored clinical trials and other clinical research) undergoes a parallel review process but must have an agreed upon agreement in the signature phase prior to IRB submission.

5.6.1.2 Other research requires the approval of a Section Chief, Department Chair and Senior Associate Dean for Clinical Affairs, as appropriate, confirming:

5.6.1.2.1 Scientific and scholarly validity

5.6.1.2.2 Adequacy of resources

5.7 Some protocol-specific situations require additional review and approval by other organizational components, or must meet their standards.

6 MATERIALS

6.1 WORKSHEET: Criteria for Approval (HRP-314)

7 REFERENCES

7.1 45 CFR 46

7.2 21 CFR 50,56,312,600,612, 812

7.3 ICF Guidelines

7.4 [VHA Handbook 1200.5](#)

7.5 AAHRPP I.1.A.; I.3.; I.8.; III.1.

SOP: Observation of Consent Process		
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HRP-012 Observation of Consent Process

1 PURPOSE

- 1.1 This procedure establishes the process to observe the consent process.
- 1.2 The process begins when the IRB determines that the consent process should be observed.
- 1.3 The process ends when the IRB determines that the consent process no longer should be observed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The IRB may consider observation of the consent process when:
 - 3.1.1 The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review.
 - 3.1.2 There are Allegations or Findings of Non-Compliance.
 - 3.1.3 The nature of the research indicates that the consent process can be improved through observation.
- 3.2 The IRB, IO/OO, or designee designates who conducts the observation. The IRB may have the observation conducted by:
 - 3.2.1 IRB staff.
 - 3.2.2 IRB members.
 - 3.2.3 A person recommended by the investigator.
 - 3.2.4 An independent person hired by the IRB but paid for by the investigator's funds.

4 RESPONSIBILITIES

- 4.1 The person designated to conduct the observation of the consent process carries out these procedures.

5 PROCEDURE

- 5.1 Observe the consent process and determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that informed consent was freely given by the subject or the legally authorized representative.
 - 5.1.1 If no, indicate that consent is not legally effective, and the prospective subject may not be entered into the research.
 - 5.1.2 If yes, document in writing that the consent process was observed, and that informed consent was freely given by the subject or legally authorized representative.

6 MATERIALS

- 6.1 AUDIT TOOL WORKSHEET: Consent Process (HRP-336)

7 REFERENCES

- 7.1 45 CFR 46.109(g)
- 7.2 21 CFR 56.109(f)
- 7.3 AAHRPP II.3.F.

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HRP-013 LARs, Children, and Guardians

1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:

- 1.1.1 Legally Authorized Representative
- 1.1.2 Children
- 1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a Legally Authorized Representative.

3.2 When research is conducted in Louisiana the following individuals meet this definition:

A legally authorized representative is an individual or body authorized under Louisiana law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. For the purposes of this policy, a legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian, tutor or curator of the person, but also next-of-kin in the following order of priority: spouse, not judicially separated; adult child (18 years of age or older); any parent, whether adult or minor, for his/her child; adult sibling (18 years of age or older); grandparent, or adult grandchild (18 years of age or older).

3.2.1 LA. C.E. 510(5) "Representative of a patient" is any person who makes or receives a confidential communication for the purpose of effectuating diagnosis or treatment of a patient.

3.2.2 LA. R.S. 44:17(A) (4) "Representative of a patient" means a person who is a parent, tutor, curator, spouse, trustee, attorney, or other legal agent of the patient and who is authorized, by and on behalf of the patient, to exercise any of the patient's rights or privileges.

3.2.3 For research outside of Louisiana a determination of who is a legally authorized representative is to be made with consultation from HRPP legal counsel.

3.3 The participation of children who are wards of the state is approved under:

- 3.3.1 45 CFR 46.406, 45 CFR 46.407 only if 45 CFR 46.409(a) is satisfied, or -21 CFR
- 3.3.2 50.53, 21 CFR 50.54 only if 21 CFR 50.56(a) is satisfied

3.4 Appropriate involvement of pregnant women, fetuses, and neonates pursuant to:

- 3.4.1 45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.206, and 45 CFR 46.207

3.5 Approval of research involving prisoners as participants under the following regulations:

- 3.5.1 45 CFR 46.305 and 45 CFR 46.306

4 DHHS and FDA's Subpart D applies to all research involving children.

4.1 When research is conducted in Louisiana all individuals under the age of 18 years are children, who prior to juvenile proceedings, have not been judicially emancipated under Civil Code Article 385 or emancipated by marriage under Civil Code Articles 379 through 384. Contact legal counsel for more information.

4.2 For research outside Louisiana, a determination of who is a child is to be made with consultation from legal counsel.

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5 Unless the IRB has waived the requirement to obtain consent when research involves children consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care⁵. Before obtaining permission from an individual who is not a parent, contact legal counsel.

6 When research is conducted in Louisiana the following individuals are Guardians.

6.1 LA ChC 116(12.1)(a)(i)(b) “Legal Guardianship” means the duty and authority to make important decisions in matters having a permanent effect on the life and development of the child and the responsibility for the child’s general welfare until he reaches the age of majority, subject to any residual rights possessed by the child’s parents. It shall include but not necessarily be limited to: The authority to consent to marriage, to enlist in the armed forces of the United States, or to major medical, psychiatric, and surgical treatment, to represent the minor in legal actions, to make other decisions of substantial legal significance concerning the minor. The term “legal guardian” means the caretaker in such a relationship.

7 RESPONSIBILITIES

7.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

8 PROCEDURE

8.1 None

9 MATERIALS

9.1 None

10 REFERENCES

10.1 45 CFR 46.102; 45 CFR 46.402

10.2 21 CFR 50.3

10.3 AAHRPP I.1.G.; II.4.B.

⁵ This is the DHHS and FDA definition of “guardian”

SOP: Flexibility Policy		
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HRP-014 Flexibility Policy

1 PURPOSE

- 1.1 This procedure establishes the process for the IRB to determine when research projects are not subject to the terms of the LSUHSC-S Federalwide Assurance.
- 1.2 The process begins when the IRB receives an application or communication regarding a research activity.
- 1.3 The process ends when the Designated Reviewer confirms HRP- 342 – WORKSHEET-Flexibility Policy and submits the determination.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 This policy is limited to studies involving no greater than minimal risk.
- 3.2 Under no circumstances will federally funded or FDA regulated research be reviewed under this policy. Projects that receive federal support are subject to the terms of the LSUHSC-S Federalwide Assurance.
- 3.3 Research projects outside the scope of the FWA and reviewed under the flexibility policy will be afforded protections commensurate with risk as determined by the IRB and institutional policy.
- 3.4 Should the funding status of a study reviewed under this policy change, it is the responsibility of the Principal Investigator to notify the IRB, immediately.
- 3.5 All human subjects research projects conducted or supported at LSUHSC-S or by the institution's faculty, students or employees remain subject to LSUHSC-S HRPP policies and IRB review, whether they qualify for this policy or not.
- 3.6 Inclusion/exclusion of non-federally funded research projects will be at the discretion of the LSUHSC-S Institutional Review Board.

4 RESPONSIBILITIES

- 4.1 The IRB staff and Designated Reviewer carry out these procedures.

5 PROCEDURE

- 5.1 Review all materials
- 5.2 Complete Pre-Review Checklist (all federal departments and agencies must be unchecked)
- 5.3 Complete the Worksheet: Expedited Review: (HRP-313) or Worksheet: Exemption: (HRP-312)
- 5.4 Verify that the research meets all the following criteria: (1) Not federally funded or supported by federal funds; (2) Minimal Risk; (3) Is not FDA regulated and does not include prisoners.

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6 REPORTING REQUIREMENTS

6.1 Research projects reviewed outside the scope of the FWA are not subject to the same federal reporting requirements as federally funded projects. For projects conducted under the flexibility policy, the LSUHSC-S HRPP and IRB follow internal reporting requirements for serious or continuing non-compliance, suspensions, or terminations, or reporting of unanticipated problems involving risk to subjects or others.

6.2 Determinations of serious or continuing non-compliance, suspensions or terminations, or unanticipated problems involving risk to subjects or others made by the HRPP Compliance Committee or the IRB related to research that falls under the scope of the Flexibility Policy are reported to the LSUHS-S Institutional Official and the investigator's Department Chair.

7 CORRECTIVE ACTIONS

7.1 Corrective measures, restrictions or other requirements for research that requires reporting under this policy will be determined by the LSUHSC-S HRPP, IRB or Institutional leadership

8 MONITORING:

8.1 Studies reviewed under this policy will be subject to audit by the HRPP to confirm compliance with institutional policies and that funding status has not changed.

9 MATERIALS

- 9.1 Pre-Review Checklist (Shields)
- 9.2 Worksheet: Expedited Review: (HRP-313)
- 9.3 Worksheet: Exemption: (HRP-312)
- 9.4 Worksheet: Flexibility Policy (HRP-342)

10 REFERENCES

- 10.1 45 CFR 46.101
- 10.2 21 CFR 50.1(a)
- 10.3 AAHRPP II.2.A.; II.2.G.; II.2.I.

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HRP-015 Undue Influence of the HRPP

1 PURPOSE

- 1.1 This procedure establishes the process to manage allegations of undue influence of the HRPP.
 - 1.1.1 Undue influence is defined as a real or perceived action that may influence the review of human subject's research outside of the scientific, regulatory, and ethical principles that guide review of such research. Such action may include, but is not limited to, attempts to influence decisions based upon financial concerns of the Institution or a department; personnel actions such as denying promotion or tenure; or verbal harassment.
- 1.2 This procedure begins when the IO or designee learns of an allegation of undue influence of the HRPP.
- 1.3 This procedure ends when any undue influence of the HRPP has been mitigated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Individuals responsible for business development may not serve as IRB members and may not be involved in daily operations of the review process, and may not discuss business development with IRB members where the discussions might influence or appear to influence review decisions.
- 3.2 Staff may explain written procedures to individuals involved in the review process.
- 3.3 Individuals in the [Institution] may not
 - 3.3.1 Provide information beyond an explanation of written procedures that might influence or appear to influence the review process determinations made as part of the criteria for approval.
 - 3.3.2 Communicate the [Institution]'s financial issues regarding specific protocols to individuals responsible for the review process, aside from relevant information regarding conflicts of interest.
 - 3.3.3 Answer questions about the [Institution]'s business issues posed by individuals responsible for the review process where the answers might influence or appear to influence review decisions.
 - 3.3.4 Attempt to influence the review of human subject's research through real or perceived action on any performance review, promotion or tenure decision of any IRB member, IRB staff or any individual involved in the conduct or review of human subject's research.
- 3.4 When the IRB does not follow written procedures, the [Institution] can require the IRB to re- review the submission and/or disapprove research approved by the IRB.
- 3.5 All individuals in the [Institution] are required to ensure that allegations of undue influence of the HRPP or review process are reported to the [Institutional Official] within 5 days of becoming aware of the allegation.

4 RESPONSIBILITY

- 4.1 The IO or designee carries out these procedures or ensures that others carry them out.

5 PROCEDURE

- 5.1 Gather information to determine the veracity of the report using your discretion regarding the most efficient and effective methods. Methods to gather information can include, but are not limited to:

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5.1.1 Interviews of individuals inside and outside the [Institution]

5.1.2 Review of records inside and outside the [Institution]

5.1.3 Consultation with internal or external entities

5.2 If the report has no basis in fact, document the findings and take no further action under this SOP.

5.3 Take appropriate steps to eliminate the undue influence using your discretion regarding the most efficient and effective methods. Steps may include, but are not limited to:

5.3.1 No action

5.3.2 Verbal counseling

5.3.3 Education

5.3.4 Reassignment of duties

5.3.5 Termination of employment

5.3.6 Evaluate policies and procedures

5.4 Document the findings and actions, if any, related to undue influence of the HRPP.

6 REFERENCES

6.1 45 CFR 46.109(a); 45 CFR 46.109(e); 45 CFR 46.112; 45 CFR 46.113

6.2 21 CFR 56.109(a); 21 CFR 56.109(f); 21 CFR 56.112; 21 CFR 56.113

6.3 AAHRPP I.1.C.

SOP: Separation of Competing Business Interests from IRB Review Functions		
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HRP-016 Separation of Competing Business Interests from IRB Review Functions

1 PURPOSE

- 1.1 To avoid influence on IRB determinations from individuals who are responsible for development activities (including raising funds), that may represent competing business interests, or be in a position to influence programmatic and budgetary decisions and exert undue influence on IRBs or individual IRB members.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Individuals responsible for business development or responsible for raising funds or financial support for LSUHSC-S research, including the Vice Chancellor of Research Affairs, will not serve as voting IRB members or be involved in the day-to-day operations of the human subjects review process.
- 3.2 Senior leadership and department chairs that are also IRB members will not be assigned as designated reviewers or participate in the IRB committee discussion or vote for any research that is submitted by faculty, residents, fellows or students in their departments, divisions or institutes.
- 3.3 Department Chairs must identify any personal financial conflict of interest that he or she has in the research sponsor or in an entity that owns or controls the investigational product that is the subject of the research in addition to any other conflict of interest.
- 3.3.1 When the Department Chair is the investigator the Senior Leadership official responsible for that division will identify any personal financial conflict of interest that he or she has in the research sponsor or in an entity that owns or controls the investigational product that is the subject of the research in addition to any other conflict of interest.
- 3.4 Neither Senior Leadership and Department Chairs, nor any other LSUHSC-S official or committee may approve research that has been deferred or disapproved by the LSUHSC-S IRB, nor apply undue pressure on the LSUHSC-S IRB to reverse a determination.
- 3.5 SOP: Institutional Conflict of Interest (HRP-054) describes policies and procedures designed to ensure that research involving human subjects at LSUHSC-S is conducted without untoward influence resulting from either the University's financial investments or holdings or the personal financial interests or holdings of key institutional leaders.

4 RESPONSIBILITIES

- 4.1 Individuals listed in the above policy and IRB members (regular and alternate) follow these procedures.

5 PROCEDURE

- 5.1 Department chairs are required to review and sign off on all human subjects research proposals being submitted by faculty, residents, fellows or students in their departments. This review occurs prior to IRB submission. Use FORM: Administrative Approval (HRP-220).
- 5.2 When the Department Chair is the investigator the Senior Leadership official responsible for that division will complete: FORM: Administrative Approval (HRP-220).

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5.3 Senior leadership and department chairs that are also IRB members will follow SOP: Conflicting Interests of IRB Members (HRP-050) for any research proposal submitted by faculty, residents, fellows or students in their departments, divisions or institutes.

6 MATERIALS

- 6.1 FORM: Administrative Approval (HRP-220)
- 6.2 SOP: Conflicting Interests of IRB Members (HRP-050)
- 6.3 SOP: Institutional Conflict of Interest (HRP-054)

7 REFERENCES

- 7.1 45 CFR 46.107(e)
- 7.2 21 CFR 56.107(e)
- 7.3 AAHRPP II.1.C.

SOP: Managing Non-Compliance in Human Subject Research		
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HRP-018 Managing Non-Compliance in Human Subject Research

1 PURPOSE

- 1.1 This procedure establishes the process to manage reports of allegations of suspected or actual noncompliance with federal regulations, state laws, Institutional policies, and/or IRB requirements with respect to human subject research.
- 1.2 HHS regulations for the protection of human subjects (45 CFR Part 46) require that institutions engaged in human subject research have in place written procedures for ensuring that incidents related to regulatory requirements under the institution's Federalwide Assurance are promptly reported to the Office of Human Research Protections (OHRP).
- 1.3 These include any serious or continuing noncompliance with the requirements or determinations of the IRB, and any suspension or termination of IRB approval and unanticipated problems.
- 1.4 This process begins when the HRPP or IRB becomes aware of any allegation of noncompliance in human subject research under the auspices of LSUHCS-Shreveport.
- 1.5 This process ends when the noncompliance is managed or the allegation is determined to be unsubstantiated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 This policy applies to faculty, staff, students, residents, fellows and affiliated investigators or other affiliated individuals who are involved in human subjects research being conducted under the auspices of the institution regardless of the location of the research, regardless of the funding source or whether the research is funded or unfunded.
- 3.2 The Institution, which includes the IRB, is expected to comply with Institutional policies as well as all federal regulations and state laws related to the protection of the safety, rights and welfare of human subjects in research.
- 3.3 Noncompliance occurs when research involving human subjects is conducted in a manner that disregards or violates federal regulations, the policies or procedures of the Institutional Review Board (IRB), or institutional policies governing human research. Noncompliance with respect to human research participant protection violates the LSUHSC-Shreveport Federalwide Assurance Registration (FWA) with the Office of Human Research Protections (OHRP). Even in the absence of intent, an unapproved or otherwise noncompliant research activity may place a research participant at unnecessary risk.
- 3.4 The LSUHSC-S IRB will review all complaints, protocol deviations, allegations of noncompliance, findings of serious or continuing noncompliance, and take any necessary action to ensure that the rights and welfare of human subjects are protected.
- 3.5 A Reportable New Information (RNI) Report must be submitted to the IRB when an investigator including LSUHSC-S personnel, the research team, faculty, staff, administration, residents, fellows or students become aware of any noncompliance with respect to a specific study.

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- 3.6 Allegations of noncompliance reported to the Institutional Official or IRB must be investigated and it must be determined whether the allegation has a basis in fact or not.
- 3.7 Investigators are required to respond promptly to any inquiries, correspondence, or directives from either the QA/QI coordinators or the IRB with respect to any allegations of or actual noncompliance. Investigators are also expected to cooperate with any requests for information or any audits or investigations.
- 3.8 Investigators are encouraged to seek the assistance of the LSUHSC-S HRPP QA/QA/QI team to develop a corrective action plan (CAP) to accompany any reports of noncompliance reported to the IRB.
- 3.9 Reports of noncompliance may come in the form of a complaint or from the result of an audit or a monitoring report.
- 3.10 Research participants, participant's family members, and others external to the Institution, including regulatory agencies may also report suspected noncompliance to the IRB or to the Institutional Official. These reports may be in the form of complaints and may be made anonymously.
- 3.11 Reports of research misconduct or Whistleblower reports are subject to different rules and will be referred to the Office of Research or LSUHSC-S Compliance Office if received by the IRB or HRPP.

4 RESPONSIBILITIES

- 4.1 The IRB and the Investigators will carry out the responsibilities as indicated.

5 PROCEDURE

- 5.1 Investigators are required to self-report to the IRB any instances of noncompliance that involves a potential risk to subjects or others, or involves failure to comply with federal regulations, state laws, Institutional policies, and/or requirements or determinations of the IRB or provisions of the approved protocol. See SOP: Reportable New Information Items HRP-029.
- 5.2 Noncompliance that is reported to the IRB by the Principal Investigator will be screened by the IRB Chair, or designee through non-committee review, or the Compliance Committee:
- 5.2.1 To make sure that sufficient information is included for IRB review
 - 5.2.2 To make sure an appropriate corrective action plan is included, when necessary.
 - 5.2.3 To see if immediate action needs to be taken to ensure subject safety
- 5.3 See SOP: New Information HRP-024 for processing the report.
- 5.4 If upon initial review by the IRB Chair or designee it is determined:
- 5.4.1 There is no serious or continuing noncompliance, correspondence will be generated with a determination of noncompliance that is neither serious nor continuing.
 - 5.4.2 The allegation has no basis in fact, correspondence will be generated with a determination of Allegation of non-compliance with no basis in fact.
 - 5.4.3 The noncompliance is serious and/or continuing it will be sent to a meeting of the convened IRB and applicable parts of this policy will apply.
 - 5.4.4 If it is determined that the activity involves research misconduct, the information will be

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referred to the appropriate LSUHSC-S office.

5.5 The IRB Chair or designee or Compliance Committee may request:

5.5.1 Additional information from the PI or from the QA/QI team prior to review by the convened IRB meeting.

5.5.2 The QA/QA/QI team to conduct an inquiry/audit into the allegation.

5.5.3 The QA/QA/QI staff may call upon the expertise within the IRB, HRPP Compliance Committee or outside consultant when conducting the audit.

5.5.3.1 The audit is administrative fact-finding and may be informal or may involve an extensive review of the study records, interviews with the research team, interviews with the complainant, and may include correspondence to the PI or the appropriate person within the institution to obtain additional information.

5.5.4 Correspondence to the PI or the appropriate person within the institution will provide the investigator or the institution with the opportunity to respond to the allegations of suspected noncompliance.

5.6 Upon completion of the initial inquiry into the allegation, the QA/QI staff will prepare a written audit report describing the allegation and the outcome of the audit.

5.6.1 The audit report will be sent to the PI, and submitted to the IRB as a Reportable New Information.

5.6.2 If the allegation involves the IRB or any other component of the institution the QA/QI team will forward the report to the HRPP Director and/or the Institutional Official as appropriate.

5.6.3 If during the audit it appears that activities in question may also involve research misconduct or whistleblowing the allegation will be directed to the appropriate office at LSUHSC-S.

5.7 When required, a corrective action plan will accompany the audit report submitted to the IRB.

5.7.1 The corrective action plan will outline what steps the investigator has taken or will take to resolve the noncompliance and sufficient detail to ensure adequate measures or training is taken to prevent future violations and to prevent such noncompliance from occurring in any current or future clinical research that may be conducted by the research team.

5.7.2 When appropriate, or upon request by an investigator, the QA/QI team will in cooperation with the PI assist in the development of the corrective action plan to accompany audit reports.

5.7.3 The QA/QI team or the investigator may request additional input from the IRB Chair or other representatives of the HRPP.

5.8 If the noncompliance cannot be resolved as described above or an appropriate corrective action plan that is acceptable to the IRB cannot be developed, the IRB has the authority to impose corrective actions and recommend sanctions to the Institutional Official (IO).

6 MATERIALS

6.1 SOP: Reportable New Information Items (HRP-029)

6.2 SOP: New Information (HRP-024)

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7 REFERENCES

- 7.1 45 CFR 46.103.b(5)
- 7.2 21 CFR 56.108 (b)(2)
- 7.3 AAHRPP I.5.D.

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HRP-020 Incoming Items

1 PURPOSE

- 1.1 This procedure establishes the process to triage information submitted to the IRB.
- 1.2 The process begins when any communication is received by the IRB.
- 1.3 The process ends when an IRB staff member determines the appropriate action for the received information.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 None

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 If the item is a request either for this IRB to review for another participating site (pSite) or for this institution to rely on an external IRB, follow “SOP: Site Validation (HRP-803).”
 - 5.1.1 Once the ability to review for the pSite is confirmed, then follow “SOP: Pre-Review (HRP-021).”
 - 5.1.2 Once the ability to rely on an external IRB is confirmed, then follow “SOP: Site Pre-Review (HRP-804).”
- 5.2 If the item is a request for an approval or determination⁶ by this institution’s IRB that does not include other pSites, follow “SOP: Pre-Review (HRP-021).”
- 5.3 If the item is an update to a study for which an external IRB is the IRB or record, follow “SOP: Site Updates (HRP-805).”
- 5.4 If the item is a request to remove a pSite from a Single IRB (sIRB) Study, remove the site by executing the “Update Site Status” activity.
- 5.5 If the item includes new or modified contact information, update the contact information.
- 5.6 If the item includes new or modified training information, update the training information.
- 5.7 If the item is a notification of an emergency use of a test article in a life-threatening situation have a Designated Reviewer follow “SOP: Emergency Use (HRP-023).”

⁶ A “request for an approval or determination” includes approval of new research, response to modifications required to secure approval, continuing review of research, modification to previously approved research, request for study closure, or a determination whether an activity is exempt Human Research or is not Human Research. Submission of an updated list study personnel is not considered a modification of research and is therefore not a “request for an approval or determination.”

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5.8 If the item is an investigator's request to continue subjects in expired research have a Designated Reviewer follow "SOP: Expiration of IRB Approval (HRP-063)."

5.9 If the item does not fit into the above categories:

5.9.1 If the item is a question, concern, or complaint:

5.9.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.

5.9.1.2 Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. If necessary, consult with your supervisor.

5.9.2 Follow "SOP: New Information (HRP-024)."

6 MATERIALS

6.1 SOP: Emergency Use (HRP-023)

6.2 SOP: Expiration of IRB Approval (HRP-063)

6.3 SOP: Financial Conflicts of Interests (HRP-055)

6.4 SOP: New Information (HRP-024)

6.5 SOP: Pre-Review (HRP-021)

6.6 SOP: Site Validation (HRP-803)

6.7 SOP: Site Pre-Review (HRP-804)

6.8 SOP: Site Updates (HRP-805)

7 REFERENCES

7.1 AAHRPP I.4.; I.7.C.; I.9.; III.1.G

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HRP-021 Pre-review

1 PURPOSE

- 1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.
- 1.2 The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study.
- 1.3 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 As part of IRB review, all submissions are reviewed by IRB Staff.
 - 3.1.1 Use WORKSHEET: Pre-Review (HRP-308) to screen submission materials
 - 3.1.2 Identify submissions with missing materials or incomplete information
 - 3.1.3 Identify and document the special determinations that the IRB needs to make to approve research. (For example. waiver of consent, children, prisoners)
 - 3.1.4 Identify, make, and document regulatory determinations that the institution needs to make to approve research (For example, IND/IDE requirements)
 - 3.1.5 Identify any relevant local, state, or international requirements
 - 3.1.6 Arrange for consultation to resolve local, state, or international requirements.
 - 3.1.7 Identify other special review issues.
 - 3.1.8 Determine the likely level of review (Committee Review versus Non-committee Review)
 - 3.1.9 The IRB Staff documents Pre-Review determinations in the electronic system or Checklist: Pre-Review (HRP-401).
 - 3.1.10 The IRB Chair ensures that issues raised by Pre-Review are covered at meetings.
 - 3.1.11 The addition of a site to a previously approved study is considered a modification to previously approved research.
 - 3.2 The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.
 - 3.3 A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.
 - 3.4 For Veterans Administration (VA) research the approval of minor conditions by the IRB chair or designated IRB voting member must be documented in the minutes of the first IRB meeting that takes place after the date of the approval of the minor conditions.
- ## **4 RESPONSIBILITIES**
- 4.1 IRB staff members carry out these procedures.

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5 PROCEDURE

- 5.1 If the submission is a request to use an external IRB follow "SOP: Use of External IRB (HRP-028).
- 5.2 If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date:
 - 5.2.1 Evaluate whether the investigator made the required modifications.
 - 5.2.2 If the investigator made the required modifications, follow "SOP: Post-Review (HRP-052)" to issue an approval.
 - 5.2.3 If the investigator did not make the required modifications or made unrequested modifications, execute the "Request Pre-Review Clarification" activity from the investigator. Offer the investigator the opportunity to correct the submission.
 - 5.2.3.1 If the investigator will correct the submission, have the investigator make changes then execute the "Submit Changes" activity and stop processing the current submission until changes are received.
 - 5.2.3.2 If the investigator will not correct the submission, have the investigator execute the "Submit Changes" activity to resubmit and continue processing.
- 5.3 For all other submissions, complete Pre-Review activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on "WORKSHEET: Pre-Review (HRP-308)" and note all remaining contingencies in the "Final Contingencies" section.
- 5.4 If the information is not complete, contact the investigator by selecting the "Request Pre-Review Clarifications" Activity. Offer the investigator the opportunity to provide additional information.
 - 5.4.1 Continue processing once the investigator responds to the request for additional information.
- 5.5 If the principal investigator is restricted, notify the investigator of IRB policy to not accept new research protocols from restricted investigators. Provide additional information as appropriate to resolve the issues or withdraw the submission and resubmit when complete.
- 5.6 Use Worksheet: Pre-Review (HRP-308).
 - 5.6.1 Select the 'Submit Pre-Review' Activity in the electronic system.
 - 5.6.2 Document any Pre-Review findings and select special determinations in the electronic system or use Checklist: Pre-Review (HRP-401).
 - 5.6.3 Then execute the Pre-Review activity to complete the action.
 - 5.6.4 For a modification Submission:
 - 5.6.5 Review the Pre-Review findings associated with prior approval(s) and revise as needed, considering the items on Worksheet: Pre-Review (HRP-308) and note all remaining contingencies in the Final Contingencies section of the electronic system or the form.
 - 5.6.6 Execute the Pre-Review activity to complete the action
 - 5.6.7 For a Continuing Review Submission:
 - 5.6.7.1 If the submission meets the Closure Criteria execute the Pre-Review Activity and assigned to a Designated Reviewer. Use Worksheet: Study Closure (HRP-335) or electronic equivalent
 - 5.6.7.2 If the Continuing Review Submission does not meet the criteria for closure, then review the finding associated with prior approval(s).
 - 5.6.7.3 Note the pre-review findings as needed and continue processing.
 - 5.6.8 Identify any relevant local, state, or international regulatory requirements related to human research.

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5.6.9 Identify any relevant institutional policy related to human research.

5.6.10 Arrange for consultation, if needed to resolve any policy or regulatory issues.

5.6.11 The 'Manage Ancillary Reviews' activity from the study/submission workspace can be used to provide materials to the consultant as needed.

5.6.12 If the submission is incomplete or requires clarification contact the investigator by selecting the "Request Pre-Review Clarifications" Activity. Offer the investigator the opportunity to make revisions or provide additional information.

5.6.13 Continue processing once the investigator responds to the request for additional information.

5.6.14 If the submission is a new information report determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval or Termination of IRB Approval and process under SOP New Information (HRP-024).

5.7 Evaluate the most likely level of review using "WORKSHEET: Human Research Determination (HRP-310)", "WORKSHEET: Engagement Determination (HRP-311)", "WORKSHEET: Exemption Determination (HRP-312)", "WORKSHEET: Expedited Review (HRP-313)", and/or "WORKSHEET: Criteria for Approval for HUD (HRP-323)" as references:

5.7.1 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow "SOP: Non-Committee Review Preparation (HRP-031)."

5.7.2 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope.

5.7.3 If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, follow "SOP: Non-Committee Review Preparation (HRP-031)" and "SOP: All Emergency Use, and Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review (HRP-023)."

6 MATERIALS

6.1 WORKSHEET: Pre-Review (HRP-308)

6.2 HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)

6.3 SOP: All Emergency Use, and Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review (HRP-023)

6.4 SOP: New Information (HRP-024)

6.5 SOP: Non-Committee Review Preparation (HRP-031)

6.6 SOP: IRB Meeting Preparation (HRP-040)

6.7 SOP: Post-Review (HRP-052)

6.8 WORKSHEET: Human Research Determination (HRP-310)

6.9 WORKSHEET: Engagement Determination (HRP-311)

6.10 WORKSHEET: Exemption Determination (HRP-312)

6.11 WORKSHEET: Expedited Review (HRP-313)

6.12 WORKSHEET: Criteria for Approval for HUD (HRP-323)

7 REFERENCES

7.1 45 CFR 46

7.2 AAHRPP II.2.

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HRP-022 Delegation of Authority Log (DOA)

1 PURPOSE

- 1.1 The purpose of this policy is to outline which study staff are required to be listed on the Delegation of Authority (DOA) Log for all human subject research projects.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 As per the following FDA guidance document: *Guidance for Industry: Investigator Responsibilities –Protecting the Rights, Safety, and Welfare of Study Subjects* <https://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf>, the Principal Investigator (PI) is ultimately responsible for the performance and supervision of a clinical investigation. While the PI may delegate some required tasks to sub-investigators and other research staff, the PI remains accountable for their conduct. The Delegation of Authority Log (DOA) lists all the study staff, including the Investigators and Clinical Research Coordinators (CRCs), and other designated site personnel who are delegated significant trial-related duties from the PI. The DOA Log must be completed for all human subject research projects.

- 3.2 Delegation of Authority log is not addressed in FDA's Federal Regulations (21 CFR 312 and 812); therefore, it is not a federal requirement. However, the investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties. The list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform the delegated tasks, and identify the dates of involvement in the study. A separate list should be maintained for each study conducted by the investigator. It may be a Sponsor requirement and Good Clinical Practice suggests documenting the PI's delegation of tasks to other members of the research team.

- 3.3 Hospital staff, including nurses (for eg. Chemotherapy certified, those who provide only FDA approved drugs and not research related drugs/IND drugs), residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E3, Section 6). The PI or the research study team must consult the IRB staff/IRB Chair prior to deciding which staff must not be included on the Delegation of Authority Log (DOA).

4 RESPONSIBILITIES

- 4.1 The PI and the study team fill out and maintain a DOA log throughout the study.

5 PROCEDURE

- 5.1 Use "HRP-509 - TEMPLATE - Delegation of Responsibility Log" to facilitate the completion of the Staff Signature and Delegation of Responsibility Log. Template provided by Sponsor can be used as well.
- 5.2 Submit it along with initial application.

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- 5.3 When “HRP-503.1 - TEMPLATE – PROTOCOL Existing Data or Specimens” is submitted, “HRP-509 - TEMPLATE - Delegation of Responsibility Log” or a separate DOA log is not required to be submitted since the “HRP-503.1 - TEMPLATE – PROTOCOL Existing Data or Specimens” includes a section which lists the DOA log.
- 5.4 Handwritten signatures must be obtained on the DOA log. Under special circumstances, electronic signatures can be obtained on the DOA log, with prior approval from the IRB Director/IRB Chair. Such requests will be considered on a case by case basis. An example of such a special circumstance would be the COVID-19 pandemic where study team members were working from home or were not available to provide handwritten signatures on the DOA logs.
- 5.5 Start Date must not be filled in when the DOA log is submitted to the IRB. It must be added upon IRB approval with either the date when the DOA log was approved by the IRB or when the Sponsor required training for that study has been completed by the study team member, whichever is later.
- 5.6 A new entry must be made for the study team member when there is a revision to the tasks delegated to him/her or their role is changed on the study.
- 5.7 End date must be filled in when the role of the study team member is complete/or they leave the institution. Then the DOA log must be submitted to the IRB for review.
- 5.8 Under special circumstances and upon consultation with the IRB Director, the procedure for revising a DOA log and obtaining IRB approval can be altered. An example of such a special circumstance would be when the IRB has approved a study with only one CRC and the PI submits a modification to delegate additional tasks to the CRC. The end date is not required to be filled in for the CRC before the IRB approval until the new entry for the CRC with revised delegated task along with the previously IRB approved delegated tasks have been approved by the IRB. In such a case, end date and start date for both entries of the CRC will be the IRB approval date.

6 MATERIALS

- 6.1 HRP-509 - TEMPLATE - Delegation of Responsibility Log

7 REFERENCES

- 7.1 21 CFR 312; 21 CFR 812
 7.2 ICH GCP E6 Guideline Section 4.1.5
 7.3 ICH GCP E3, Guideline Section 6

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HRP-023 All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

1 PURPOSE

- 1.1 This procedure establishes the process to review notifications of:
 - 1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
 - 1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).
 - 1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.
- 1.2 The process begins when the IRB receives a notification of a proposed or actual use.
- 1.3 The process ends when a Designated Reviewer has:
 - 1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and
 - 1.3.2 Notified the physician and IRB staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.
 - 3.1.1 The one-time emergency use of a test article is permitted provided a patient is in a life-threatening situation in which no standard acceptable treatment is available, and when there is not sufficient time to obtain IRB review and approval. Any subsequent use of a test article at the institution shall have prospective IRB review and approval.
 - 3.1.2 The investigator must obtain the informed consent of the participant (or the participant's legally authorized representative), unless the requirements of an exception from the informed consent requirement (21 CFR 50.23(a)) are satisfied. In addition to obtaining informed consent, the protocol director must obtain the HIPAA authorization from the participant (or the participant's legally authorized representative). Exception from the informed consent requirement are listed in CHECKLIST: Waiver of Consent for Emergency Research (HRP-419).
 - 3.1.2.1 If, in the investigator's opinion, immediate use of the test article is required because the patient is confronted by a life-threatening or severely debilitating situation and if time is not sufficient to obtain the independent physician determination that the four conditions above apply, the protocol director should make the determination and, within five working days after the use of the article, have the determination reviewed and evaluated in writing by an independent physician, and submit that evaluation to the IRB.
- 3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device, for the purpose of obtaining concurrence from an IRB Chair.
- 3.3 Emergency uses and device compassionate uses cannot be claimed as research.

SOP: All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

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3.4 Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug “Request for Authorization to Use Alternative IRB Review Procedures” identified on FDA Form 3926 (field 10.b.) or a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee.

4 RESPONSIBILITIES

4.1 A Designated Reviewer carries out these procedures.

4.2 IRB staff processes written communications.

5 PROCEDURE

5.1 Determine if the notification/request is one of the following:

5.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation. If so, use the “WORKSHEET: Emergency Use (HRP-322)” to determine whether the circumstances will meet, or if the use described in the 5-day report have met, the regulatory and guidance criteria for emergency use, and indicate the results of this determination to the IRB staff (or directly to the physician if time sensitive).

5.1.1.1 If the notice is in advance of the use, inform the IRB staff (or physician if time sensitive) that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. Set a 5-day reminder to request the 5-day report.

5.1.1.2 If the actual emergency use described in the 5-day report did not follow FDA requirements, manage use “SOP: New Information (HRP-024)” as Non-Compliance.

5.1.2 Compassionate use of a device. If so, use “WORKSHEET: Compassionate Use of a Device (HRP-325)” to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.

5.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use “WORKSHEET: Criteria for Approval (HRP-314)” to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111⁷ and indicate the results of this determination to the IRB staff.

5.1.3.1 Execute the “Submit Designated Review” activity. In the “Notes” section document that the decision is to concur (or not) is in lieu of review and approval at a convened IRB meeting at which a majority of the members are present per the request for a waiver under 21 56.105 of the requirements in 56.108(c).

5.1.4 If none of the above, stop processing the request and inform the physician or submitter.

5.2 Inform IRB staff of the results of the evaluation.

6 MATERIALS

6.1 SOP: Definitions (HRP-001)

6.2 SOP: New Information (HRP-024)

⁷ “The IRB chairperson (or designated IRB member) would consider the same information that the full IRB would consider, to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use.” Per FDA correspondence dated 10/10/17

**SOP: All Emergency Use, Compassionate Use (Device Only) & IRB Waiver for
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- 6.3 WORKSHEET: Criteria for Approval (HRP-314)
- 6.4 WORKSHEET: Emergency Use (HRP-322)
- 6.5 WORKSHEET: Compassionate Use of a Device (HRP-325)
- 6.6 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)

7 REFERENCES

- 7.1 21 CFR 50; 21 CFR 50.23; 21 CFR 50.24
- 7.2 21 CFR 56.102(d); 21 CFR 50; 21 CFR 56.104(c); 21 CFR 56.111
- 7.3 21 CFR 812.36; 21 CFR 812.47
- 7.4 (FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors) Frequently Asked Questions About Medical Devices: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf>.
- 7.5 Individual Patient Expanded Access Applications: Form FDA 3926 Guidance for Industry; <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm432717.pdf>
- 7.6 AAHRPP I.7.C.; III.1.; III.2.

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HRP-024 New Information

1 PURPOSE

- 1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.
- 1.2 The process begins when the IRB receives an information item.
 - 1.2.1 Information items requiring submission to the IRB are listed on SOP: Reportable New Information Items (HRP-029).
- 1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The Flexibility Policy may be followed when appropriate. See SOP: Flexibility Policy (HRP-014)
- 3.2 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Organizational Official for further action.
- 3.3 The organization will promptly notify the federal department or agency funding the research of any for cause investigation of that research by another federal department or agency or national organization.
 - 3.3.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.
- 3.4 The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.
- 3.5 For Veterans Administration (VA) research:
 - 3.5.1 The determination that Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance must be determined and documented by the convened IRB.
 - 3.5.2 An initial report to the VA Medical Center Director and others of an IRB determination that Serious Non-Compliance or Continuing Non-Compliance is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report.
 - 3.5.3 The convened IRB must review notifications of apparent Serious Non-Compliance, Continuing Non-Compliance, and external Suspension of IRB Approval, or Termination of IRB Approval within 30-45 days after receiving the notification.
 - 3.5.4 The IRB Chair may take interim action on notifications of apparent Serious Non-Compliance or Continuing Non-Compliance as needed to eliminate apparent immediate hazards to subjects.
 - 3.5.5 Remedial actions involving a specific study or research team must be completed within 120 days after the IRB's determination.
 - 3.5.6 Remedial actions involving programmatic Non-Compliance must be completed within 120 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.

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3.5.7 In the context of a multi-center study, internal adverse events are defined as those experienced by subjects, research staff, or others at the reporting individual's own Veterans Administration (VA) facility or Veterans Administration (VA) approved research site. The term "local adverse event" is considered to be synonymous with the term "internal adverse event."

3.5.8 The IRB must review a report of apparent serious or continuing non-compliance at its next convened meeting.

3.5.9 For Unanticipated Problems Involving Risks to Subjects or Others that are local research deaths, they must be reported orally and in writing to the IRB immediately upon becoming aware of the information.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Review each item of information and answer the following questions and complete the Submit RNI Pre-Review Activity: *(See attached flowchart for a diagram of the flow of this procedure.)*

5.1.1 Is this an Allegation of Non-Compliance?

5.1.2 Is this a Finding of Non-Compliance?

5.1.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.2 After completing the Pre-Review Activity assign the New Information item to the IRB chair or designated reviewer.

5.3 If the IRB chair or designated reviewer are unable to answer a question, follow "SOP: Investigations (HRP-025)."

5.4 If the answer is "yes" to one or more questions, then follow the corresponding sections below.

5.4.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.4.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.4.1.2 If no, follow any other corresponding sections.

5.4.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.4.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.4.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.4.3 Non-Serious/Non-Continuing Non-Compliance

5.4.3.1 Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.

5.4.3.2 If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

5.4.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others

5.4.4.1 Confirm your decision with the IRB chair or IRB Director.

5.4.4.2 Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

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- 5.5 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair or IRB Director to consider a Suspension of IRB Approval following the “SOP: Suspension or Termination Issued Outside of Convened IRB (HRP-026).”
- 5.6 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:
- 5.6.1 Confirm that the subject is currently a Prisoner.
 - 5.6.1.1 If the subject is currently not a Prisoner no other action is required.
 - 5.6.2 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner would present risks to the subject.
 - 5.6.2.1 If the subject’s involvement in the research cannot be stopped for health or safety reasons, do one of the following:
 - 5.6.2.1.1 Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.
 - 5.6.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.
 - 5.6.2.2 If the subject’s involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner,
 - 5.6.3 For Department of Defense (DOD) research promptly report all decisions to the Department of Defense (DOD).
 - 5.6.4 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.
- 5.7 If the information involves any of the following, complete and send a “TEMPLATE LETTER: - AAHRPP Notice of Information Item (HRP-529)” to AAHRPP as soon as possible but generally within two days of the receipt of the information, in addition to other applicable procedures listed in this SOP:
- 5.7.1 Negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
 - 5.7.2 Litigation, arbitration, or settlements initiated related to human research protections.
 - 5.7.3 Press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization’s HRPP.
- 5.8 Take any additional actions required to resolve any concerns or complaints associated with the information.
- 5.9 For Veterans Administration (VA) research:
- 5.9.1 If the information represents Unanticipated Problem Involving Risks to Subjects or Others that is a local research death, alert the ORO by email or telephone within 2 business days after receipt of notification with concurrent notification to the VA facility Director and the Associate Chief of Staff/R&D
 - 5.9.2 Within 5 business days of receipt of information that appears to represent an Unanticipated Problem Involving Risks to Subjects or Others, have the IRB Chair or a Designated Reviewer determine and document whether the reported incident was serious and unanticipated and related to the research, and have the IRB Chair or a Designated Reviewer determine and document whether any actions are warranted to eliminate apparent immediate hazards to subjects.

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5.9.2.1 All determinations of the IRB Chair or Designated Reviewer must be reported to the IRB at its next convened meeting.

5.9.2.2 Schedule the Unanticipated Problem Involving Risks to Subjects or Others for the next IRB meeting to be reviewed by the convened IRB.

5.9.2.2.1 If the IRB determines that the problem or event is serious and unanticipated and related to the research, the IRB Chair or designee must report in writing the unanticipated problem or event within 5 business days to:

5.9.2.2.1.1 Facility Director.

5.9.2.2.1.2 Associate chief of staff for research.

5.9.2.2.1.3 The Research and Development Committee.

5.9.2.3 If the IRB determines that the problem or event was serious and unanticipated and related to the research, a simultaneous determination is required regarding the need for any action (e.g., suspension of activities; notification of participants) necessary to prevent an immediate hazard to participants.

5.9.3 If the information appears to represent Serious Non-Compliance or Continuing Non-Compliance, schedule the information for the next IRB meeting to be reviewed by the convened IRB (not to exceed 30 days after receipt of the information).

5.9.3.1 If the IRB determines that the information constitutes Serious Non-Compliance or Continuing Non-Compliance, within 5 business days after the determination, the IRB Chair or designee must provide a written report of the determination directly to:

5.9.3.1.1 Facility Director.

5.9.3.1.2 Associate chief of staff for research.

5.9.3.1.3 The Research and Development Committee.

5.9.3.1.4 The Research Compliance Officer (RCO), if the apparent Serious Non-Compliance or Continuing Non-Compliance was identified by an RCO audit, regardless of the outcome.

5.10 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, complete review and prepare and send letter per SOP: Post-Review (HRP-052).

6 MATERIALS

6.1 SOP: Flexibility Policy (HRP-014)

6.2 FORM: Reportable New Information (HRP-214)

6.3 SOP: Investigations (HRP-025)

6.4 SOP: Suspension or Termination Issued Outside of Convened IRB (HRP-026)

6.5 SOP: Post-Review (HRP-052)

6.6 TEMPLATE LETTER: - AAHRPP Notice of Information Item (HRP-529)

7 REFERENCES

7.1 45 CFR 46.103(b)(5); 45 CFR 46.108(a)

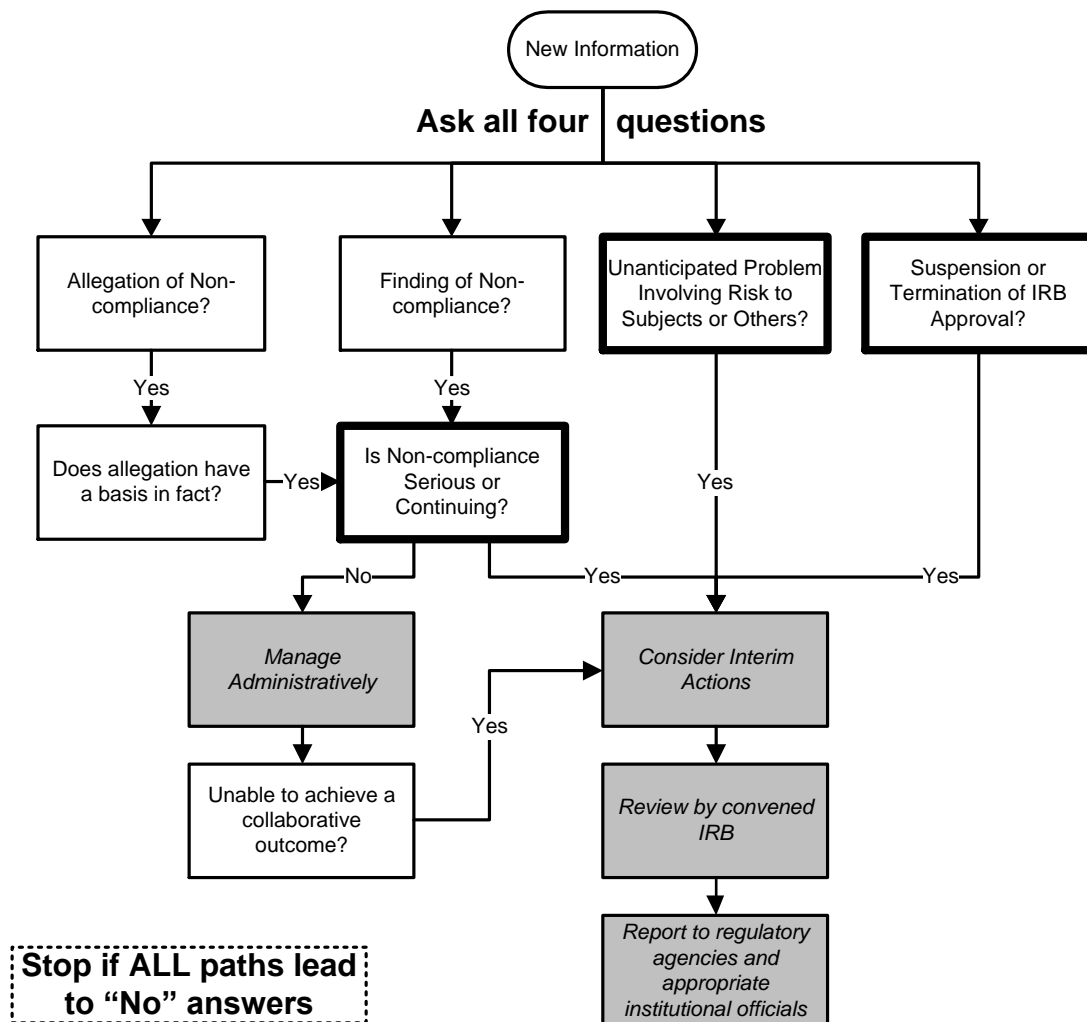
7.2 21 CFR 56.108(b)

7.3 VHA Handbook 1058.01

7.4 AAHRPP I.1.F.; I.4.; I.5.D.; II.2.F.; II.2.G.; II.4.A.; II.4.B.

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8 Flowchart



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HRP-025 Investigations

1 PURPOSE

- 1.1 This procedure establishes the process to conduct investigations.
- 1.2 The process begins when the IRB staff members and chair cannot answer a question required by "SOP: New Information (HRP-024)."
- 1.3 The process ends when the investigation is complete, and the answer has been provided to the Institutional Official/Organizational Official (IO/OO) or IO designee.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 None

4 RESPONSIBILITIES

- 4.1 The IO/OO or IO designee:
 - 4.1.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.
 - 4.1.2 Appoints a chair of the investigative committee.
 - 4.1.3 Charges the investigative committee with the question to be answered.
- 4.2 The investigative committee carries out these procedures within 60 days.
- 4.3 Investigative committee members make their decisions based on a preponderance of the evidence.
- 4.4 Investigative committee decisions are made by majority vote.
- 4.5 Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person's presence is disruptive.

5 PROCEDURE

- 5.1 Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.
- 5.2 Determine what information to gather and what individuals to interview.
- 5.3 Gather information and interview individuals.
- 5.4 If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may request a court stenographer to record all interviews.
- 5.5 Repeat information gathering and interviews until a decision can be made.

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5.6 The investigative committee provides a written report of the investigative committee's decision to the IO/OO or IO designee.

6 MATERIALS

6.1 SOP: New Information (HRP-024)

7 REFERENCES

7.1 AAHRPP I.1.B.

SOP: Suspension or Termination Outside Convened Meeting		
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HRP-026 Suspension or Termination Outside Convened Meeting

1 PURPOSE

- 1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.
- 1.2 The process begins when the Organizational Official / Institutional Official (IO/OO) or IO designee institutes a Suspension of IRB Approval or a Termination of IRB Approval.
- 1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been placed on the agenda for review by the convened IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The IRB chair or IRB Director may institute a Suspension of IRB Approval when in the opinion of the IRB chair or IRB Director subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB. The risk of adverse effects may be due to Non-Compliance with institutional or other regulatory requirements or an Unanticipated Problem Involving Risks to Participants or Others.
- 3.2 The IO/OO or IO designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.
- 3.3 Whenever possible the individual following these procedures communicates with investigators orally and in writing.
- 3.4 Administrative Hold:
 - 3.4.1 An “administrative hold” is a voluntary interruption of research enrollments and ongoing research activities by the research investigator or sponsor.
 - 3.4.2 An administrative hold cannot be used to extend IRB approval beyond the expiration date of a protocol without approval of continuing review.
 - 3.4.3 The term “administrative hold” does not apply to interruptions of research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others.
 - 3.4.4 An “administrative hold” must not be used to avoid reporting deficiencies or circumstances otherwise covered by institutional policies or other regulatory requirements governing research.
 - 3.4.5 An Administrative Hold directed by the IRB is a suspension and must be classified and reported as such.
- 3.5 For Veterans Administration (VA) research:
 - 3.5.1 An “administrative hold” is a voluntary interruption of research enrollments and ongoing research activities by an appropriate VA facility official, research investigator, or sponsor (including the Office of Research and Development (ORD) when ORD is the sponsor).
 - 3.5.2 The term “administrative hold” does not apply to interruptions of VA research related to concerns regarding the safety, rights, or welfare of human research subjects, research investigators, research staff, or others.

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3.5.3 An “administrative hold” must not be used to avoid reporting deficiencies or circumstances otherwise covered by VHA Handbooks or other federal requirements governing research.

4 RESPONSIBILITIES

4.1 The individual instituting a Suspension of IRB Approval or Termination of IRB Approval follows these procedures.

5 PROCEDURE

5.1 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision.

5.2 Ask the investigator for a list of Human Subjects currently involved in the research.

5.3 Ask the investigator whether any actions are required to protect those subjects’ rights and welfare or to eliminate an apparent immediate hazard.

5.4 Consider whether any of the following additional actions are required to protect those or other subjects’ rights and welfare or to eliminate an apparent immediate hazard:

- 5.4.1 Transferring subjects to another investigator.
- 5.4.2 Planning for clinical care outside the research.
- 5.4.3 Allowing continuation of some research activities under the supervision of an independent monitor.
- 5.4.4 Requiring or permitting follow-up of subjects for safety reasons.
- 5.4.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
- 5.4.6 Notification to current Human Subjects.
- 5.4.7 Notification to former Human Subjects.

5.5 For Veterans Administration (VA) research report the Suspension of IRB Approval or Termination of IRB Approval to the VA facility Director, the Associate Chief of Staff/R&D, and RCO within 5 business days of the determination(s).

5.6 Refer to the IRB staff to place on the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval. Follow “SOP: IRB Meeting Conduct (HRP-041)” for convened IRB review of the item.

5.7 Complete and send to the investigator a “TEMPLATE LETTER: Suspension or Termination (HRP-515).”

6 MATERIALS

- 6.1 SOP: IRB Meeting Conduct (HRP-041)
- 6.2 TEMPLATE LETTER: Suspension or Termination (HRP-515)

7 REFERENCES

- 7.1 45 CFR 46.103(b)(5)(ii); 45 CFR 46.108(a); 45 CFR 46.113
- 7.2 21 CFR 56.108(b)(3); 21 CFR 56.113
- 7.3 VHA Handbook 1058.01
- 7.4 AAHRPP I.5.D.; II.2.F.; II.2.G.; II.2.H.

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HRP-027 Planned Emergency Research

1 PURPOSE

- 1.1 This guidance establishes the process for an investigator conducting planned emergency research with a waiver of consent when more than minimal risk is involved.
- 1.2 The guidance begins when preparing for any planned emergency research or clinical investigation activity that involves human subjects.
- 1.3 The guidance ends when IRB involvement in the LSUHSC-S planned emergency research or clinical investigation activity is determined.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The Health and Human Services (HHS) waiver, just as the Food and Drug Administration (FDA) regulatory change (21 CFR 50.24), provides a narrow exception to the requirement for obtaining and documenting informed consent from each human subject or his or her legally authorized representative prior to initiation of research if the waiver of informed consent is approved by an IRB. The waiver authorization applies to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have available a legally authorized representative.
- 3.2 The intent of these regulations is to allow research on life-threatening conditions for which available treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent, while establishing additional protections to provide for safe and ethical studies.
- 3.3 Important Notes:
 - 3.3.1 Planned Emergency Research is not the same as Emergency Use of a Test Article SOP: Emergency Use Review (HRP-023).
 - 3.3.2 In addition, Federal law provides for the conduct of planned research with surrogate informed consent when potential research participants are unable to consent due to decisional impairment. See SOP: LARs, Children, and Guardians (Surrogate Consent) (HRP-013).

4 RESPONSIBILITIES

- 4.1 Investigators, IRB members, and IRB staff perform these procedures.

5 PROCEDURE

- 5.1 The LSUHSC-S IRB reviews and may approve planned emergency research without requiring that informed consent of all subjects be obtained if the LSUHSC-S IRB (with the concurrence of a licensed physician who is a member of the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following seven points:
 - 5.1.1 The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
 - 5.1.2 Obtaining informed consent is not feasible because:

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5.1.2.1 The subjects will not be able to give their informed consent as a result of their medical condition.

5.1.2.2 The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible.

5.1.2.3 There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

5.2 Participation in the research holds out the prospect of direct benefit to the subjects because:

5.2.1 Subjects are facing life-threatening situation that necessitates intervention.

5.2.2 Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects.

5.2.3 Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

5.3 The clinical investigation could not practicably be carried out without the waiver.

5.4 The proposed investigational plan:

5.4.1 Defines the length of the potential therapeutic window based on scientific evidence

5.4.2 The investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time, and if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent.

5.4.3 The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the same time of continuing review. FORM: Continuation Request or Final Closure Report (HRP-212).

5.5 The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with 21 CFR 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with information below.

5.6 Additional protections of the rights and welfare of the subjects will be provided, including, at least:

5.6.1 Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn.

5.6.2 Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits

5.6.3 Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results

5.6.4 Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation

5.6.5 If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the

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subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

5.6.6 Consenting is an ongoing process. All applicable criteria that would trigger re-consenting a subject in any study also apply to subjects whose consent has been provided by a surrogate. See SOP: LARs, Children, and Guardians (Surrogate Consent) (HRP-013) for additional information.

5.7 In addition to the situations described under section 5.3 of the SOP: LARs, Children, and Guardians (Surrogate Consent) (HRP-013), if the subject is entered into research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the research should be provided to the subject's legally authorized representative or family member, when feasible.

6 MATERIALS

- 6.1 SOP: LARs, Children, and Guardians (Surrogate Consent) (HRP-013)
- 6.2 SOP: Emergency Use Review (HRP-023)

7 REFERENCES

- 7.1 21 CFR 50.24
- 7.2 FDA Guidance: Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble – Information Sheet
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126482.htm>
- 7.3 OPRR Reports: Informed Consent Requirements in Emergency Research, October 31, 1996
<http://www.hhs.gov/ohrp/policy/hsdc97-01.html>
- 7.4 AAHRPP II.4.C.

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HRP-028 Use of External IRB

1 PURPOSE

- 1.1 This procedure describes how the Institution may use an external IRB for human research.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 LSUHSC-S may rely on an external IRB to serve as the IRB of Record for certain LSUHSC-S research protocols.
- 3.1.1 LSUHSC-S may rely upon the IRB of another organization when investigators at LSUHSC-S receive a NIH grant or sub-award (or other federal funds) that mandate the use of an external IRB or when the Institution agrees to rely on an external IRB after evaluating the external IRB and the circumstances of the request.
- 3.1.2 When relying on an external IRB, whether it is for a single research project or a portion the institution's research portfolio, the external IRB will meet Federal Agency regulations for the conduct of human subject research and IRB review. Non-commercial IRBs will have a Federalwide Assurance and will be part of an AAHRPP organization. Commercial IRBs will be registered with OHRP and will be AAHRPP accredited.
- 3.1.3 When LSUHSC-S relies on an external IRB to serve as the IRB of record, the external IRB is evaluated by the LSUHSC-S IRB to determine if it meets specific criteria for the protection of human research subjects and, if so, written agreements are executed.
- 3.1.4 There will be a formal written agreement between LSUHSC-S and the external IRB delineating the roles and specific responsibilities of each party.
- 3.2 Authorization Agreement:
- 3.2.1 An authorization agreement, initiated by either the external IRB or LSUHSC-S, is used to document the agreement of both parties.
- 3.2.2 The written authorization agreement must outline the responsibilities of the external IRB and LSUHSC-S and the researcher/s.
- 3.2.3 The authorization agreement is kept in the IRB administrative files and will be made available upon official request.

4 RESPONSIBILITIES

- 4.1 The Institution in conjunction with HRPP is responsible for carrying out the policy.

5 PROCEDURE

- 5.1 LSUHSC-S IRB Responsibilities:
- 5.1.1 The investigator seeks approval from the Assistant Vice Chancellor for Research Management and/or IO designee to use an external IRB to serve as the IRB of Record and provides justification for reliance on the external IRB. Use TEMPLATE: Request for External IRB
- 5.1.2 The Assistant Vice Chancellor for Research Management in conjunction with the IO designee and IRB Director/designee assess whether an external IRB is qualified to serve as the IRB of Record for LSUHSC-S human subject research project by verifying the following:
- 5.1.2.1 The organization's Human Research Protection Program is accredited by AAHRPP.
- 5.1.2.2 The non-commercial IRB has an active Federalwide Assurance (FWA) on file with the Federal Office for Human Research Protection.
- 5.1.2.3 The commercial IRB is registered with OHRP.

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5.1.2.4 The organization or external IRB has not received any recent FDA warning letters or OHRP determination letters within the last year.

5.1.2.5 The Board Membership satisfy the requirements of 45 CFR 46.107 and 21 CFR 56.107.

5.1.2.6 The external IRB has an adequate process in place to notify the LSUHSC-S IRB and researcher(s) of its approvals, determinations, reportable events, suspensions, and terminations.

5.1.3 In the opinion of LSUHSC-S IRB leadership, the external IRB can fulfill its responsibilities as outlined in the written authorization agreement.

5.2 If it is determined that the external IRB is qualified to serve as the IRB of Record, a written authorization agreement is initiated, by either the external IRB or LSUHSC-S, which documents the agreement of both parties.

5.3 The following information from the external organization is provided to the LSUHSC-S Assistant Vice Chancellor for Research Management or designee.

5.3.1 A copy of the non-commercial IRB's Federalwide Assurance (FWA)

5.3.2 The commercial IRB's Institution/organization (IORG) number

5.3.3 The contact information for the external IRB's Institutional Official (name, address, telephone number, e-mail address)

5.3.4 The contact information for the external IRB's Administrator and/or designated point of contact (name, address, telephone number, e-mail address)

5.4 LSUHSC-S Investigator Responsibilities:

5.4.1 Comply with the external IRB's requirements, directives per the Authorization Agreement and local institutional requirements.

5.4.2 Must not enroll individuals in any research protocol prior to the following:

5.4.2.1 Review and approval by the external IRB, and

5.4.2.2 Verification of local review requirements and confirmation of the external IRB approval from the LSUHSC-S IRB Administrative Office.

5.4.3 Ensure the safe and appropriate performance of the research. This includes, but is not limited to ensuring the qualifications of research staff, monitoring protocol compliance, maintaining compliance with state, local or organizational requirements related to the protection of human subjects; providing a mechanism to receive and address concerns from local study subjects and others about the conduct of the research; and investigating, managing, and providing notification to the external IRB and the LSUHSC-S IRB Administrative Office of any study-specific incidence, experience, or outcome that rises to the level of an unanticipated problem and/or serious or continuing non-compliance.

5.4.4 Provide the external IRB with any local context issues relevant to the research protocol.

5.4.5 Disclose financial conflicts of interest according to the agreed upon process and comply with any conflict management plans that may result.

5.4.6 Promptly report to the external IRB any proposed changes in the research. The

5.4.7 investigator must not initiate changes in the research (including changes in the consent document) without prior IRB review and approval or LSUHSC-S IRB Administrative Office confirmation, except where necessary to eliminate apparent immediate hazards to the subjects.

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5.4.8 When responsible for enrolling subjects, will obtain, document, and maintain records of consent for each subject or subject's legally authorized representative as stipulated by the IRB. The investigator will utilize the LSUHSC-S consent, assent, and/or HIPAA templates, as appropriate.

5.4.9 Will provide to the external IRB any data and safety monitoring reports they receive, either at continuing review, upon request by the reviewing IRB, or on an emergent basis, if appropriate.

5.4.10 Provide updates to the external IRB and LSUHSC-S IRB Administrative Office whenever a principal investigator is no longer the responsible party for a research project under the purview of the external IRB.

5.4.11 Provide the contact person and contact information for the LSUHSC-S Assistant Vice Chancellor for Research Management, IRB Director or Designee to the external IRB.

5.4.12 Documenting reliance on the External IRB through the IRB electronic system (Shields).

5.4.12.1 Document the initial request for reliance. (Use TEMPLATE: Request for External IRB)

5.4.12.2 Document any updates, continuing reviews and modifications to the research approved by the external IRB including the following reportable new information:

5.4.12.2.1 new risks and unanticipated problems

5.4.12.2.2 harm experienced by a subject

5.4.12.2.3 non-compliance, audits by external agencies

5.4.12.2.4 monitoring reports, protocol deviations

5.4.12.2.5 breach of confidentiality

5.4.12.2.6 un-reviewed changes taken to eliminate apparent immediate harm to a

subject

5.4.12.2.7 incarceration of a subject

5.4.12.2.8 unresolved subject complaint

5.5 External IRB Responsibilities include, but are not limited to:

5.5.1 Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to previously approved research.

5.5.2 Conduct review of potential unanticipated problems, adverse events, and/or serious or continuing non-compliance.

5.5.3 Provide notification to researcher staff and relying institution in writing of its determinations and decisions.

5.5.3 Make available relevant IRB minutes, IRB membership rosters, and standard operating procedures to the relying institution upon request.

5.5.4 When appropriate, conduct on-site or remote post-approval monitoring or audits, unless delegated to the relying institution.

5.5.5 Maintain an IRB membership that satisfies the requirements of 45 CFR 46.107 and 21 CFR 56.107 and which provides special expertise as needed to adequately assess all aspects of each study.

5.5.6 Promptly notify the LSUHSC-S Institutional Official or designee if there is a suspension or termination of the external IRB's authorization to review a study.

5.5.7 Provide the LSUHSC-S Assistant Vice Chancellor for Research Management, IRB Director or Designee, the contact person and contact information for the reviewing IRB.

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5.5.8 Maintain appropriate documentation per record retention policies, including an OHRP-approved Federalwide Assurance (non-commercial IRBs) for human subject research. Notify the LSUHSC-S IRB Director or designee of any changes to external IRB's FWA.

5.6 Documenting the Reliance on an External IRB of Record

5.6.1 The Investigator is responsible for documenting the reliance when an External IRB is allowed to serve as the IRB of Record for any LSUHSC-S research by completing the following:

5.6.2 Create a new study in the IRB electronic system (Shields) and complete all forms, as applicable.

5.6.3 Choose 'Yes' when asked: Will an external IRB act as the IRB of record for this study?

5.6.4 Attach copies of protocol specific materials, supporting documents and correspondence in the IRB electronic system. Use Worksheet: External IRB Review of Onsite Research (HRP-335) as guide.

5.6.5 Submit External IRB study to the IRB Administrative Staff for Institutional Confirmation of External IRB Research.

5.7 Institutional Confirmation of Research and verification of local review requirements when LSUHSC-S relies on an external IRB to serve as the IRB of record.

5.7.1 The IRB administrative staff carries out these activities:

5.7.1.1 Use Worksheet: External IRB Review of Onsite Research (HRP-335) to verify that the External IRB Research submitted by the investigator is complete.

5.7.1.2 If submission is not complete or requires clarifications, contact the investigator by selecting the "Request Pre-Review Clarifications" Activity. Offer the investigator the opportunity to make to provide additional information.

5.7.1.3 Continue processing once the investigator responds to the request for additional information.

5.7.1.4 Select the 'Submit Pre-Review' Activity in the electronic system and document any special determination made by the external IRB.

5.7.1.5 Then execute the Pre-Review activity to complete the action.

5.7.1.6 Obtain institutional approvals, when necessary, through the 'Manage Ancillary Reviews' Activity in the electronic system.

5.7.1.7 If a required ancillary review is not received or requires clarification, obtain clarification as needed or arrange a meeting with the ancillary review team.

The ancillary review team will make one of the following determinations. The research is appropriate for the institution and may be conducted in accordance with the protocol approved by the external IRB.

5.7.1.8 The research is not appropriate for the institution. (Provide the reason for the determination).

5.7.2 Assign the submission to a staff designated reviewer for processing after ancillary review team makes determination.

5.7.3 The staff designated reviewer will choose the following option in Shields if the ancillary review team determines the new research is appropriate for the institution: 'Modifications Required to Secure Approval'.

5.7.3.1 The IRB staff will generate correspondence notifying the investigator that they may submit a request to the External IRB to add this site to the research.

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5.7.3.2 Upon receipt of external IRB correspondence approving the local site as part of the research, the investigator is to submit the correspondence as a response to the 'Modifications Required'.

5.7.3.3 The IRB staff will verify the External IRB approval and generate correspondence to the investigator 'Confirming External IRB Review of On-Site Research' allowing the investigator to proceed with study procedures.

5.7.4 If the ancillary review team determines the research is not appropriate for the institution, the staff designated reviewer will choose the following option in Shields: Reject External IRB Review of On-Site Research.

5.7.5 The IRB staff will generate correspondence notifying the investigator that the research may not be carried out at this site

6 MATERIALS

6.1 Worksheet: External IRB Review of Onsite Research (HRP-335)

6.2 TEMPLATE: Request for External IRB

7 REFERENCES

7.1 45 CFR 46.114

7.2 AAHRPP I.1.F.; I.4.; I.6.

SOP: Reportable New Information Items		
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HRP-029 Reportable New Information Items

1 PURPOSE

- 1.1 This procedure establishes the process to identify new information that requires reporting to the IRB.
- 1.2 The process begins when an individual receives an information item.
- 1.3 The process ends when the item is submitted to the IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 New Information Items are to be reported to the IRB within 5 business days.
- 3.2 The IRB will manage the new information item in accordance with SOP: New Information Process (HRP - 024).

4 RESPONSIBILITY

- 4.1 Investigators or other individuals receiving reportable new information items carry out these procedures.

5 PROCEDURE

- 5.1 Report information items that fall into one or more of the following categories to the IRB within five (5) business days.

- 5.1.1 Information that indicates a new or increased risk, or a new safety issue. For example:

- 5.1.1.1 New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor correspondence or report, CRO report, or investigator finding) that may indicate an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

- 5.1.1.2 An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk.

- 5.1.1.3 Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

- 5.1.1.4 Protocol deviation/violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

- 5.1.1.5 Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.

- 5.1.1.6 Any changes significantly affecting the conduct of the research

- 5.1.2 Harm experienced by a subject or other individual, which in the opinion of the investigator are unexpected and probably related to the research procedures.

- 5.1.2.1 A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

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5.1.2.2 A harm is “probably related” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.

5.1.3 Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB or the institution or an allegation of such non-compliance.

5.1.4 Audit, inspection, or inquiry by a federal agency or any other outside entity and any resulting reports (e.g. FDA Form 483.)

5.1.5 Written reports of study monitors.

5.1.6 Failure to follow the protocol due to the action or inaction of the investigator or research staff whether planned or unplanned.

5.1.7 Change to the protocol taken without prior IRB review to eliminate an apparent immediate

5.1.8 Breach of confidentiality (inappropriate disclosure of or access to confidential information).

5.1.9 Incarceration of a subject in a study not approved by the IRB to involve prisoners.

5.1.10 Complaint of a subject that cannot be resolved by the research team.

5.1.11 Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

5.1.12 Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.)

5.1.13 For Veterans Administration (VA) research all local or internal serious adverse events.

5.2 Use the IRB electronic submission system (Shields) or equivalent to submit the reportable new items.

5.2.1 Select the Action “Report New Information”.

5.2.2 Name the report so that it can be easily identified.

5.2.4 Provide the date you became aware of the problem.

5.2.4 Provide a description of the problem and determine the following:

5.2.4.1 Does this information indicate a new or increased risk, or a safety issue?

5.2.4.2 Does the study need revision?

5.2.4.3 Does the consent document need revision?

5.3 Provide a list of all studies related to the reportable new information.

5.4 Attach supporting documentation and a description of any corrective actions when required.

5.5 Submit the item to the IRB when your description of the reportable new information is complete.

6 MATERIALS

6.1 SOP: New Information Process (HRP – 024)

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7 REFERENCES

- 7.1 45 CFR 46.103(b)(5); 45 CFR 46.108(a)
- 7.2 21 CFR 56.108(b)
- 7.3 AAHRPP I.5.D.; II.2.F.; II.2.G.; II.4.A.; II.4.B.

SOP: Designated Reviewers		
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HRP-030 Designated Reviewers

1 PURPOSE

- 1.1 This procedure establishes the process for an IRB chair to designate or remove IRB members who can conduct Non-Committee Reviews.
- 1.2 The process begins when the IRB chair instructs IRB Director to designate an Experienced IRB Member to conduct Non-Committee Reviews.
- 1.3 The process ends when the IRB member has been noted in the IRB roster to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using the "IRB Roster."

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Obtain from the IRB chair the name of the IRB member designated to conduct Non-Committee Reviews.
- 5.2 Review list of IRB members designated to conduct Non-Committee Reviews in the "Assign Designated Reviewer" activity. Verify that the IRB member is an Experienced IRB Member who has been an IRB member for a period of at least one year and the IRB chair considers the IRB member to have sufficient experience in and knowledge of the criteria for approval and conducting IRB reviews.
- 5.3 Update the "IRB Roster" to indicate that the IRB member is a Designated Reviewer.
- 5.4 Use the "Update Eligible Designated Reviewers" activity to indicate that the IRB member is a Designated Reviewer.
- 5.5 Notify the IRB member of the decision.

6 MATERIALS

- 6.1 IRB Roster

7 REFERENCES

- 7.1 45 CFR 46.110(b)
- 7.2 21 CFR 56.110(b)
- 7.3 AAHRPP II.2.E.

SOP: Non-Committee Review Preparation		
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HRP-031 Non-Committee Review Preparation

1 PURPOSE

- 1.1 This procedure establishes the process to assign a Designated Reviewer for a Non-Committee Review.
- 1.2 The process begins when the Pre-Review of a submission is complete and an IRB staff member or the IRB Chair identifies an application as being possibly eligible for Non-Committee Review.
- 1.3 The process ends when the IRB staff member provides the materials to the Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using "IRB Roster."
- 3.2 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in the "WORKSHEET: Review Materials (HRP-301)" according to their role: "Documents Provided to All IRB Members and Alternate IRB Members," "Additional Items Provided to Primary Reviewer," and "Additional Items Provided to Scientific/Scholarly Reviewer". Reviewers are expected to review, as applicable, the materials according to their role as described in SOP: IRB Review Expectations (HRP-045).

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Refer to "IRB Roster" and select a Designated Reviewer.
 - 5.1.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.
- 5.2 Use the "Assign Designated Reviewer" activity and select a Designated Reviewer.
 - 5.2.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.
 - 5.2.2 Execute the "Assign Designated Reviewer" activity
- 5.3 For individuals who are provided materials to review, prepare the review materials using the "WORKSHEET: Review Materials (HRP-301)" and include all materials listed under the columns according to the individual's role.
- 5.4 Use the following worksheets when needed to judge eligibility for Non-Committee Review: 1.3WORKSHEET: Human Subjects Determination (HRP-310), WORKSHEET: Engagement Determination (HRP-311), WORKSHEET: Exemption Determination (HRP-312), WORKSHEET: Expedited Review (HRP-313).
- 5.5 Execute the "Assign Designated Reviewer" activity to send to the Designated Reviewer.
- 5.6 For research that does not involve interaction with prisoners (e.g. existing data, record review) reviewed by the expedited procedure: Research that does not involve interaction with prisoners may be reviewed by the expedited procedure (Non-Committee Review), if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

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5.6.1 Review by a prisoner representative is not required.

5.6.2 The prisoner representative may review the research as a reviewer or consultant if designated by the IRB Chair.

6 MATERIALS

6.1 IRB Roster

6.2 WORKSHEET: Review Materials (HRP-301)

6.3 WORKSHEET: Human Subjects Determination (HRP-310)

6.4 WORKSHEET: Engagement Determination (HRP-311)

6.5 WORKSHEET: Exemption Determination (HRP-312)

6.6 WORKSHEET: Expedited Review (HRP-313)

7 REFERENCES

7.1 21 CFR 56.110(b)

7.2 45 CFR 46.110(b)

7.3 AAHRPP II.2.E.

SOP: Non-Committee Review Conduct		
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HRP-032 Non-Committee Review Conduct

1 PURPOSE

- 1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.
- 1.2 The process begins when the Designated Reviewer has the provided materials.
- 1.3 The process ends when the Designated Reviewer completes the review and returns the completed materials to an IRB staff member.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Designated Reviewers are to review the material described in 'SOP: IRB Member Review Expectations (HRP-045)'.
- 3.2 The Designated Reviewer may not disapprove research.

4 RESPONSIBILITIES

- 4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

- 5.1 Review all materials.
- 5.2 Consider whether you have a Conflicting Interest. If not:
 - 5.2.1 If the submission is a request to close the study and meets the study closure criteria, close the study, and notify the IRB staff.
 - 5.2.2 If the submission does not meet the study closure criteria communicate with the investigator and stop processing until the investigator revises the submission.
 - 5.2.3 If the investigator will not revise the submission, return to the IRB staff member handling the submission for assignment to Committee Review.
- 5.3 Determine the required level of review. (Not Human Research, Human Research not Engaged, exempt Human Research (including exempt Human Research that requires Limited IRB Review), Human Research approved using the expedited procedure, or Human Research that requires review by a convened IRB.
- 5.4 If there is missing information
 - 5.4.1 'Request Clarification by Designated Reviewer and execute activity; or
 - 5.4.2 Contact IRB staff and follow the procedures in SOP: Pre-Review (HRP-021).
- 5.5 Approve the initial, continuing or modification submission if meets either:
 - 5.5.1 The criteria in Exemption Determination (HRP-312)
 - 5.5.2 The criteria in WORKSHEET Eligibility for Review Using the Expedited Procedure – (HRP-313) and WORKSHEET Criteria for Approval and Additional Consideration (HRP-314) and other applicable worksheets and checklists as determined by the Pre-Review.
 - 5.5.3 "Modifications Required to Secure Determination of Not Human Research": The submission with changes can be determined "Not Human Research."

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5.5.4 “Modifications Required to Secure Approval”: The submission with changes can be given the action of “Approve.”

5.5.5 For Veterans Administration (VA) research the approval of minor conditions by the IRB chair or designated IRB voting member must be documented in the minutes of the first IRB meeting that takes place after the date of the approval of the minor conditions.

5.5.6 Use WORKSHEET: Approval Intervals (HRP-302) to calculate approval period.

5.5.7 Document using the electronic form ‘Submit Designated Review’ or Checklist – Non-Committee Review (HRP-402).

5.5.8 The determination action:

5.5.8.1 If the determination is “Approve” or “Modifications Required to Secure Approval,” document whether the approval level was “Exempt” or “Expedited.”

5.5.8.2 For “Exempt,” document the category or categories allowing the exemption on the electronic form or in “WORKSHEET: Exemption (HRP-312)” and document if there will be an end/termination date which cannot exceed a period of three years.

5.5.8.2.1 Limited IRB review must be performed by the IRB Chair or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. Disapprovals must be made by the convened board. If the limited IRB review does not result in approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories. Expedited research must meet all the approval criteria under 45 CFR 46.111, including either informed consent or waiver of consent. Use “WORKSHEET: Limited IRB Review and Broad Consent (HRP-319)”.

5.5.8.2.2 If a secondary research study that involves human subjects does not qualify for any exemption, the study must comply with the criteria for IRB approval of research at 45 CFR 46.111 (which includes the requirement for seeking the informed consent from every prospective subject or legally authorized representative, unless informed consent is waived by the IRB).

5.5.8.3 For “Expedited,” document the category or categories allowing review using the expedited procedure on the electronic form or in “WORKSHEET: Expedited (HRP-313)” and document the period of approval which cannot exceed one year.

5.5.9 Under the revised Common Rule, continuing review is not required for:

5.5.9.1 Research that is eligible for expedited review,

5.5.9.2 Exempt research conditioned on limited IRB review,

5.5.9.3 Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable,

5.5.9.4 Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures.

5.5.10 The IRB can override this default and still choose to require continuing review if the IRB documents the decision and the rationale for this decision.

5.5.11 Update Pre-Review findings as needed.

5.5.12 Execute the “Submit Designated Review” activity.

5.6 Notify the IRB staff member handling the submission when done.

5.7 If consultation is needed follow “SOP: Consultation (HRP-051).”

5.8 Execute the “Submit Designated Review” activity.

5.9 Broad Consent will not be used at this institution.

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6 MATERIALS

- 6.1 SOP: Pre-Review (HRP-021)
- 6.2 SOP: IRB Meeting Preparation (HRP-040)
- 6.3 SOP: IRB Member Review Expectations (HRP-045)
- 6.4 SOP: Consultation (HRP-051)
- 6.5 WORKSHEET: Limited IRB Review and Broad Consent (HRP-319)
- 6.6 WORKSHEET: Approval Intervals (HRP-302)
- 6.7 WORKSHEET: Exemption Determination (HRP-312)
- 6.8 WORKSHEET: Eligibility for Review Using the Expedited Procedure (HRP-313)
- 6.9 WORKSHEET: Criteria for Approval and Additional Consideration (HRP-314)
- 6.10 Checklist: Non-Committee Review (HRP-402)

7 REFERENCES

- 7.1 45 CFR 46.102; 45 CFR 46.104; 45 CFR 46.110(b)
- 7.2 21 CFR 56.110(b)
- 7.3 AAHRPP II.2.A.; II.2.B.; II.2.C.; II.2.E.; II.4.; III.1.E.

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HRP-040 IRB Meeting Preparation

1 PURPOSE

- 1.1 This procedure establishes the process to prepare for a convened IRB meeting.
- 1.2 The process begins when the agenda is closed, approximately a week before a meeting date.
- 1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 At least one IRB member or consultant is responsible for scientific/scholarly review of research.
- 3.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.
- 3.3 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
- 3.4 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
- 3.5 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.
- 3.6 Review materials are provided to all IRB members at least 7 days before convened meetings.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.
- 5.2 Consult the IRB Roster to be aware of the experience, expertise, and representational capacity of the IRB.
- 5.3 Review all submissions placed on the agenda for a convened IRB meeting.
- 5.4 Prepare an agenda for the meeting.
 - 5.4.1 Execute the "Assign Reviewers" activity in the meeting workspace to assign a primary reviewer to each agenda item.

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5.4.2 Execute the Assign Reviewers” activity in the meeting workspace to assign a scientific/scholarly reviewer to each initial submission item, who has scientific/scholarly expertise in the area of research. The primary reviewer and scientific/scholarly reviewer may be the same individual.

5.4.3 Execute the Assign Reviewers” activity in the meeting workspace to assign a literacy reviewer to each initial submission item (that includes consent form and materials that will be handed out to the subjects) who has expertise in the area of research.

5.4.4 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in “SOP: Definitions (HRP-001).” If so, assign another scientific/scholarly reviewer.

5.5 Use “WORKSHEET: Quorum and Expertise (HRP-305)” to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

5.5.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.

5.5.2 Follow the procedures in “SOP: Consultation (HRP-051)” to obtain consultants. Note any consultants on the agenda.

5.6 For individuals who are provided materials (IRB members, scientific/scholarly reviewers, consultants):

5.6.1 Execute the “Send Agenda” activity in the meeting workspace to deliver review materials to reviewers.

5.7 Participation from Remote Locations

5.7.1 Members unable to attend an IRB meeting in person may participate via teleconference/videoconference.

5.7.2 Members participating by a remote mechanism will receive and have access to IRB submission materials and will be able to participate in the discussion as if they were physically present.

6 MATERIALS

6.1 IRB Roster

6.2 SOP: Consultation (HRP-051)

6.3 SOP: Definitions (HRP-001)

6.4 WORKSHEET: Review Materials (HRP-301)

6.5 WORKSHEET: Quorum and Expertise (HRP-305)

7 REFERENCES

7.1 45 CFR 46.108(b)

7.2 21 CFR 56.108(b)

7.3 AAHRPP II.1.E.

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HRP-041 IRB Meeting Conduct

1 PURPOSE

- 1.1 This procedure establishes the process to conduct convened meetings.
- 1.2 The process begins when the IRB members gather for a convened meeting.
- 1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
- 3.2 The IRB chair votes as a regular member.
- 3.3 IRB attendance is captured by documenting in the IRB meeting minutes the IRB members and alternates in attendance, replacement of a voting member by an alternate, attendance of IRB members who participate through teleconference/videoconference, and IRB members who are recused due to a conflicting interest.
- 3.4 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.
- 3.5 Substantive changes or requirements (deferral), requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
- 3.6 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
- 3.7 The worksheets and checklists described in "WORKSHEET: Review Materials (HRP-301)" and listed below in "Section 6: MATERIALS" are provided to IRB members in advance of meetings per "SOP: IRB Meeting Preparation (HRP-040)" to conduct meetings and meet regulatory requirements.
- 3.8 For Veterans Administration (VA) Research "Substantive Changes" are defined as that ineligible for "Modifications Required to Secure Approval" as defined in this SOP.

4 RESPONSIBILITIES

- 4.1 The IRB chair carries out these procedures, unless otherwise noted.
- 4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

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5 PROCEDURE

- 5.1 Call the meeting to order.
- 5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.
- 5.3 Ask IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB prior to the meeting.
- 5.4 For each agenda item:
 - 5.4.1 Table the item when notified by IRB staff that requirements for review of a specific item as defined in "WORKSHEET: Quorum and Expertise (HRP-305)" are not met.⁸
 - 5.4.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference/videoconference, be placed on hold or disconnect for discussion and voting.
 - 5.4.2.1 For Veterans Administration (VA) research, members with a Conflicting Interest present by teleconference/videoconference are to disconnect for discussion and voting.
- 5.5 Participation from Remote Locations
 - 5.5.1 Members unable to attend an IRB meeting in person may participate via teleconference/videoconference. They may vote and be counted towards the quorum.
 - 5.5.2 Members participating by a remote mechanism will receive and have access to IRB submission materials and will be able to participate in the discussion as if they were physically present.
 - 5.5.3 The meeting minutes will indicate which members attended via an alternate mechanism (e.g. teleconference/videoconference).
- 5.6 For each agenda item involving the initial review, modification, or continuing review of a protocol:
 - 5.6.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.
 - 5.6.2 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.
 - 5.6.3 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
 - 5.6.4 Ask the primary reviewer to lead the IRB through a discussion of the criteria in the "WORKSHEET: Criteria for Approval (HRP-314)" and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.
 - 5.6.5 Restate the IRB's consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
 - 5.6.6 Make a motion for one of the following actions:

⁸ "Tabled" is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.

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5.6.6.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.

5.6.6.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): Made when IRB members require specific modifications such that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes

5.6.6.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendation to make the research approvable.

5.6.6.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.

5.6.6.5 Suspension or Termination: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use the "WORKSHEET: Review of Information Items (HRP-321)" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

5.7 Review any deferral reasons to ensure that the IRB staff has recorded them.

5.8 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

5.8.1 Ensure that the required modifications include all final contingencies in the Pre-Review activity.

5.8.2 For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be verified by the IRB staff, but if there is a management plan, it must return to the convened IRB for review.

5.9 For each agenda item that is new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval):

5.9.1 Have the primary reviewer use the "WORKSHEET: Review of Information Items (HRP-321)" to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.9.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

5.9.3 Make a motion for the IRB's determination(s) regarding the action items (e.g. the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects).

5.9.4 Open the floor for additional discussion.

5.9.5 Call for a vote.

5.9.5.1 Only IRB members may vote.

5.9.5.2 If a member and an alternate are both present, only one may vote.

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5.9.5.3 Consultants may not vote.

5.9.5.4 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)

5.9.6 Re-invite IRB members with a Conflicting Interest back into the meeting.

5.9.7 Provide any written information provided by a member or consultant to the IRB staff.

5.10 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

6 MATERIALS

- 6.1 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- 6.2 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- 6.3 CHECKLIST: Pregnant Women (HRP-412)
- 6.4 CHECKLIST: Non-Viable Neonates (HRP-413)
- 6.5 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 6.6 CHECKLIST: Prisoners (HRP-415)
- 6.7 CHECKLIST: Children (HRP-416)
- 6.8 CHECKLIST: Cognitively Impaired Adults (HRP-417)
- 6.9 CHECKLIST: Non-significant Risk Device (HRP-317)
- 6.10 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
- 6.11 SOP: IRB Meeting Preparation (HRP-040)
- 6.12 WORKSHEET: Review Materials (HRP-301)
- 6.13 WORKSHEET: Quorum and Expertise (HRP-305)
- 6.14 WORKSHEET: Pre-Review (HRP-308)
- 6.15 WORKSHEET: Criteria for Approval (HRP-314)
- 6.16 WORKSHEET: Advertisements (HRP-315)
- 6.17 WORKSHEET: Payments (HRP-316)
- 6.18 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 6.19 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 6.20 WORKSHEET: Criteria for Approval for HUD (HRP-323)
- 6.21 WORKSHEET: Review of Information Items (HRP-321)

7 REFERENCES

- 7.1 45 CFR 46.109; 45 CFR 46.116; 45 CFR 46.117
- 7.2 21 CFR 50.20; 21 CFR 50.25; 21 CFR 50.27; 21 CFR 56.109; 21 CFR 56.111
- 7.3 AAHRPP I.1.F.; I.7.A.; II.2.D.; II.2.E.; II.3.

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HRP-042 IRB Meeting Attendance Monitoring

1 PURPOSE

- 1.1 This procedure establishes the process to monitor quorum at convened IRB meetings.
- 1.2 The process begins when the IRB staff member responsible for monitoring quorum notifies the IRB chair that quorum has been attained.
- 1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 None

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 At meetings consult the "WORKSHEET: Quorum and Expertise (HRP-305)" to determine that the meeting is appropriately convened by meeting the "QUORUM REQUIREMENTS" and notify the IRB chair when the meeting is appropriately convened.
- 5.2 Before each protocol consult the "WORKSHEET: Quorum and Expertise (HRP-305)" to determine that the meeting is appropriately convened by meeting the "EXPERTISE REQUIREMENTS" and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.
- 5.3 When a member leaves the meeting room for any reason (including a Conflicting Interest) consult the "WORKSHEET: Quorum and Expertise (HRP-305)" to determine that the meeting continues to be appropriately convened by meeting the "QUORUM REQUIREMENTS" and notify the IRB chair when the meeting is not appropriately convened.
- 5.4 An IRB member may also join the meeting via teleconference/videoconference to present their review if there is a circumstance precluding their attendance at the meeting.

6 MATERIALS

- 6.1 WORKSHEET: Quorum and Expertise (HRP-305)

7 REFERENCES

- 7.1 45 CFR 46.108(b)
- 7.2 21 CFR 56.108(c)
- 7.3 AAHRPP II.1.; II.2.D.

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HRP-043 IRB Meeting Minutes

1 PURPOSE

- 1.1 This procedure establishes the process to record minutes for convened meetings.
- 1.2 The process begins when the meeting is called to order.
- 1.3 The process ends when the minutes are approved by the IRB chair.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Minutes are to comply with regulatory and guidance requirements.
- 3.2 Minutes are to record separate deliberations for each action.
- 3.3 Minutes are officially approved on behalf of the IRB by the IRB chair.
- 3.4 IRB members may make corrections to minutes.
- 3.5 The IRB writes minutes and makes them available for review within 21 days of the meeting date.
- 3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Execute the "Convene Meeting" activity.
- 5.2 The IRB Chair conducts the meeting with the IRB Staff. IRB staff makes notes of all the items discussed during the meeting.
- 5.3 Execute the "Close Meeting" activity.
- 5.4 Use HRP-501 - TEMPLATE – MINUTES, to create minutes document.
- 5.5 Record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under "Attendance Table.")
 - 5.5.1 Name.

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5.5.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, **Veterans Administration (VA) representative**, or alternate member.

5.5.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.

5.5.4 Whether the member was present by teleconference/videoconference.

5.6 Record the total number of members on "IRB Roster." Exclude alternate members in this count.

5.7 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the "IRB Roster," then $10/2 = 5$ and the next whole number is 6. If there 11 IRB members on the "IRB Roster," then $11/2=5.5$ and the next whole number is 6.

5.8 Indicate whether members present by teleconference/videoconference received all pertinent material before the meeting and were able to participate in all discussions actively and equally. Delete if no members were present by teleconference/videoconference.

5.9 Record the meeting start time.

5.10 For each submission reviewed record in the "Submit Committee Review" activity or "Submit RNI Committee Review" activity, as appropriate:

5.10.1 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.

5.10.2 Risk Level: Minimal Risk or more than Minimal Risk.

5.10.3 Last Day of Approval Period: Record the study expiration date.

5.10.4 Recommended Changes and Reasons: If the motion is Modifications required to secure approval or deferral/disapproval, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate "None"

5.10.5 Controverted Issues and their Resolutions: Summarize the issues where IRB members expressed a difference of opinion. For each issue indicate the resolution or indicate that there was None If no controverted issues, indicate "None"

5.10.6 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or cognitively impaired adults, enter "See attached Supporting Documents" and ensure that the corresponding completed checklist is uploaded as a supporting document. If no determinations that require documentation, indicate "None"

5.10.7 RNI Determinations: Record the determination of unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval, serious non-compliance, continuing non-compliance, non-compliance that is neither serious nor continuing, allegation of non-compliance with no basis in fact, or none of the above.

5.10.8 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.

5.10.9 Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions

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5.10.10 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.

5.10.11 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.

5.10.11.1 For: Voting for the motion.

5.10.11.2 Against: Voting against the motion.

5.10.11.3 Abstain: Present for the vote, but not voting “For” or “Against.”

5.10.11.4 Absent: Listed under “Members Present” but not present for the discussion and vote on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0”

5.10.11.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of recused members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India) Substitutions: 0”

5.10.11.6 Substitutions: Listed under “Members Present” When regular members and their alternate(s) are listed under “Members Present” and an alternate member substitutes for the regulator member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India)”.

5.10.12 For Veterans Administration (VA) research that involves an Unanticipated Problem Involving Risks to Subjects or Others, complete and attach “TEMPLATE VA Minutes Supplement (HRP-509).”

5.10.13 For an Unanticipated Problem Involving Risks to Subjects or Others, in the “Submit RNI Committee Review,” document the IRB’s determination as to whether a protocol or consent document modification is warranted, and if so, document the IRB’s determination as to whether previously enrolled subjects must be notified of the modification and, if so, when such notification must take place and how such notification must be documented.

5.11 Record the meeting end time.

5.12 Within 7 business days revise minutes for accuracy and notify the IRB chair for review.

5.13 Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.

5.14 Include link to the minutes in the agenda of the next IRB meeting.

5.15 IRB members have 7 days to review the minutes.

5.16 During the next IRB meeting, the IRB members will vote on approval of the minutes if no errors have been found. If errors are found, IRB members will notify the IRB Staff to make corrections to the minutes. The IRB members will vote to approve the corrected minutes at the next meeting.

5.17 Once the IRB members vote on approval of the minutes, The IRB Chair or a qualified voting member of the IRB designated by the IRB chair sign the minutes.

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5.17.1 For minutes of Veterans Administration (VA) research have the IRB chair or a qualified voting member of the IRB designated by the IRB chair sign the minutes

5.17.2 The IRB staff will upload signed version of the minutes into the meeting workspace

5.18 Email minutes to:

5.18.1 Veterans Administration (VA) Research and Development Committee, OSPTT Office, Compliance Office and the IO Office

5.18.2 When an affiliate IRB is the IRB of Record, the affiliate may either:

5.18.2.1 Provide VA with unredacted copies of meeting minutes, or

5.18.2.2 Provide VA with redacted copies of meeting minutes and permit relevant VA personnel (including, but not limited to, ORO staff, local VA Research Office staff, local RCOs, and R&D Committee members) to review the unredacted meeting minutes within two business days of a written request from VA. Such review may occur at the affiliate site during normal business hours, or as otherwise mutually acceptable to VA and the affiliate.

5.19 Attach the following documents to the meeting workspace:

5.19.1 List of protocols granted approval using the expedited procedure.

6 MATERIALS

6.1 TEMPLATE – MINUTES (HRP-501)

6.2 TEMPLATE VA MINUTES SUPPLEMENT (HRP-509)

7 REFERENCES

7.1 45 CFR 46.115(a)(2)

7.2 21 CFR 56.115(a)(2)

7.3 AAHRPP II.5.B.

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HRP-045 IRB Member Review Expectations

1 PURPOSE

- 1.1 This policy establishes for the review of Human Research the expectations of IRB members in advance of a meeting or when serving as a Designated Reviewer (experienced reviewers designated by the chairperson from among members of the IRB).

2 POLICY

- 2.1 In this policy, "all IRB members" refers to all members of the committee who will be present with voting status.
- 2.1.1 For review using the expedited (non-committee) procedure, the Designated Reviewer fulfills the roles described for the primary reviewer, and the scientific/scholarly reviewer, or obtains consultation for these roles.
- 2.2 All IRB members are to treat all oral, written, and electronic information obtained as part of the review process as confidential. IRB members must not disclose, use, share or duplicate review documents or confidential information without prior authorization.
- 2.3 All IRB members are to know the definition of Conflicting Interest.
- 2.3.1.1 No IRB member may participate in any review (including discussion or voting) in which he or she has a Conflicting Interest, except to provide information requested by the IRB.
- 2.3.1.2 When reviewing an item each IRB member is to consider whether he or she has a Conflicting Interest and if so, self-identify that Conflicting Interest.
- 2.4 All IRB members are provided a user account in the electronic IRB submission system for access to review materials.
- 2.4.1 All IRB members are to access all review materials through the electronic system.
- 2.4.2 IRB members attending by teleconference/videoconference are to access all review materials through the electronic system.
- 2.4.3 Any IRB member may request review materials be delivered outside the electronic system by contacting the IRB staff.
- 2.5 All members assigned as a primary reviewer or scientific/scholarly reviewers are to consider whether they have sufficient expertise to review the submission. If additional expertise is required, follow SOP Consultation (HRP-051). Sufficient expertise includes as applicable for the research:
- 2.5.1 Scientific or scholarly expertise
- 2.5.2 Knowledge of or experience working with vulnerable populations
- 2.5.3 Qualifications as a prisoner representative
- 2.5.4 Knowledge of the country in which the research is conducted
- 2.5.5 Medical licensure for FDA-regulated test articles
- 2.6 All IRB members review the Pre-Review findings for each submission, if any.
- 2.7 All IRB members consider the criteria in all applicable worksheets and checklists.
- 2.7.1 Worksheets and checklists are available in the IRB Library through the electronic system or can be available outside the electronic system by contacting the IRB staff.

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2.7.2 The primary presenter for each submission is expected to use applicable worksheets and checklists for preliminary judgments as to whether each criterion is met and provide preliminary study-specific findings justifying determinations.

2.7.3 The primary presenter leads the discussion.

2.7.4 IRB members who are not the primary presenter for a submission do not need to complete any checklists.

2.7.5 “WORKSHEET: Criteria for Approval (HRP-314)” applies to all non-exempt research.

2.7.6 The IRB must approve any and all recruitment materials/advertisements prior to posting and/or distribution for studies that are conducted under the purview of the LSUHSC-S IRB (See WORKSHEET: Advertisements (HRP-315)). The IRB will review:

2.7.6.1 The information contained in the advertisement.

2.7.6.2 The mode of its communication.

2.7.6.3 The final copy of printed advertisements prior to posting.

2.7.6.4 The final audio/video taped advertisements.

2.7.7 All advertisements are required to include the following information: IRB Project number, the date of original IRB approval of protocol, and the date of IRB approval of the advertisement. Once approved by the IRB, an Advertisement is not to be altered or manipulated in any way without prior IRB approval.

2.8 For initial review: In advance of the meeting, all IRB members review the following materials to a depth sufficient to determine whether the criteria in applicable worksheets and checklists are met:

2.8.1 Application form with local context (TEMPLATE PROTOCOL - HRP-503)

2.8.2 Study Protocol

2.8.3 Consent/Assent document(s) and script(s), when applicable

2.8.4 HIPAA Authorization

2.8.5 Recruitment materials, when applicable

2.9 For review of a modification: In advance of the meeting, all IRB members review the modification, determine which criteria in applicable worksheets and checklists are affected, and criteria are met:

2.9.1 Protocol

2.9.2 Consent document(s) and script(s) when they exist

2.9.3 HIPAA Authorization

2.9.4 Recruitment materials when they exist

2.10 For continuing review: In advance of the meeting, all IRB members review continuing review progress report and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the following materials as necessary to a depth sufficient to determine whether affected criteria are met:

2.10.1 Protocol

2.10.2 Current consent document(s) and script(s) when they exist

2.10.3 Recruitment materials when they exist

2.11 For review of new information¹: In advance of the meeting, all IRB members review the new information and attachments, determine which criteria in applicable worksheets and checklists are affected, and review the relevant

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sections of the following materials to a depth sufficient to determine as necessary whether affected criteria are met:

- 2.11.1 Protocol
- 2.11.2 Previously submitted modifications or a summary thereof
- 2.11.3 Consent document(s) and script(s) when they exist
- 2.11.4 Written reports of consultants or auditors when they exist

2.12 The primary presenter reviews all submitted materials for consistency with the materials reviewed by all IRB members, including the following additional documents when they exist:

- 2.12.1 The complete research protocol including any previously approved protocol modifications
- 2.12.2 Investigator brochure
- 2.12.3 Contract or grant application
- 2.12.4 Model template consent document
- 2.12.5 New Information reported during the current period of approval for continuing review submissions.

2.13 If the HHS supported research involves prisoners as subjects, the prisoner representative reviews the submitted information to determine whether the criteria in "CHECKLIST: Prisoners (HRP-415)" are met, be present when the research is reviewed, and provide a review either orally or in writing.

2.14 IRB members or consultants with scientific or scholarly expertise review the submitted information in enough depth to answer the questions in "WORKSHEET: Scientific and Scholarly Review (HRP-320)."

2.15 All IRB members review written reports of consultants, if any.

2.16 Any IRB member who needs to access additional information in the IRB records can contact an IRB staff member for assistance.

2.17 A subset of materials that are to be made available for review include (see: WORKSHEET: Review Materials (HRP-301))

2.17.1 List of protocols approved using the expedited procedure (For Veterans Administration (VA) Research, include the review category.)

7.6 List of protocols approved after verification of Modifications Required to Secure Approval for VA Research.

- 2.17.2 Information for Other Business items
- 2.17.3 Educational Materials when applicable

3 MATERIALS

- 3.1 WORKSHEET: Review Materials (HRP-301)
- 3.2 WORKSHEET: Criteria for Approval (HRP-314)
- 3.3 WORKSHEET: Advertisements (HRP-315)
- 3.4 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 3.5 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 3.6 WORKSHEET: Scientific or Scholarly Review (HRP-320)
- 3.7 WORKSHEET: Review of Information Items (HRP-321)

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- 3.8 WORKSHEET: Criteria for Approval for HUD (HRP-323)
- 3.9 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- 3.10 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- 3.11 CHECKLIST: Pregnant Women (HRP-412)
- 3.12 CHECKLIST: Non-Viable Neonates (HRP-413)
- 3.13 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 3.14 CHECKLIST: Prisoners (HRP-415)
- 3.15 CHECKLIST: Children (HRP-416)
- 3.16 CHECKLIST: Cognitively Impaired Adults (HRP-417)
- 3.17 CHECKLIST: Non-Significant Risk Device (FDA) (HRP-418)
- 3.18 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
- 3.19 CHECKLIST: HIPAA Waiver of Authorization HRP-441
- 3.20 TEMPLATE PROTOCOL - HRP-503

4 REFERENCES

- 4.1 AAHRPP I.1.F.; II.2.C.; II.2.D.; II.2.E.; II.3.; II.4.

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HRP-050 Conflicting Interests of IRB Members

1 PURPOSE

- 1.1 This procedure establishes the process to identify and manage Conflicting Interest of IRB members.
- 1.2 The process begins when an IRB member is asked to review an IRB submission.
- 1.3 The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflicting Interest.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB members are responsible to know the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.

4 RESPONSIBILITIES

- 4.1 IRB members (regular and alternate) follow these procedures.

5 PROCEDURE

- 5.1 Before reviewing research, IRB members are to determine whether they have a Conflicting Interest with research.
- 5.2 If an IRB member has a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials.
- 5.3 If an IRB member has a Conflicting Interest for review of a submission for which he or she has been assigned as a primary or scientific reviewer, he or she is to notify the IRB staff so the submission can be re-assigned.
- 5.4 If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to notify the IRB chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 45 CFR 46.107(e)
- 7.2 21 CFR 56.107(e)
- 7.3 AAHRPP II.1.D.; II.2.A.

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HRP-051 Consultation

1 PURPOSE

- 1.1 This procedure establishes the process for the IRB to obtain consultants.
- 1.2 The process begins when the IRB staff or IRB member has identified the need for consultation.
- 1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- 3.2 Consultants with a Conflicting Interest may not provide information to the IRB.

4 RESPONSIBILITIES

- 4.1 For review by a convened IRB, IRB staff members carry out these procedures.
- 4.2 For Non-Committee Review, the Designated Reviewer carries out these procedures.

5 PROCEDURE

- 5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
 - 5.1.1 IRB members from other committees
 - 5.1.2 Other employees of the organization
 - 5.1.3 External consultants
- 5.2 Contact the consultant and determine availability for review.
- 5.3 Determine whether the consultant has a Conflicting Interest as defined in "SOP: Definitions (HRP-001)." If so, obtain another consultant.
- 5.4 Use "WORKSHEET: Review Materials (HRP-301)" to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.
- 5.5 For review by the convened IRB:
 - 5.5.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.
 - 5.5.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.

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5.6 For Non-Committee Review:

- 5.6.1 Directly obtain the information (oral or written) from the consultant.
- 5.6.2 Document information received with the name of the consultant.

6 MATERIALS

- 6.1 SOP: Definitions (HRP-001)
- 6.2 WORKSHEET: Review Materials (HRP-301)

7 REFERENCES

- 7.1 45 CFR 46.107(f)
- 7.2 21 CFR 56.107(f)
- 7.3 AAHRPP II.1.D.; II.2.A.

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HRP-052 Post Review

1 PURPOSE

- 1.1 This procedure establishes the process for communications after a protocol is reviewed.
- 1.2 The process begins when:
 - 1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff, OR
 - 1.2.2 An IRB meeting is adjourned, and the IRB chair or IRB Director has approved the minutes, OR
 - 1.2.3 An IRB staff member has verified that modifications required to secure approval have been made.
- 1.3 The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The IRB reports its findings and actions to the investigator.
- 3.2 The IRB reports its findings and actions to the institution.
- 3.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.
- 3.4 Communication of review results to investigators are to be completed within 10 business days of the IRB meeting or receipt of the completed Non-Committee Review materials.
- 3.5 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.
 - 3.5.1 For Veterans Affairs (VA) research notification to the VA facility Director and the Associate Chief of Staff/R&D must occur within 5 business days of the convened IRB's determination(s).
 - 3.5.1.1 If the apparent Serious Non-Compliance or Continuing Non-Compliance notification was from a Research Compliance Officer (RCO), also notify the RCO within 5 business days of the convened IRB's determination(s).
- 3.6 Appeal of IRB Decisions
 - 3.6.1 If an investigator disagrees with a decision of the IRB, the investigator may submit a written appeal to the IRB Chair within 30 days of being notified of the decision.
 - 3.6.1.1 The appeal should include information supporting any disagreement made in the appeal.
 - 3.6.1.2 For appeals involving research conducted by designated review the appeal is reviewed by the designated reviewer, IRB Chair, and IRB Director.

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3.6.1.3 For appeals involving research reviewed by the convened board, the appeal is reviewed by the convened board.

3.6.1.3.1 The investigator may request to address the board at the meeting to provide clarification or additional information to the IRB.

3.6.1.4 The investigator is notified in writing of the decision.

3.6.2 If the investigator does not agree with IRB's decision regarding the appeal, the investigator may submit a written appeal to the Institutional Official or designee within 30 days of being notified of the decision.

3.6.2.1 3.6.2.1 The IO may organize a meeting to help facilitate discussion between the IRB and the investigator.

3.6.2.2 3.6.2.2 The IO may provide input and make recommendations for a resolution of the matter.

3.6.2.3 3.6.3 The IO or other LSUHSC-S Senior Leadership may override the IRB's decision to approve research; however they may not approve the research if it has not been approved by the IRB or overrule other decisions made by the IRB.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures. The IRB Chair facilitates any appeal process.

4.2 When the IRB staff analyst is logged into the electronic IRB system using a valid username and password, and uses the system to generate correspondence that communicates the results of IRB decisions, including approval determinations, the correspondence is considered to have been signed under the authority of the IRB chair or designee.

5 PROCEDURE

5.1 If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow "SOP: Non-Committee Review Preparation (HRP-031)."

5.2 Refer to "WORKSHEET: Approval Intervals (HRP-302)" to calculate approval intervals (if applicable).

5.3 Execute the "Finalize Documents" to stamp and accept all changes for attached documents.

5.3.1 Execute the "Prepare Letter" activity, and modify the letter as needed.

5.3.2 Execute the "Send Letter" activity.

5.4 For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:

5.4.1 Use "LETTER TEMPLATE: External Report (HRP-520)" to send to outside agencies within 30 business days from the determination of a reportable problem.

6 MATERIALS

6.1 SOP: Non-Committee Review Preparation (HRP-031)

6.2 WORKSHEET: Communication of Review Results (HRP-303)

6.3 WORKSHEET: Approval Intervals (HRP-302)

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7 REFERENCES

- 7.1 45 CFR 46.103(b)(4)(i); 45 CFR 46.207; 45 CFR 46.306(2)(C); 45 CFR 46.306(2)(D); 45 CFR 46.407; 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)
- 7.2 21 CFR 50.24(e); 21 CFR 50.54(b); 21 CFR 56.108(a)(1); 21 CFR 812.66
- 7.3 [VHA Handbook 1058.01](#)
- 7.4 AAHRPP I.5.C.; II.4.C.

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HRP-054 Institutional Conflicts of Interests

1 PURPOSE

- 1.1 This procedure establishes the process to identify institutional financial interests that may cause an institutional conflict of interests.
- 1.2 The process begins when the Organizational Official/Institutional Official (IO/OO) or designee is informed of a change in the institution's financial holdings outside of standard investments.
- 1.3 The process ends when the IRB staff are provided an updated list of the institution's financial holdings.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 See Chancellor's Memorandum – 23
- 3.2 An institutional financial conflict of interests exists when any of the following might affect the design, conduct, or reporting of research:
 - 3.2.1 Licensing, technology transfer, patents
 - 3.2.2 Investments of the organization
 - 3.2.3 Gifts to the organization when the donor has an interest in the research
 - 3.2.4 Financial interests of senior administrative officials
 - 3.2.5 Other financial interests
- 3.3 Senior administrative officials are required to disclose their financial interests to the Conflict of Interests Officer:
 - 3.3.1 Upon joining the organization
 - 3.3.2 Every year
 - 3.3.3 When there are changes to financial interests
- 3.4 For purposes of HRPP policy, the definition of Senior administrative leadership under this policy is as follows:
 - 3.4.1 All individuals whose title includes Chancellor, Dean, Hospital Administrator, Counsel, and others determined by the Chancellor.
 - 3.4.2 A faculty member or administrator who has direct authority over personnel appointments, salaries, promotions, and/or allocation of organizational resources (e.g., funding, space, assignment of graduate students, residents, fellows or other trainees) for individuals involved in the design, conduct, reporting, review, or oversight of human subjects research.
- 3.5 The Technology Transfer Office, Grants and Contracts Office, legal counsel, and the Conflict of Interests Officer are to notify the IO/OO or designee of any change in the institution's financial holdings not controlled by the institution's investment Directors related to:
 - 3.5.1 Licensing (e.g., licensing or technology transfer agreements)
 - 3.5.2 Investments of the organization

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- 3.5.3 Gifts to the organization when the donor has an interest in the research
- 3.5.4 Financial interests of senior administrative officials
- 3.5.5 Other financial interests

3.6 Annual Disclosure Certifications and quarterly updates will be provided to the Senior COI Project Director or COI Project Coordinator within the Office of Legal Affairs and Organizational Integrity.

3.7 The fiduciary responsibility of the institution's investment Directors is to maintain a diversified portfolio of holdings that meets the institution's goals in terms of capital appreciation, income, and risk. Institutional officials may not influence the decisions of the institution's investment Directors. This institution considers such investments to be like diversified mutual funds and not subject to disclosure under this policy.

3.8 The evaluation and management of an institutional conflict of interest may not vary by funding or regulatory oversight.

3.9 If an institutional financial holding related to prospective or ongoing Human Research is identified, it will be managed according to "SOP: Financial Conflicts of Interests (HRP-055)"

4 RESPONSIBILITIES

4.1 The Senior COI Project Director or COI Project Coordinator within the Office of Legal Affairs and Organizational Integrity carry out these responsibilities.

5 PROCEDURE

5.1 Upon receipt of information of a change in financial interest update the list of investments that are not controlled by the institution's investment Directors. Include information about the name of the company, the names of related companies, and affected products or services.

5.2 Provide a copy of the updated list to the IRB staff.

6 MATERIALS

- 6.1 SOP: Financial Conflicts of Interests (HRP-055)
- 6.2 Chancellor's Memorandum – 23

7 REFERENCES

- 7.1 42 CFR 50 7.1; 45 CFR 94 7.2
- 7.2 AAHRPP I.6.; II.1.D.; II.2.A.; III.1.B.

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HRP-055 Financial Conflicts of Interests

1 PURPOSE

- 1.1 This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research or an institutional financial interest Related to the Research.
- 1.2 The process begins when COI Office determines that an investigator or research staff has reported a financial interest Related to the Research or the IRB staff have detected an institution financial interest Related to the Research.
- 1.3 The process ends when the reported financial interest has been evaluated and the results of the evaluation have been communicated to the IRB to make the final decision as to whether any financial interest and any management plan allows the research to be approved.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The Assistant Vice Chancellor for Legal Affairs serves as the Conflicts of Interests Officer.
- 3.2 This policy complies with 3.1
 - 3.2.1 LSUHSC-S Chancellor's Memorandum – 23
 - 3.2.2 Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
 - 3.2.3 Title 21 Code of Federal Regulations (CFR), Part 54, Financial Disclosure by Clinical Investigators
- 3.3 For any or all steps of this procedure, the Conflicts of Interests Officer may have the Conflicts of Interests Committee follow the procedure whenever the Conflicts of Interests Officer believes that institutional consensus is needed to make a decision.
- 3.4 Individuals are considered to have an institutional responsibility and are subject to this policy when they are involved in any of the following:
 - 3.4.1 The design, conduct, or reporting of research
 - 3.4.2 Research consultation
 - 3.4.3 Teaching
 - 3.4.4 Professional practice
 - 3.4.5 Institutional committee memberships
 - 3.4.6 Service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards
- 3.5 Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:
 - 3.5.1 Joining the organization
 - 3.5.2 Financial conflicts policies are revised in a manner that changes investigator requirements

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3.5.3 Non-compliant with financial conflicts policies and procedures

3.6 Individuals subject to this policy are required to disclose their institutional responsibility to conduct research and the financial interests Related to the Research:

3.6.1 On submission of an initial review.

3.6.2 At least annually on submission of continuing review.

3.6.3 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest

3.7 Travel disclosures are to include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration.

3.8 Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

3.8.1 With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

3.8.2 With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

3.8.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

3.9 Violations of this policy or proscribed management plans can lead to:

3.9.1 Loss or restriction of privileges to conduct research

3.9.2 Other employment actions as allow by Human Resources Policies and Procedures.

3.10 Records related to disclosures and management of financial conflicts of interest are to be retained for at least three years from completion of the research.

4 RESPONSIBILITIES

4.1 The COI Officer or COI Project Director within the Office of Legal Affairs and Organizational Integrity carries out these procedures or ensures that a committee follows these procedures.

5 PROCEDURE

5.1 Ensure committee members do not participate in the review of any conflict of interests in which the member has Conflicting Interest.

5.2 Review the reported financial interest and the research protocol.

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- 5.2.1 If the financial interest and research protocol has already been reviewed, and if needed, managed, notify the IRB staff of this determination in writing, and stop processing subsequent steps of this procedure
- 5.3 Determine whether the reported financial interest is related to the research.
 - 5.3.1 If the financial interest is not related to the research, notify the IRB staff of this determination in writing, and stop processing subsequent steps of this procedure.
- 5.4 Determine whether the reported financial interest could directly and significantly affect the design, conduct, or reporting (i.e., the reported financial interest is a conflict of interests) of the Human Research.
 - 5.4.1 If there is no conflict of interests, notify the IRB staff of this determination in writing and stop processing subsequent steps of this procedure.
- 5.5 If a conflict of interests exists, determine under what circumstances, if any, should a conflicted individual (in the case of individual financial interest) or the organization (in case of institutional financial interest) be allowed to participate in:
 - 5.5.1 Subject recruitment.
 - 5.5.2 Prescreening for inclusion/exclusion criteria.
 - 5.5.3 The consent process
 - 5.5.4 The clinical treatment of subjects, separate from the research interventions or procedures.
 - 5.5.5 Clinical evaluation of subjects during the research, separate from the research interventions or procedures, including adverse event evaluation and reporting.
- 5.6 Create a written management plan, considering the following options:
 - 5.6.1 Public disclosure of the financial interests.
 - 5.6.2 Disclosure of the financial interests to subjects.
 - 5.6.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest.
 - 5.6.4 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
 - 5.6.5 Reduction or elimination of the financial interest (e.g., sale of an equity interest).
 - 5.6.6 Severance of relationships that create financial conflicts.
 - 5.6.7 Modification of the research plan.
 - 5.6.8 Involvement of external individuals in key portions of the protocol
 - 5.6.9 Use of an external IRB.
 - 5.6.10 A retrospective review.
 - 5.6.11 A mitigation report.
 - 5.6.12 A plan to monitor and enforce the implementation of the management plan.
- 5.7 Provide the written management plan to the involved individual or office for comment and review.
- 5.8 Finalize the written management plan.

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5.9 Provide the IRB staff of the reviewing IRB with the written management plan so the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.

5.10 When required provide the final determination to the funding or regulatory agencies.

5.11 Maintain a copy of determinations and management plans in the records.

5.12 For National Science Foundation Research Note: Although current NSF regulations specify a higher threshold for SFI than PHS (NIH) the LSUHSC-S CM-23 policy identifies \$5,000 as the monetary threshold.

5.13 For FDA regulated research follow INVESTIGATOR MANUAL (HRP-103) Appendix A-2 -Additional Requirements for FDA-Regulated Research.

6 MATERIALS

6.1 LSUHSC-S Chancellors Memorandum – 23 6.1

6.2 INVESTIGATOR MANUAL (HRP-103)

7 REFERENCES

7.1 42 CFR 50; 45 CFR 94

7.2 NSF GPM Section 510 7.2

7.3 21 CFR 54 7.3

7.3 AAHRPP I.6.; II.1.D.; II.2.A.; III.1.B.

SOP: Annual Evaluations of the HRPP		
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HRP-060 Annual Evaluations of the HRPP

1 PURPOSE

- 1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.
- 1.2 The process begins the first business day of each July.
- 1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The human research protection program is evaluated annually.
- 3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making the document "BROCHURE: Should I Take Part in Research (HRP-104)" available to the patient population.

4 RESPONSIBILITIES

- 4.1 IRB staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 Have the Institutional Official or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process.
 - 5.1.1 Space
 - 5.1.2 HRPP educational program
 - 5.1.3 Legal counsel
 - 5.1.4 Conflicts of interests
 - 5.1.5 Quality improvement plan
- 5.2 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
 - 5.2.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.2.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the Institutional Official or designee to modify the IRB structure.
- 5.3 Have the IRB chair or IRB Director evaluate the knowledge, skills, and performance of each regular and alternate IRB member.
 - 5.3.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.3.2 Provide each IRB member with a copy of his or her evaluation.
 - 5.3.3 Send a copy of the "TEMPLATE LETTER: IRB Member Appreciation (HRP-562)" to the IRB member's supervisor.

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5.3.4 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.

5.4 Have the Institutional Official or designee evaluate the knowledge, skills, and performance of each IRB chair.

5.4.1 Provide a copy of the evaluation to the Institutional Official or designee.

5.4.2 Provide each IRB chair with a copy of his or her evaluation.

5.4.3 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.

5.5 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.

5.5.1 Provide a copy of the evaluation to the Institutional Official or designee.

5.5.2 Provide each IRB staff with a copy of his or her evaluation.

5.5.3 If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance.

5.6 Use the "WORKSHEET: IRB Composition (HRP-304)" to evaluate whether the composition of the IRB meets regulatory and organizational requirements.

5.6.1 Provide a copy of the evaluation to the Institutional Official or designee.

5.6.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the Institutional Official or designee to modify the IRB composition.

5.7 Evaluate the subject outreach plan.

5.7.1 Consider the following areas when evaluating the outreach plan:

5.7.1.1 Whether the existing scope and content of HRPP outreach materials continue to be adequate.

5.7.1.2 Whether modifications to existing outreach materials are necessary.

5.7.1.3 Whether or not the HRPP's existing materials are being regularly utilized by the IRB Office or by members of the research community in their own interaction with the communities in which they conduct research.

5.7.1.4 Whether there are new opportunities to provide outreach activities to the community and

5.7.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.

5.7.2 Provide a copy of the evaluation to the Organizational Official or designee.

5.7.3 If the subject outreach program is not meeting organizational goals, work with the Institutional Official or designee to modify the plan. Modifications may include, but are not limited to:

5.7.3.1 Modifying existing outreach materials.

5.7.3.2 Developing new materials.

5.7.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and

5.7.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.

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5.8 Check whether each member of a Veterans Administration (VA) IRB or Veterans Administration (VA) representative has been a member longer than 3 years, and if so, send the member a “TEMPLATE LETTER: IRB Member Appointment (HRP-560).”

5.9 Review “SOP: IRB Formation” (HRP-080) to determine if IRB registration requires updating.⁹

5.10 Check when the last time the Federalwide Assurance (FWA) was updated or renewed. If more than 2 years, update/renew the Federalwide Assurance (FWA).¹⁰

6 MATERIALS

- 6.1 BROCHURE: Should I Take Part in Research (HRP-104)
- 6.2 TEMPLATE LETTER: IRB Member Appreciation (HRP-562)
- 6.3 WORKSHEET: IRB Composition (HRP-304)
- 6.4 SOP: IRB Formation (HRP-080)

7 REFERENCES

- 7.1 AAHRPP I.4.B.; II.1.

⁹ See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <https://ohrp.cit.nih.gov/efile/>.

¹⁰ See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <https://ohrp.cit.nih.gov/efile/>.

SOP: Expiration of IRB Approval		
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HRP-063 Expiration of IRB Approval

1 PURPOSE

- 1.1 This procedure establishes the process for a Designated Reviewer to determine whether current subjects may continue in expired research.
- 1.2 The process begins when the Designated Reviewer is notified of a request by an investigator of a request for current subjects to continue in expired research.
- 1.3 The process ends when the Designated Reviewer has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 If research is granted “Modifications Required to Secure Approval” and expires before responsive materials are reviewed and approved, these procedures are to be followed.

4 RESPONSIBILITIES

- 4.1 A Designated Reviewer is responsible to follow these procedures.

5 PROCEDURE

- 5.1 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.
- 5.2 Do not allow new subjects to be enrolled under any circumstances.
- 5.3 Determine which subjects can continue in the research based on these principles:
 - 5.3.1 In general, research procedures should be safely discontinued.
 - 5.3.2 In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.
 - 5.3.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.
 - 5.3.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.
- 5.4 In the case of Veterans Administration (VA) research, have the IRB chair consult with the Veterans Administration (VA) Chief of Staff to make a final determination within 2 business days whether participants may continue participating in the research interventions or interactions.
- 5.5 Communicate with the investigator using “TEMPLATE LETTER: Continuation of Subjects in Expired Research (HRP-532).”

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6 MATERIALS

6.1 TEMPLATE LETTER: Continuation of Subjects in Expired Research (HRP-532)

7 REFERENCES

7.1 45 CFR 46

7.2 AAHRPP II.2.

SOP: NIH GDS Institutional Certification		
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HRP-064 NIH GDS Institutional Certification

1 PURPOSE

- 1.1 This procedure establishes the process to certify approval for investigator submission of large-scale human genomic data to an NIH-designated data repository.
- 1.2 The process begins when an investigator contacts IRB staff for certification of the genomic data sharing plan.
- 1.3 The process ends when the Organizational Official / Institutional Official (IO/OO) has certified and communicated to the investigator.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Investigators must request certification from IRB staff prior to investigator submission of large-scale human genomic data or approval of funding.

4 RESPONSIBILITIES

- 4.1 The IRB Director or designee verifies for the IO/OO that all data meet criteria for submission to the data repository.

5 PROCEDURE

- 5.1 Use "WORKSHEET: NIH GDS Institutional Certification (HRP-332)" to evaluate and document whether the investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository.
- 5.2 Populate "LETTER: NIH GDS Institutional Certification (HRP-528)" with submission-specific information. Pass the letter to the IO/OO for review and certification.
- 5.3 Save a copy of the signed letter and Checklist in IRB Office records.
- 5.4 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification letter for the investigator to forward to the NIH.

6 MATERIALS

- 6.1 CHECKLIST: NIH GDS Institutional Certification (HRP-332)
- 6.2 LETTER: NIH GDS Institutional Certification (HRP-528)

7 REFERENCES

- 7.1 National Institutes of Health Final Genomic Data Sharing Policy (<https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/>)
- 7.2 NIH Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications Under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) (https://osp.od.nih.gov/wp-content/uploads/PTC_for_IRBs_and_Institutions.pdf)

SOP: IRB Records		
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HRP-070 IRB Records

1 PURPOSE

- 1.1 This procedure establishes the process to maintain IRB records.
- 1.2 The process begins when records are received or created.
- 1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB records are to include:

- 3.1.1 Protocol files.
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all correspondence between the IRB and the investigators.
- 3.1.4 Current and all previous IRB member rosters.
- 3.1.5 Current and all previous IRB member files.
- 3.1.6 Current and all previous policies and procedures.

- 3.2 Protocol files are to include, as applicable:

- 3.2.1 All submitted materials.
- 3.2.2 Protocols.
- 3.2.3 Investigator brochures.
- 3.2.4 Scientific evaluations.
- 3.2.5 Recruitment materials.
- 3.2.6 Consent documents.
- 3.2.7 DHHS-approved sample consent document and protocol when they exist.
- 3.2.8 Progress reports submitted by investigators.
- 3.2.9 Reports of injuries to subjects.
- 3.2.10 Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
- 3.2.11 Data and safety monitoring board reports.
- 3.2.12 Amendments.
- 3.2.13 Reports of unanticipated problems involving risks to subjects or others.
- 3.2.14 Documentation of non-compliance.
- 3.2.15 Correspondence between the IRB and investigator related to the protocol.
- 3.2.16 Significant new findings and statements about them provided to subjects.
- 3.2.17 For initial and continuing review of research by the expedited procedure:
 - 3.2.17.1 The specific permissible category.
 - 3.2.17.2 Description of action taken by the reviewer.
 - 3.2.17.3 Any findings required under the regulations.
 - 3.2.17.4 The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.
- 3.2.18 For exemption determinations the specific category of exemption.

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3.2.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.

- 3.2.19.1 Waiver or alteration of the consent process.
- 3.2.19.2 Research involving pregnant women, fetuses, and neonates.
- 3.2.19.3 Research involving Prisoners.
- 3.2.19.4 Research involving children.
- 3.2.19.5 Research involving adults unable to consent.
- 3.2.19.6 Significant/non-significant device determinations.

3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review, including the rationale for requiring continuing review for protocols approved by expedited review that otherwise would not require continuing review.

3.2.21 For Veterans Administration (VA) research:

- 3.2.21.1 Correspondence between the IRB and the Veterans Administration (VA) Research and Development Committee.
- 3.2.21.2 Internal or local serious adverse events.
- 3.2.21.3 Documentation of protocol deviations.
- 3.2.21.4 Reports of complaints from subjects
- 3.2.21.5 Records of expedited review activities
- 3.2.21.6 HIPAA Authorization documents
- 3.2.21.7 Audit results and documentation of compliance with remediation requirements

3.2.22 Records for FDA-regulated research are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

3.2.23 Records for research conducted, supported, or otherwise subject to regulation by a federal department or agency are to be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner.

3.2.23.1 Records maintained that document compliance or <Noncompliance> with Department of Defense (DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.

3.3 Policies and procedures include:

- 3.3.1 Checklists.
- 3.3.2 Forms.
- 3.3.3 SOPs.
- 3.3.4 Template letters.
- 3.3.5 Template minutes.
- 3.3.6 Worksheets.

3.4 IRB member files include a resume for each IRB member.

4 RESPONSIBILITIES

4.1 IRB staff members are responsible to carry out these procedures.

5 PROCEDURE

5.1 Ensure that the IRB Records and Protocol files are maintained in the electronic system. Paper records may be used as indicated below or as a back-up system:

- 5.1.1 Minutes of IRB meetings: File a paper copy in minutes binder and electronic meeting workspace.

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5.1.2 Store all protocol-specific information (communications, documents, determinations) in the electronic system and make paper copy as needed.

5.2 File correspondence NOT related to a specific protocol in a file related to that person or topic.

5.3 IRB member rosters: File paper copy in IRB member roster binder; add list of members to electronic system.

5.4 IRB membership records (e.g., curricula vita and resumes): File paper copy in IRB member files.

5.5 Policies and procedures:

5.5.1 File paper copy of current policies and procedures in the policies and procedures binder and electronic equivalent in the IRB Library in the electronic system.

5.5.2 File paper copy of replaced policies and procedures in the policies and procedures history file.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR 46.115 7.2

7.2 21 CFR 56.115 7.1

7.3 AAHRPP I.4.; I.5.C.; I.7.A.; II.5.A.; II.5.B.

SOP: Standard Operating Procedures		
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HRP-071 Standard Operating Procedures

1 PURPOSE

- 1.1 This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.
- 1.2 The process begins when the IRB Director or Institutional Official / Organizational Official (IO/OO) or designee determines that a standard operating procedure needs to be created or modified.
- 1.3 The process ends when the new or revised standard operating procedure has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 None

4 RESPONSIBILITIES

- 4.1 The IRB Director carries out these procedures.

5 PROCEDURE

- 5.1 For a new standard operating procedure, assign a number.
- 5.2 Assign an author and approver.
- 5.3 Have the author create or update the standard operating procedure following the "TEMPLATE SOP (HRP-505)" or update the associated checklist or worksheet.
- 5.4 Have the approver review and approve the document.
- 5.5 Once approved by the approver:
 - 5.5.1 Update the approval/effective date.
 - 5.5.2 File and maintain the approved new or revised document in the standard operating procedure files.
 - 5.5.3 Post the approved procedure on the Human Research Protection Program Web site.
 - 5.5.4 File and retain the previous version in the standard operating procedure files.
 - 5.5.5 Send an email to affected individuals informing them of the change.

6 MATERIALS

- 6.1 TEMPLATE SOP (HRP-505)

7 REFERENCES

- 7.1 None

SOP: IRB Records Retention		
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HRP-072 IRB Records Retention

1 PURPOSE

- 1.1 This procedure establishes the process to retain IRB records.
- 1.2 The process begins each year in June.
- 1.3 The process ends when records that no longer need to be retained are destroyed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Protocol files are to be retained as long as required by law or as stated in the clinical trial agreement but no less than three (3) years after completion of research and then destroyed.
- 3.2 Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six (6) years after completion of the research.
- 3.3 Protocols in which there was no subject enrollment, or no research was conducted are to be retained the same as protocols where research was conducted.
- 3.4 All records not in protocol files are retained indefinitely.
- 3.5 Records may be maintained in printed form or electronically.
- 3.6 All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.
- 3.7 Records maintained that document compliance or non-compliance with Department of Defense (DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.
- 3.8 All records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.
- 3.9 All records are to be accessible for inspection and copying by the Veterans Administration (VA) Research and Development Committee at reasonable times and in a reasonable manner.
- 3.10 Veterans Administration (VA) IRB records are retained in accordance with VHA's Records Control Schedule.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

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5 PROCEDURE

- 5.1 Destroy protocol files for Veterans Administration (VA) research when approved by the National Archives and Records Administration.
- 5.2 Destroy protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.
- 5.3 Destroy all other protocol files when the protocol has been closed, withdrawn, or terminated more than three years unless otherwise required by law.
 - 5.3.1 In the case of multi-center research, three years is referenced to the organization's involvement in the research, not the entire study.

6 MATERIALS

- 6.1 None

7 REFERENCES

- 7.1 45 CFR 46.115
- 7.2 21 CFR 56.115
- 7.3 AAHRPP II.5.A.; II.5.B.

SOP: IRB Formation		
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HRP-080 IRB Formation

1 PURPOSE

- 1.1 This procedure establishes the process to form a new IRB or update the OHRP IRB registration of an existing IRB.
- 1.2 The process begins when the Institutional Official / Organizational Official (IO/OO) or designee determines the need for a new IRB or updated OHRP IRB registration.
- 1.3 The process ends when the IRB is registered, the Federalwide Assurance (FWA) is updated (if needed), and all members have completed training (if needed).

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using the "IRB Roster."
- 3.2 IRB registrations on file with OHRP will be made or updated as follows:
 - 3.2.1 To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS.
 - 3.2.2 Within 90 days after changes regarding the contact person who provided the IRB registration information or the IRB chairperson,
 - 3.2.3 Within 30 days of the change if an FDA-regulated IRB decides to review additional types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.
- 4.2 The IO/OO or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.)

5 PROCEDURE

- 5.1 For new IRBs:
 - 5.1.1 Determine from the IO/OO or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the "IRB Scope" tab of the "IRB Roster."
 - 5.1.1.1 Select:
 - 5.1.1.1.1 At least five individuals to serve as IRB members.
 - 5.1.1.1.2 Additional individuals to serve as alternate IRB members, if needed.
 - 5.1.1.1.3 At least one of the individuals to be the IRB chair.
 - 5.1.1.2 Follow "SOP: IRB Member Addition" for each IRB member.
 - 5.1.1.3 Use "WORKSHEET: IRB Composition (HRP-304)" and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
 - 5.1.1.4 Notify the IRB Director when all individuals have completed training.
 - 5.1.1.5 Using the "Create Committee" Smart Form, create the new committee in the system.

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5.1.1.6 Once training is completed, add committee members to the system with the Committee Member role.

5.1.1.7 Assign any designees eligible to conduct non-committee reviews using the “Update Eligible Designated Reviewers” activity.

5.2 Register the new IRB, or update an existing IRB’s OHRP registration as required by this policy, by following the instructions available at the OHRP website, <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html>

6 MATERIALS

- 6.1 IRB Roster
- 6.2 FORM: IRB Member Information (HRP-202)
- 6.3 SOP: IRB Member Addition (HRP-082)
- 6.4 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
- 6.5 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

- 7.1 45 CFR 46.103; 45 CFR 46.107; 45 CFR 46.108; 45 CFR 46.115(a)(5)
- 7.2 21 CFR 56.107; 21 CFR 56.115(a)(5)
- 7.3 AAHRPP II.1.

SOP: IRB Removal		
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HRP-081 IRB Removal

1 PURPOSE

- 1.1 This procedure establishes the process to remove/deactivate an IRB.
- 1.2 The process begins when the Institutional Official / Organizational Official (IO/OO) or designee determines that an IRB is no longer needed.
- 1.3 The process ends when the IRB is unregistered with OHRP and the Federalwide Assurance (FWA) is updated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using the "IRB Roster."

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 For internal IRBs:
 - 5.1.1 For each IRB member who will no longer serve as an IRB member prepare a "TEMPLATE LETTER: IRB Member Thank You (HRP-561)," have them signed by the IO/OO or designee and send to the former IRB members.
 - 5.1.2 Unregister the IRB with OHRP¹¹.
 - 5.1.3 Remove the IRB from the FWA.
 - 5.1.4 Remove members from "IRB Roster."
 - 5.1.5 Remove the individual's Committee Member role in the system.
 - 5.1.6 File:
 - 5.1.6.1 IRB Roster
 - 5.1.6.2 FWA
 - 5.1.6.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.
 - 5.2.1 Update the roster of IRB(s).

6 MATERIALS

- 6.1 IRB Roster
- 6.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)

7 REFERENCES

- 7.1 45 CFR 46.107; 45 CFR 46.103(b)(3); 45 CFR 46.115(a)(5)
- 7.2 21 CFR 56.107; 21 CFR 56.115(a)(5)
- 7.3 AAHRPP II.1.A.

¹¹ See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <https://ohrp.cit.nih.gov/efile/>.

SOP: IRB Membership Addition		
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HRP-082 IRB Membership Addition

1 PURPOSE

- 1.1 This procedure establishes the process to appoint and re-appoint an IRB member.
- 1.2 The process begins when an individual expresses interest, is nominated or applies to join the IRB IO/OO (This may be a completely new IRB member, or re-appointment of a previous member).
- 1.3 The process ends when the IRB roster is updated, and the new member has completed training.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using the “IRB Roster.”
- 3.2 IRB members /alternates are appointed for a three-year term. Members/alternates are eligible for re-appointment at the end of their term.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.
- 4.2 The Institutional Official / Organizational Official (IO/OO) or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

5 PROCEDURE

- 5.1 Have the individual complete the “FORM: IRB Member Information (HRP-202).”
- 5.2 Obtain a copy of the individual’s résumé or curriculum vita.
- 5.3 Interview the individual to assess suitability and availability.
 - 5.3.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
 - 5.3.2 In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the Institutional Official or designee will be consulted before proceeding with the appointment.
 - 5.3.3 For Veterans Administration (VA) representatives, communicate with the Veterans Administration (VA) Medical Center Director in writing to obtain confirmation of the appointment.
- 5.4 Add the individual to the “IRB Roster.”
- 5.5 Complete “WORKSHEET: IRB Composition (HRP-304)” and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.6 An appointment letter from the IO will be sent to the individual.
 - 5.6.1 If the individual requires training, schedule the individual for training. Training includes IRB Orientation, completion of CITI (IRB Members Course) and completion of COI disclosure in SHIELDS.

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5.7 Update the registration of all affected IRBs at <https://ohrp.cit.nih.gov/efile/> within 90 days.

5.8 File:

- 5.8.1 IRB Roster
- 5.8.2 Signed IRB appointment/re-appointment letter
- 5.8.3 FORM: IRB Member Information (HRP-202).
- 5.8.4 Résumé or curriculum vita.
- 5.8.5 Any other signed agreements.

5.9 Notify the IRB Director when the individual has completed training.

5.9.1 Assign individual the “Committee Member” role in the system.

5.9.2 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

6 MATERIALS

- 6.1 IRB Roster
- 6.2 FORM: IRB Member Information (HRP-202)
- 6.3 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
- 6.4 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 6.5 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

- 7.1 45 CFR 46.107; 45 CFR 46.108(a)(2); 45 CFR 46.115(a)(5)
- 7.2 21 CFR 56.107; 21 CFR 56.115(a)(5)
- 7.3 AAHRPP II.1.A.; II.1.B.;

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HRP-083 IRB Membership Removal

1 PURPOSE

- 1.1 This procedure establishes the process to remove an IRB member.
- 1.2 The process begins when an IRB member resigns or is removed from one or more IRBs. This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.
- 1.3 The process ends when the IRB registration is updated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 The Institutional Official / Organizational Official (IO/OO) or designee may remove IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs) with consultation from the IRB Director and IRB chair(s).
- 3.2 IRB rosters are maintained using the "IRB Roster."

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Remove the individual from "IRB Roster."
- 5.2 Complete "WORKSHEET: IRB Composition (HRP-304)" to ensure that the IRB is appropriately constituted.
- 5.3 Revise membership as needed. Prepare a "TEMPLATE LETTER: IRB Member Thank You (HRP-561)," have it signed by the IO/OO or designee and send to the individual.
- 5.4 Update the registration of all affected IRBs.¹²
- 5.5 File:
 - 5.5.1 IRB Roster
 - 5.5.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.6 Remove individual's "Committee Member" role in the system.
 - 5.6.1 If applicable, update the "Update Eligible Designated Reviewers" activity.

6 MATERIALS

- 6.1 IRB Roster
- 6.2 SOP: IRB Member Addition (HRP-082)
- 6.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 6.4 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

- 7.1 45 CFR 46.107; 45 CFR 46.103(b)(3); 45 CFR 46.115(a)(5)

¹² See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <https://ohrp.cit.nih.gov/efile/>.

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7.2 21 CFR 56.107; 21 CFR 56.115(a)(5)

7.3 AAHRPP II.1.A.

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HRP-084 IRB Meeting Scheduling and Notification

1 PURPOSE

- 1.1 This procedure establishes the process to schedule and notify individuals of convened meetings.
- 1.2 The process begins when there are approximately fewer than 90 days of meetings on the current schedule.
- 1.3 The process ends when meetings are scheduled at least three months in advance and individuals in the organization are notified of the schedule.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Whenever possible the IRB schedules meetings at least 90 days in advance.
- 3.2 Scheduled meetings are to occur at intervals appropriate for the quantity, complexity, and frequency of required actions, and to permit adequate oversight of the progress of approved research.
- 3.3 Additional meetings may be scheduled on an ad hoc basis to deal with urgent issues provided members are given sufficient notification and materials.

4 RESPONSIBILITIES

- 4.1 The IRB staff carries out these procedures.

5 PROCEDURE

- 5.1 Create a schedule of meetings for each IRB.
 - 5.1.1 Execute the "Create Meeting" Smart Form in the system for each scheduled meeting.
- 5.2 Post the schedule on the organization's Web site.
- 5.3 Notify the following individuals of the updated schedule with an email providing a link to the IRB Web page with the schedule information:
 - 5.3.1 IRB members.
 - 5.3.2 Investigators and research staff on the IRB email list.
 - 5.3.3 Institutional Official / Organizational Official (IO/OO) or designee.
- 5.4 Special meetings may be called by the IRB Chair/designee at any time to deal with urgent issues.
- 5.5 Under special circumstances, such as during the COVID-19 pandemic, when IRB board members and staff cannot meet in person, the IRB meetings can be scheduled and conducted remotely via teleconference/videoconference.

6 MATERIALS

- 6.1 None

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7 REFERENCES

- 7.1 ICH-GCP E6 3.3.2
- 7.2 AAHRPP II.2.C.; II.2.D.

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HRP-090 Informed Consent Process for Research

1 PURPOSE

- 1.1 This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children and recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof.
- 1.2 The process begins when an individual identifies a subject as a potential candidate for a research study.
- 1.3 The process ends when a subject or the subject's LAR provides legally effective informed consent or declines to do so.
- 1.4 Broad consent will not be implemented at this time.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.
- 3.2 In this procedure "subject/representative" means:
 - 3.2.1 The subject when the subject is an adult capable of providing consent.
 - 3.2.2 LAR when the subject is an adult unable to give consent.
 - 3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.
- 3.3 The exchange of information between the investigator and study participant can occur via one or more of the following modes of communication, among others: face to face contact, mail, telephone, fax or electronically. However, the most preferred methods to obtain informed consent must be face to face between the investigator and the potential study participant/study participant's legally authorized representative.
 - 3.3.1 When appropriate, (retrospective chart reviews, electronic surveys, and questionnaires) a request for waiving or altering some or all required elements of informed consent is required for any consent process that is not conducted face-to-face.
- 3.4 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.
- 3.5 If the subject is an adult unable to consent:
 - 3.5.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
 - 3.5.2 Permission is obtained from a LAR.
 - 3.5.3 A LAR must be in the class or persons approved by institutional policy or the IRB. See "SOP: LARs, Children, and Guardians (HRP-013)."

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- 3.6 If the subject is a child:
 - 3.6.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
 - 3.6.2 Permission is obtained from both parents unless:
 - 3.6.2.1 One parent is deceased, unknown, incompetent, not reasonably available.
 - 3.6.2.2 Only one parent has legal responsibility for the care and custody of the child or
 - 3.6.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
 - 3.6.3 If investigators foresee that obtaining consent remotely from the second parent (by e.g. fax, mail, electronically) may be necessary for a study, the consenting plan submitted for IRB review and approval should include how this would be accomplished.
 - 3.6.4 In the absence of a parent permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.
- 3.7 Generally, the IRB requires assent from children 7 or older but this may vary depending on other factors. Once the IRB has enough information about the assent process, the IRB determines whether assent is a requirement of all children, some of the children or none of the children
 - 3.7.1 Provide an assent document to children that are capable of providing assent when required by the IRB.
- 3.8 If the subject/representative cannot speak English:
 - 3.8.1 The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak language that the subject understands.
 - 3.8.2 When non-English speaking subjects are expected to enroll in the research the non-English consent documents require a certificate of translation to verify the translations are accurate.
 - 3.8.3 Those who translate the consent document are to provide a brief description of their qualifications, skill or experience or serving in this role and sign the certificate of translation form. See FORM: Translation Certificate (HRP-225).
 - 3.8.4 The research investigator may wish to delay the initial translation of the consent documents until after the IRB has reviewed and approved the English versions.
 - 3.8.5 Translation/Interpreting Services: Services are provided by the Institution using contracted professional resources that have been identified as able to provide multi-lingual translation/interpreting services. Nursing units shall have a princess phone stored on the unit with a splitter that will be used to access interpreting services. When interpretative services are needed, the extra phone with the splitter will be taken into the room and the phone in the room will be taken out of the wall jack, the splitter inserted into the wall jack and both lines connected to the splitter. This will allow the patient and another person to speak and hear responses without delay. A princess phone line with splitter can be obtained from Telecommunication. These services shall be made available upon request by contacting the Social Services Department. A list of employees that can provide interpretive services is also maintained by Social Services.
- 3.9 Conduct all discussions in a private and quiet setting.
- 3.10 Any knowledgeable individual may:
 - 3.10.1 Review the study with subject/representative to determine preliminary interest.
 - 3.10.2 If the subject/representative is interested, notify an investigator.
 - 3.10.3 If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

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3.11 In Sponsored research, medical care for participants is addressed by:

3.11.1 Including in its standard contract template a provision that the sponsor provides for the cost of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury to a participant, without regard as to the fault of the Sponsor. All Funding agreements will indicate who will provide care and who is responsible to pay for it.

3.11.2 Asking for an inclusion of such a provision in any proposed contract that does not use LSUHSC-S Institutional standard template.

3.11.3 Including the substance of any such provision in the consent form (See LSUHSC-S consent form template).

3.11.4 Including a statement in the consent form that participants do not waive any liability rights for personal injury by signing consent form.

3.12 Remote Consent:

3.12.1 FDA's requirements for electronic records/electronic signatures, informed consent, and IRBs are set forth in 21 CFR parts 11, 50, and 56, respectively. HHS requirements regarding the protection of human subjects are set forth in 45 CFR part 46. The information presented to the subject, processes used for obtaining informed consent, and documentation of the electronic informed consent (eIC) must meet the requirements of these and other applicable regulations.

3.12.2 For studies with no greater than minimal risk, the purpose of remote consent is to allow the investigator/study team member and potential subject to engage in the informed consent process in a way that is similar to what would be conducted in-person under normal circumstances. These conversations may occur via telephone, conference call, video conferencing, or telemedicine. Since the subject/LAR and witness needs to reference the informed consent form during the conversation, the informed consent must be sent electronically or via mail to them prior to engaging in the informed consent conversation.

3.12.3 For studies with greater than minimal risk, obtaining face to face consent using regular procedure is preferred. If the protocol includes remote consenting procedure, it would be considered on a case by case basis by the IRB.

3.12.4 Under special circumstances, electronic signatures/digital signatures may be allowed in lieu of traditional "wet ink" or "handwritten" signatures on informed consent form by the subject/LAR, the witness and the investigator. An example of such a special circumstance would be the COVID-19 pandemic, during which the investigators and the subjects are facing challenges with the informed consent process as the subjects participating in IRB approved studies are restricted to visit the study sites/investigator clinics in order to minimize the exposure.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

5.1 If the consent process will be documented in writing with the long form of consent documentation:

5.1.1 Obtain the current IRB approved consent form.

5.1.2 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in language understandable to the subject/representative.

5.1.3 Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion.

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5.1.4 If the subject/representative cannot read obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.1.5 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.1.6 Read the consent document (or have an interpreter read the translated consent document) with the subject/representative.

5.1.7 New section of consent – key information.

5.1.7.1 “Consent forms must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in research.”

5.1.7.2 Begin with a concise and focused presentation of key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.1.8 As per the revised common rule, New Elements of Informed Consent include,

5.1.8.1 One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: 13 (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

5.1.9 New additional elements of consent (optional):

5.1.9.1 A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

5.1.9.2 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

5.1.9.3 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

5.2 If the consent process will be documented in writing with the short form of consent documentation:

5.2.1.1 NOTE: The short form is used only when subjects cannot speak English.

5.2.1.2 Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).

5.2.1.3 Verify that you are using the most current IRB-approved version of the study specific short consent form and summary that the short consent form is in language understandable to the subject/representative.

5.2.1.4 Provide copies to the subject/representative. Whenever possible provide the short consent form and summary to the subject/representative in advance of the consent discussion.

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5.2.1.5 Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, family member, or friend of the subject/representative.

5.2.1.6 Obtain the services of an impartial witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness and the interpreter may be the same person. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.2.1.7 Have the interpreter translate the summary (not the short consent form) to the subject/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research.

5.2.1.8 Through the interpreter explain the details in such a way that the subject/representative understand what it would be like to take part in the research study. When necessary provide a different or simpler explanation to make the information understandable.

5.2.1.9 Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.

5.2.2 If the requirement for written documentation of the consent process has been waived by the IRB:

5.2.2.1 Obtain the current IRB approved script.

5.2.2.2 Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative.

5.2.2.3 When possible provide a copy of the script to the subject/representative.

5.2.2.4 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.2.3 Read the script (or have an interpreter translated the script) with the subject/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.2.4 Invite and answer the subject/representative's questions.

5.2.5 Give the subject/representative time to discuss taking part in the research study with family members, friends, and other care providers as appropriate.

5.2.6 Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

5.2.7 Ask the subject/representative questions to determine whether all the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:

5.2.7.1 The subject/representative understands the information provided.

5.2.7.2 The subject/representative does not feel pressured by time or other factors to make a decision.

5.2.7.3 The subject/representative understands that there is a voluntary choice to make.

5.2.7.4 The subject/representative is capable of making and communicating an informed choice.

5.2.8 If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

5.2.9 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

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5.3 If the subject/representative agrees to take part in the research study:

5.3.1 If the subject is a child:

5.3.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.

5.3.1.2 Request the assent (affirmative agreement) of the child unless:

5.3.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.

5.3.1.2.2 The IRB determined that assent was not a requirement.

5.3.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.

5.3.2 If the subject is an adult unable to consent:

5.3.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.

5.3.2.2 Request the assent (affirmative agreement) of the adult unless:

5.3.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.

5.3.2.2.2 The IRB determined that assent was not a requirement.

5.3.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.

5.4 Obtain written documentation of the consent process according to "SOP: Written Documentation of Consent (HRP-091)."

5.5 For minimal risk research such as simple surveys and questionnaires, where the IRB is not likely to require written documentation of consent process, use "Consent Letter Template for Surveys or Questionnaires Research.doc"

5.6 Remote Consent:

5.6.1 If the study is conducted or supported by HHS and involves an FDA-regulated product, the study is subject to both 45 CFR part 46 and 21 CFR parts 50 and 56, meaning that both sets of regulations must be followed. Where the regulations differ, the regulations that offer the greater protection to human subjects should be followed. Research not subject to 21 CFR parts 50 and 56 is also not generally subject to 21 CFR part 11 (FDA regulations regarding electronic records and electronic signatures).

5.6.2 Procedure:

5.6.2.1 Obtain the current IRB approved consent form.

5.6.2.2 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in language understandable to the subject/LAR.

5.6.2.3 If the subject/LAR is unable to be available in person for the informed consent process due to a special circumstance such as the COVID-19 pandemic, provide a copy of the consent form to the subject/LAR in advance of the consent discussion either by mailing the consent form to the subject/LAR's physical address or by providing it to him electronically such as via email.

5.6.2.4 Setup a time with the subject/LAR to discuss the informed consent and answer any questions they may have about the study. The investigator/designee must implement a method to ensure

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the identity of the subject/LAR (e.g. verification of state issued ID or use of personal questions or visual methods).

5.6.2.5 Perform the informed consent process as a regular process.

5.6.2.6 A witness must be present during the telephone/videoconferencing consent process. This witness must not be a member of the research team and must be impartial. The witness must be able to hear both sides of the conversation (e.g., speaker phone, conference line). A witness is required to attest to the adequacy of the consent process and to the subject's voluntary consent. Therefore, the witness must be present during the entire consent interview, not just for signing the documents. Requirements for social distancing may dictate that the witness may be in a different location than both the potential participant and/or the investigator/designee obtaining consent. Any arrangement is acceptable if the witness can listen to both parties in the informed consent discussion. If the potential participant or LAR agrees to participation, they sign the consent form and return it to the investigator (e.g., via mail, fax or email). If postal mail is used, a pre-paid, self-addressed envelope should be provided to the participant or LAR to mail the signed consent form back to the investigator.

5.6.2.7 Once the research team receives the signed informed consent document from the participant or LAR, the investigator/designee who conducted the consent process must sign and date the document using the current date. Under the signature line, the investigator/designee must document whether consent was obtained over the telephone or video conferencing, the date of the telephone/video conference, and the date the signed consent was received. For example, "Discussed with [participant or LAR name] via [telephone or videoconferencing] on [insert date] and received signed consent form on [insert date]." Include a brief reason for performing the informed consent discussion over the telephone/videoconferencing.

5.6.2.8 Electronic Consent

5.6.2.8.1 If an electronic consent will be used, it must contain all elements of informed consent required by HHS and/or FDA regulations (45 CFR 46.116 and 21 CFR 50.25). The information must be in language understandable to the potential subject or the subject's LAR and conveyed in a manner that minimizes the possibility of coercion or undue influence regarding the subject's decision to participate in a study (45 CFR 46.116 and 21 CFR 50.20). To ensure that the electronic consent is presented appropriately and that subjects will have enough time to dedicate to the electronic consent process, the subjects should be informed of approximately how long the process will take and what information will be presented to them.

5.6.2.8.2 Any electronic consent should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful. The electronic consent may also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.

5.6.2.8.3 Electronic consent may be used to either supplement or replace paper-based informed consent processes in order to best address the subject's needs throughout the course of the study.

5.6.2.8.4 The investigator is responsible for ensuring that legally effective informed consent is obtained before that subject takes part in the study (see 45 CFR 46.116 and 21 CFR 50.20, 312.60, and 812.100).

5.6.2.9 Signatures:

5.6.2.9.1 The procedure for electronic informed consent may include an electronic method to capture the signature of the subject or the subject's LAR. OHRP and FDA regulations permit the use of electronic signatures when written informed consent is required. OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted.

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5.6.2.9.2 Electronic signatures/digital signatures may be allowed in lieu of traditional “wet ink” or “handwritten” signatures on informed consent form by the subject/LAR, the witness, and the investigator.

5.6.2.9.3 LSU Health Shreveport has an institutional Docusign account. Investigators or research study staff that are approved to obtain informed consent must use institutional thirdparty document service. The investigators and research study staff wanting to utilize the service will need to contact Kenny Brown (kbrown@lsuhsc.edu) or Lamar Nunnery (rnunne@lsuhsc.edu) for an account. Once the Docusign account is established, the investigator and/or the research study staff can email the electronic consent form to the subject/LAR/witness. Then they should be able to provide their signatures through Docusign.

5.6.2.9.4 For FDA-Regulated Clinical Investigations

5.6.2.9.4.1 FDA regulations found at 21 CFR part 11 set forth the criteria under which FDA considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper (see 21 CFR 11.1(a)). In order to be considered equivalent to full handwritten signatures, electronic signatures must comply with all applicable requirements under 21 CFR part 11.[10] The electronic system must also capture and record the date that the subject or subject’s LAR provides consent (see 21 CFR 50.27(a)).

5.6.2.9.4.2 The regulations found at 21 CFR part 11 permit a wide variety of methods to create electronic signatures, including using computer-readable ID cards, biometrics,[11] digital signatures,[12] and user name and password combinations. FDA does not mandate or specify any particular methods for electronic signatures, including any particular biometric method upon which an electronic signature may be based.

5.6.2.9.4.3 Electronic signatures based on biometrics must be designed to ensure that they cannot be used by anyone other than their genuine owners (21 CFR 11.200(b)). Therefore, suitable biometrics should be uniquely identified with the individual and should not change with time. In addition, electronic signatures based upon biometrics are accepted provided they meet the requirements found in 21 CFR part 11 (i.e., they must contain pertinent information associated with the signing (see 21 CFR 11.50(a)); they are subject to the same controls as electronic records and must be included as part of any human readable form of the electronic record (see 21 CFR 11.50(b)); and they must be linked to their respective electronic records (see 21 CFR 11.70).

5.6.2.9.4.4 IRB, investigators, and sponsors should consider such issues as how the electronic signature is created and whether the informed consent or permission document can be produced in hard copy for review by the subject upon request. IRBs, investigators, and sponsors may rely on a statement from the vendor of the electronic system used for obtaining the electronic signature that describes how the signature is created and that the system meets the relevant requirements contained in 21 CFR part 11.

5.6.2.9.4.5 A copy of the informed consent must be provided to the person signing the form (see 21 CFR 50.27(a)).

5.6.2.9.4.6 The electronic informed consent process can be used to obtain assent from pediatric subjects (when required) and parental permission from their parent(s) or guardian. The general requirements for informed consent, found in 45 CFR 46.116 and 46.117 and 21 CFR 50.20, 50.25, and 50.27, apply to parental permission, in addition to the requirements for permission by parents or guardians and for assent by children found at 45 CFR 46.408 and 21 CFR 50.55. Therefore,

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parental permission may be obtained and documented using the same electronic informed consent procedures as would be used for informed consent.

5.6.2.9.4.7 Compliance with the requirements in Part 11 is meant in part to prevent fraudulent use. Therefore, the regulations found at 21 CFR part 11 require that an organization verify the identity of an individual before it establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature or any element of such electronic signature (see 21 CFR 11.100(b)).

5.6.2.9.4.8 FDA regulations do not specify any particular method for verifying the identity of an individual and accepts many different methods. For example, verifying someone's identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. In addition, use of security questions to confirm an individual's identity can also be considered.

5.6.2.9.4.9 For FDA-regulated clinical investigations, the electronic system that supports the electronic informed consent must be secure with restricted access (see 21 CFR 11.10 and 11.30) and should include methods to ensure confidentiality regarding the subject's identity, study participation, and personal information after informed consent has been obtained. If the entity holding the subject's personal information is a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law No.104-191) or acting as a business associate of a HIPAA-covered entity, the requirements in the HIPAA Privacy, Security, and Breach Notification Rules apply (see 45 CFR parts 160 and 164). For example, the subject's information within an electronic system must be encrypted, unless the entity documents why encryption is not reasonable and appropriate in their specific circumstances and implements a reasonable and appropriate equivalent measure.

5.6.2.9.4.10 HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject's personal representative) is a valid electronic signature under applicable laws and regulations. The Electronic Signatures in Global and National Commerce Act (E-Sign Act) (Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form. The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a subject (or a subject's personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.

5.6.2.9.4.11 The investigator should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process. The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy (see 45 CFR 46.109 and 21 CFR 56.109). It is recommended that an investigator discuss plans for using electronic informed consent with the IRB before finalizing development of the electronic informed consent to ensure that the IRB agrees that such a format may be used for the applicable research for obtaining informed consent.

5.6.2.9.5 LSU Health Shreveport has an institutional DocuSign account. Investigators or research study staff that are approved to obtain informed consent must use institutional thirdparty document service. The investigators and research study staff wanting to utilize the service will need to contact Kenny Brown (kbrown@lsuhsc.edu) or Lamar Nunnery (rnunne@lsuhsc.edu) for an account. Once the DocuSign account is established, the investigator and/or the research study staff can email the electronic consent form to the subject/LAR/witness. Then they should be able to provide their signatures through DocuSign.

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5.6.2.9.5.1

5.6.3 The investigator must document the verbal consent of the subject/LAR after the informed consent discussion and prior to proceeding with the research activities.

5.6.4 The final informed consent document must be filed in the designated investigator/site regulatory file location. A copy of the final informed consent document, signed by the participant or LAR, the investigator, and the witness (if applicable), must be sent back to the participant via email/scan, fax, or postal mail.

5.6.5 IRB responsibilities

5.6.5.1 HHS and FDA regulations require that an IRB review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by the applicable regulations (see 45 CFR 46.109(a) and 21 CFR 56.109(a)). A critical part of this responsibility is for the IRB to ensure there is an adequate informed consent process that protects the rights and welfare of subjects participating in HHS-regulated research and FDA-regulated clinical investigations (see 45 CFR 46.109(b) and 21 CFR 56.109(b) and 56.111(a)(4)). Therefore, the IRB must review and approve the electronic informed consent and any amendments to it that the subject will receive and view (see 45 CFR 46.109(a) and 21 CFR 56.109(a)). The IRBs must maintain and retain copies of materials that have been reviewed in accordance with 45 CFR 46.115 and 21 CFR 56.115.

The IRB should also review any optional questions or methods used to gauge subject comprehension of key study elements. The IRB should also review the usability of the electronic informed consent materials to ensure that they are easy to navigate. If the program uses hyperlinks to convey study-related information, IRB should review the contents to which subjects are referred in order to determine if the study-related information that has been supplied is accurate and appropriate. Because Web sites are often modified over time, IRB must maintain the version of the Web site information that contains the study-related information that the IRB reviews and approves, either electronically or as a hard copy (see 45 CFR 46.115 and 21 CFR 56.115).

6 MATERIALS

6.1 Long form of consent documentation:

6.1.1 Consent form

6.2 Short form of consent documentation:

6.2.1 Short consent form

6.2.2 Summary (same information as the English consent form used for long form of consent documentation)

6.3 Requirement for written documentation of the consent process has been waived by the IRB:

6.3.1 Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

6.4 SOP: LARs, Children, and Guardians (HRP-013).

6.5 SOP: Written Documentation of Consent (HRP-091)

6.6 Consent Letter Template for Surveys or Questionnaires Research.doc

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6.7 <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html#:~:text=For%20the%20purposes%20of%20this,card%20readers%2C%20to%20convey%20information>

7 REFERENCES

- 7.1 45 CFR 46.109; 45 CFR 46.116; 45 CFR 46.117
- 7.2 21 CFR 11; 21 CFR 50; 21 CFR 56
- 7.3 AAHRPP I.8.A.; II.3.F.; II.4.B.; III.1.F.

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HRP-091 Written Documentation of Consent

1 PURPOSE

- 1.1 This procedure establishes the process to document the informed consent process in writing.
- 1.2 The process begins when a subject agrees to take part in a research study.
- 1.3 The process ends when the consent process is documented in writing, including in an electronic format, to the extent required by this procedure (As per revised common rule, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.)

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.
- 3.2 In this procedure "subject/representative" means:
 - 3.2.1 The subject when the subject is an adult capable of providing consent.
 - 3.2.2 The Legally Authorized Representative (LAR) when the subject is an adult unable to give consent.
 - 3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child's general medical care.
 - 3.2.4 When the subject is a child an assent document will be used for children capable of providing assent when required by the IRB.

4 RESPONSIBILITIES

- 4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

- 5.1 If the consent process will be documented in writing with the long form of consent documentation:
 - 5.1.1 Verify that the consent form is in language understandable to the subject/representative.
 - 5.1.2 Print the name of the following individuals on the consent document:
 - 5.1.2.1 Subject/Representative
 - 5.1.2.2 Person obtaining consent
 - 5.1.3 Have the following individuals personally sign and date the consent document:
 - 5.1.3.1 Subject/Representative
 - 5.1.3.2 Person obtaining consent
 - 5.1.4 Have a witness observe and verify that the signature of the subject is original.
 - 5.1.4.1 The witness to the signature cannot be a member of the research team.
 - 5.1.4.2 The witness to the signature is not attesting that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject.
 - 5.1.5 If the IRB required written documentation of assent, note on the signature block one of the following:

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- 5.1.5.1 Assent of the child was obtained.
- 5.1.5.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
- 5.1.6 Have the person obtaining consent personally sign and date the consent document.
- 5.1.7 If an impartial witness was part of the consent process:
 - 5.1.7.1 Print the name of the impartial witness on the consent document.
 - 5.1.7.2 Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.
- 5.1.8 Provided copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.
- 5.2 If the consent process will be documented in writing with the short form of consent documentation:
 - 5.2.1 Verify that the short consent form is in language understandable to the subject/representative.
 - 5.2.2 Print the name of the following individuals on the short form consent document and the summary:
 - 5.2.2.1 Subject/Representative
 - 5.2.2.2 Person obtaining consent
 - 5.2.2.3 Impartial witness
 - 5.2.3 Have the following individuals personally sign and date the short form consent document and/or the summary:
 - 5.2.3.1 Subject/Representative sign short form consent document
 - 5.2.3.2 Person obtaining consent sign short form consent document
 - 5.2.3.3 Impartial witness sign both short form consent document and summary
 - 5.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:
 - 5.2.4.1 Assent of the child was obtained.
 - 5.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 - 5.2.5 Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.
- 5.3 If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent is writing, offer the subject/representative the option to document his or her consent is writing.
 - 5.3.1 If the subject/representative declines, take no further action.
 - 5.3.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation
- 5.4 Place the signed and dated documents in the subject's binder.
- 5.5 Place a copy of the signed and dated consent document along with the HIPAA Authorization with the subjects medical record also for drug studies, place a copy of the IDIR in the subjects medical record and for device studies place a copy of the label and instructions for use in the subjects medical record.

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5.6 When following GCP requirements for clinical trials, the case history for each individual subject should document that informed consent was obtained prior to participation in the study.

6 MATERIALS

6.1 If the consent process will be documented in writing with the long form of consent documentation:

6.1.1 Consent document

6.2 If the IRB requires documentation of assent for children that are capable:

6.2.1 Assent document

6.3 If the consent process will be documented in writing with the short form of consent documentation:

6.3.1 Short consent document

6.3.2 Summary (same content as the long form of consent documentation)

6.3.3 Assent document

6.4 If the assent of a child will be documented in writing with the short form of assent documentation:

6.4.1 6.4.1 Short assent document

6.5 CHECKLIST - Waiver of Written Documentation of Consent (HRP-411)

7 REFERENCES

7.1 45 CFR 46.117

7.2 21 CFR 50.27

7.3 AAHRPP II.3.F.; II.3.G.; III.1.F.

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HRP-092 Humanitarian Use Devices (HUD)

1 PURPOSE

- 1.1 This procedure establishes the process for LSUHSC-S physicians to use Humanitarian Use Devices (HUDs) in a facility after the IRB has approved their use in that facility.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in no more than 8,000 individuals in the United States per year. HUDs cannot be sold for profit except in narrow circumstances and they can only be used in a facility after an IRB has approved their use in that facility, except in emergencies where the physician determines that approval cannot be obtained in time to prevent serious harm or death to the patient. Although the use of a HUD within treatment does not constitute research, the FDA requires IRB approval to be obtained before a HUD can be used in a facility.
- 3.2 The FDA defines a device user facility as a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment, which is not a physician's office. The name of the facility where a device will be used must be stated in the SHIELDS application and will be listed on the approval letter. Approval is for the facility listed on the letter.
- 3.3 If a HUD is used outside its approved indication(s), FDA recommends that the physician obtain informed consent from the patient and ensure that reasonable patient protection measures are followed, such as devising schedules to monitor the patient, taking into consideration the patient's specific needs and the limited information available about the risks and benefits of the device. FDA further recommends that the physician submit a follow-up report on the patient's condition to the HDE holder.

4 RESPONSIBILITIES

4.1 Principal Investigator Responsibilities:

4.1.1 It is the primary physician's responsibility to provide this institution with oversight of the HUD. The physician is responsible for regulatory requirements, local communications, and storage management of the HUD. The primary physician must obtain IRB approval prior to first use of the HUD and maintain IRB approval (continuing review) if the HUD continues to be used at the institution.

4.1.2 Informed Consent: HUD devices are not investigational, and their treatment use is not considered research, therefore, informed consent from individuals as research subjects is NOT applicable. This institution requires physician to obtain informed consent from each patient prior to use of the HUD utilizing the HUD Brochure, patient information packet (if available), standard procedural consent and the LSUHSC-S off-label informed consent addendum (if applicable).

4.1.3 An HDE holder may collect safety and effectiveness data in a clinical investigation for the HDE-approved indication(s) without an IDE. Clinical investigations of a HUD for a different indication must be conducted under IDE regulations.

4.1.4 Continuing Review: The treating physician must fulfill continuing review requirements at the designated IRB intervals.

4.1.5 Modifications: All modifications to the HUD submitted and approved by the FDA must be submitted as a modification. As applicable, the submission should be accompanied by 1) the FDA's approval of the

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modification; 2) the HDE holder's amendments to the HUD product labeling, HUD brochure and/or other pertinent materials corresponding to the requested modifications.

4.1.6 Whenever a HUD may have caused or contributed to a death or serious injury or has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [21 CFR 814.126(a) and [21 CFR 803], it must be reported to the HDE holder, FDA and to the IRB. This HDE regulation requires that MDR reports submitted to FDA, in accordance with 21 CFR Part 803 shall also be submitted to the IRB. Medical Device Reports (MDRs) must be submitted to FDA and to the IRB if the device may have caused or contributed to death or serious injury and for certain malfunctions (21 CFR 803). Only one medical device report from the user facility or manufacturer is required if the reporting entity becomes aware of information from multiple sources regarding the same patient and same event (21 CFR 803.22)

4.1.7 Emergency Use: The physician must report the emergency use within five days providing written notification of the use to the IRB Chair. The notification must include the following: the identification of the patient involved, the date of the use, and the reason for the use. Upon notification, the designated reviewer will use the "Worksheet: Emergency Use (HRP-322)" to determine whether the circumstances will meet the regulatory requirements or, if the report is received after the emergency use, if the circumstances met the regulatory requirements. The IRB will provide the results of this determination in writing to the physician. The Notification of Emergency Use will be documented in the IRB Emergency Use Log.

4.2 IRB Responsibilities: IRB approval is required before a HUD is used at this institution/facility. The only exception to prior IRB approval is an emergency use when IRB approval cannot be obtained in time to prevent serious harm or death to the patient.

4.2.1 For initial review of a HUD, the IRB is required to conduct a full board review. For continuing review the IRB may use expedited review procedures if the IRB determines that full board review is not required.

4.2.1.1 At initial convened review, the IRB may provide review and approval for on-label and off-label use. The IRB may use its discretion to determine how to approve the use of a HUD.

4.2.2 Emergency Situations: If a physician in an emergency situation determines that IRB approval for the use of a HUD cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be used within the scope of its labeling or off-label without prior IRB approval. Emergency use situations are those in which:

4.2.2.1 The patient has a life-threatening condition that needs immediate treatment.

4.2.2.2 No generally acceptable alternative treatment for the condition exists.

4.2.2.3 Because of the immediate need to use the device, there is no time to obtain IRB approval.

Whenever possible, physicians should obtain informed consent from the patient or a legally authorized representative.

4.3 When HUD will be used outside its approved indication(s) (i.e. off-label use), the IRB will conduct a full board review during initial and continuing review.

5 PROCEDURES

5.1 Follow "HRP-021: SOP-Pre-review".

5.2 When HUD will be used as per approved indication, use standard procedural consent.

5.3 When HUD will be used outside its approved indication(s) (i.e. off-label use), use "HUD_Off Label Consent Addendum Template.

6 MATERIALS

6.1 Worksheet: Emergency Use (HRP-322)

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6.2 WORKSHEET: Criteria for Approval for HUD (HRP-323)

6.3 HUD_Off Label Consent Addendum Template

7 REFERENCES

7.1 21 CFR 814.126(a)

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HRP-093 Activities that require IRB Review

1 PURPOSE

- 1.1 This policy establishes the process to determine which activities require LSUHSC-S IRB review.
- 1.2 The policy begins when planning or preparing for any research activity or clinical investigation activity that involves human subjects.
- 1.3 The policy ends when IRB involvement in the LSUHSC-S research or clinical investigation activity is determined.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY STATEMENT

- 3.1 This policy covers all human subjects research including preparatory to research activities that involve interventions or interactions with living individuals (e.g. advertising, recruitment, and/or screening of potential subjects for research) and/or accessing or obtaining identifiable, private information from or about living individuals for the purpose of conducting research (e.g., review of medical records).
- 3.2 In this policy, human research means any research or clinical investigation that involves human subjects as defined in SOP: Definitions (HRP-001).
- 3.3 Requests for Human Subjects Determinations must be submitted through the electronic submission system, Shields. Requests sent through other mechanisms (email, phone, fax) will not be processed.

4 RESPONSIBILITIES

- 4.1 Investigators perform these procedures.

5 PROCEDURE

- 5.1 Investigators should review the definitions to determine whether an activity is human research. See SOP: Definitions (HRP-001).
- 5.2 Investigators should submit their activities to the IRB for a determination whenever the activity involves human subjects or their identifiable private information.
- 5.3 Investigators should submit their activities to the IRB for a determination when they anticipate that correspondence from the IRB will be required for presentation or publication.
- 5.4 Investigator must submit "Template: Determination of Human Subject Research"; if there is any question whether the project/activity is human subject research. The IRB will determine if it is human subject research. If the IRB determines the activity to be Not Human Subject Research, the investigator will receive a Notice of Determination of Human Subject Research.

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5.5 Activities that are clinical investigations covered under FDA regulations (FDA 21CFR50.3(c); 21CFR 50.3(e); 21 CFR 56.102(g)) require IRB review. Submit a full application to the IRB.

5.6 The following table is a list of activities that may or may not require IRB review. Other activities not on the list may also represent human subjects research.

ACTIVITY	DESCRIPTION	IRB Determination
Cadaver or autopsy material or specimens	Research involving deceased individuals does not require IRB oversight. Note: If using or disclosing decedents PHI see HIPAA Privacy Rule; https://privacyruleandresearch.nih.gov/pr_08.asp#8f	NO
Case Report Studies	Retrospective review of a patient's medical record with intent to document a specific situation or the experience of an individual without intent to form a research hypothesis, draw conclusions or generalize findings. The data will be de-identified.	NO if using only 1-2 records. YES if using 3 or more records.
	Prospective: A single subject study with clear intent, before recruiting or interacting with the participant, to use data that would not ordinarily be collected in the course of treatment. The intent is to report and publish the case study.	YES
Classroom Assignments/ Research Methods Classes	Normal educational activities designed to teach students research methods or demonstrate course concepts. The activities are not intended to create new knowledge or generalize outside the classroom.	NO Faculty/Instructors have an obligation to protect students and others
Clinical Investigations	Experiments using a test article on one or more human subjects that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the Food and Drug Administration. Products regulated include foods (dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives), drugs for human use, medical devices for human use, biological products for human use, and electronic products.	YES
"Compassionate" or Treatment Use of an Investigational Drug or Device	A treating physician determines an unapproved drug or device is the best treatment for a patient, and ALL of the following criteria apply: 1. The patient has a condition that is life-threatening or a serious disease, 2. No comparative or satisfactory alternative treatment is available, 3. A controlled, clinical trial of drug/device is ongoing,	YES

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	4. Sponsor is pursuing marketing approval.	
Planned Emergency Research with a Waiver of Consent	The exception to the consent requirements applies to a limited class of research activities involving individuals who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized representative.	YES See SOP: Planned Emergency Research with a Waiver of Consent (HRP-027) for the Conditions to conduct the research and for Requirements for IRB approval
Emergency Use of an Investigational Drug or Device	A treating physician determines an unapproved drug or device is the best treatment for a patient, and ALL of the following criteria apply: 1. The test article is used one time per institution to treat a single patient, 2. The patient has a condition that is life-threatening or severely debilitating, 3. No standard treatment is available, 4. There is not sufficient time to obtain IRB review and approval, 5. The emergency use is reported to the IRB within five working days; when possible, the treating physician should consult with the IRB prior to use.	IRB NOTIFICATION REQUIRED WITHIN 5 DAYS OF USE See SOP: Emergency Use Review (HRP-023) for more information.
	Sponsor or manufacturer of the drug/device requires IRB approval before release in an emergency use situation.	YES
Humanitarian Use Device (HUD)	A HUD is a "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the U.S. per year [21 CFR 814.3(n)]. They can only be used in a facility after an IRB has approved their use in that facility, except in certain emergencies.	YES

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Innovative or Novel Procedures, Treatment, or Instructional Methods	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants in order to compare to standard of care or normal procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, thus to develop or contribute to generalizable knowledge.	YES
	The use of innovative interventions that are designed solely for therapeutic purposes to enhance the well-being of an individual patient with a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to an individual patient. Research is not involved.	NO
Internet Research	Online websites set up for the purposes of collecting data regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc.	YES
In Vitro Device Studies	Current FDA guidance indicates that IRB review is required for any IVD study involving human specimens/samples, even when the research involves no identifiers and the biological materials cannot be linked to any identifying information.	YES
Literature Review	An assessment of a body of published research that addresses a research question. Identifies or summarizes what is already known about an area of study or may identify questions a body of research does not answer.	NO
Oral Histories	Oral histories represent a technique that usually involves a series of taped interviews with participants regarding a particular historical event or period. When the focus is a recollection of societal or institutional events rather than the interviewees subjective perceptions then the project is not usually human subjects research.	NO
	Oral histories that involve the testing or confirmation of a hypothesis or the subjective perceptions of the interviewees may be human subjects research.	YES
Pilot Studies	Pilot studies that meet the definition of human research, regardless of the number of subjects enrolled or the duration of the studies.	YES
Professional Recognition	Employees or agents of LSUHSC-S involved in research projects carried out at other locations when the services performed merit professional recognition or publication privileges.	YES

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Quality Assurance (QA) and Quality Improvement (QI) Activities	<p>Systematic, data-guided activities designed to implement promising ways to improve patient outcomes, system performance or professional development. The activity usually occurs within standard of care or normal educational or business practices confined to the local setting.</p> <p>Intent is only one element considered. The activity often involves an iterative process that may change over time in response to ongoing feedback. The plan may include mechanisms for assessment, intervention, analysis and implementation. Any risk should be confined to privacy or confidentiality. One-time activities designed to meet personal educational requirements are generally not QA or QI. Since QI and research often overlap all investigator initiated QI/QA projects should be sent to the IRB for a determination.</p>	<p>YES – must have a determination</p> <p>(All QA/QI activities implemented in a patient or educational setting require oversight by compliance or quality services).</p>
	Proposed QI/QA activities that may have research intent, address a specific deficit in scientific knowledge or are intended to be generalized beyond the local setting require submission to the IRB for a determination.	YES
Repositories, Registries or other specimen or record keeping mechanisms (e.g., data, specimens)	Proposed activity involves accessing a storage site or mechanism by which identifiable human tissue, blood, genetic material, records or data are stored or archived.	YES
	Proposed activity involves accessing stored human tissue, blood, genetic material or data that will be de-identified by study personnel at the time of collection or when the investigator will retain a code or link that enables re-identification of data or specimens.	YES
	Proposed activity involves accessing a controlled repository where the investigator does not receive any PHI or links to the data or specimens, AND the investigator must enter into an agreement with the repository provider that states under no circumstances will the identity of the subjects be released to the investigator.	NO
	Proposed activity involves accessing publically available specimens or data.	NO
Self - Experimentation	Any research where the investigator is also a subject (investigator self-experimentation) requires IRB review and approval.	YES

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Standard Diagnostic or Therapeutic procedures	The collection of data about established and accepted diagnostic, therapeutic procedures, or instructional methods is intended for dissemination or contribution to generalizable knowledge.	YES
	There is an alteration in patient care or assignment for research purposes or the alteration is in a way that standard diagnostic or therapeutic procedures are not completely up to the discretion of a practitioner.	YES
	A diagnostic procedure is added to a standard treatment for the purpose of research.	YES
	An established and accepted diagnostic, therapeutic procedure or instructional method is performed only for the benefit of a patient and not for research purposes.	NO
Student Conducted Research	Thesis or dissertation projects involving human participants conducted to meet the requirements of a graduate degree.	YES
Surveys	Interacting with participants directly or through third party survey administrators to answer a research question requires IRB review even if not collecting identifiable information.	YES

6 MATERIALS

- 6.1 SOP: Definitions (HRP-001)
- 6.2 SOP: Planned Emergency Research (HRP-022)
- 6.3 SOP: Emergency Use Review (HRP-023)

7 REFERENCES

- 7.1 45 CFR §46.102
- 7.2 21 CFR §50.3; 21 CFR §56.102; 21 CFR §56.103; 21 CFR §312.3(b); 21 CFR §812.3(h)
- 7.3 AAHRPP I.1.A.; III.1.

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HRP-094 Repositories: Banking of Specimen and/or Data

1 PURPOSE

- 1.1 This policy establishes a process for the banking of specimens (human biological materials)/data by LSUHSC-S investigators. The banking of specimens/data refers to the creation of banks and/or databases ("repositories") to collect, store, and distribute human biological materials (specimens) and data for future research purposes. Repository activities involve three components: (1) Collection of specimens/data; (2) storage and management of the specimens/data; and (3) distribution of specimens/data to "recipient" investigators for use in a future research project.
- 1.2 The policy begins when the Institutional Review Board (IRB) has determined that the banking of specimens/data is intended by an investigator, and/or research site designee.
- 1.3 The policy ends when the IRB determines that the policy should no longer be observed or the repository is no longer in use and the IRB is notified.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY STATEMENT

3.1 Non-Research Repositories:

3.1.1 If specimens or data were originally collected for non-research purposes (clinical care) AND were added to a non-research repository/database without any identifiable private data or information or links (codes, pathology numbers, medical record numbers) to identifiable private data or information, it is a "non-research" repository/database. If links are included, this policy section does not apply. Studies using specimens/data from non-research repositories or databases are generally considered Not Human Subjects Research.

3.2 Research Repositories:

3.2.1 If specimens or data were collected for research purposes, it is a research repository. Collection of specimens/data, repository storage or data management and use of specimens or disclosure of data are all considered "research activities" and require IRB review and approval.

3.2.2 Specimen/data repositories may include two kinds of specimens/data: a) those collected with the expressed purpose of distribution to other investigators, and b) those collected by individual investigators, and not originally intended to be shared with others, but which are subsequently shared as part of a repository.

3.2.3 Any collection which contains specimens/data that are potentially identifiable (i.e. directly or indirectly with a code or link) and are distributed to someone other than the original named investigator(s) making the collection, regardless of the original intent, may be considered to be a repository requiring IRB oversight.

3.2.4 If the original named investigator(s) wishes to use the potentially identifiable specimens or data for any future use that is not part of the original IRB approved protocol then the subsequent use will also require IRB approval and oversight.

3.3 Collection of a Specimen/data for a Repository:

3.3.1 Investigators who collect directly or indirectly identifiable specimen/data must request IRB review and approval of the activity. Under most circumstances, written informed consent and HIPAA Authorization from the

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subject is required and should include information about the repository, the conditions under which the specimens/data will be shared with others and if the specimen/data will be store for future use beyond the current research.

- 3.4 Confidentiality risks of research participation may extend beyond the duration of the subject's direct participation in research. This is common when records or samples with identifiers are retained by the investigator. These confidentiality risks and/or new disclosure concerns are important to consider.
- 3.5 The ability to re-test samples containing extractable DNA has made it possible that retained samples may contain information that cannot be foreseen at the time of initial collection, but that may eventually be of great importance or sensitivity. Investigators should destroy identifiers to their samples/data when possible.
- 3.6 In regards to storing data/ specimens outside of LSUHSC-S, if the repository is located at an external institution or organization, the investigator must submit (to the LSUHSC-S IRB) a copy of the external site's IRB approval letter for operation of the repository at that institution or organization.
- 3.7 The IRB at the institution where the repository is located must approve and maintain oversight of a protocol that: (a) specifies the conditions under which data and specimens may be accepted and shared with other investigators or designees and (b) ensures adequate privacy and confidentiality protections for subjects contributing to the repository.
- 3.8 Any "research" specimen/data repository that distributes materials/data requires IRB approval prior to the distribution. The investigator must follow the conditions under which the specimens/data will be shared as described in the IRB initial review application.
- 3.9 These conditions must consider the privacy of the individuals from whom the tissue came, what the informed consent permitted, and the intent of the person to whom the tissue is sent. The recipient of the tissue samples must abide by the conditions specified.
- 3.10 A gatekeeper or repository director, established under the IRB guidelines and pursuant to the IRB approval for the repository, should evaluate each request for samples to see if the request is consistent with the IRB's conditions for sharing samples and with the original informed consent and the repository's policies.
- 3.11 The transfer of data to outside collaborators or to external repositories requires a Data Use Agreement or other types of agreements/contracts between the parties involved. All agreements need to be signed by an authorized agent of LSUHSC-S.
- 3.12 The transfer of materials to outside collaborators requires the use of Material Transfer Agreements (MTAs). MTAs ensure LSUHSC-S rights are protected when specimens or reagents are shared with outside investigators or institutions. An MTA protects the intellectual and other property rights of the provider and generally addresses:
 - 3.12.1 Limits on the use of the research materials, inventions, and results
 - 3.12.2 Prohibitions on the redistribution of the material
 - 3.12.3 Conditions of use, including prohibitions of use in animals or humans
 - 3.12.4 Conditions for publication, usually with provisions that the manuscript must be seen by the donor before submission for publication

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- 3.12.5 A hold-harmless cause, meaning that the donor has no liability resulting from the use of the material
- 3.12.6 The return of unused materials.

3.13 The Office of Sponsored Programs and Technology Transfer (OSPTT) coordinates the completion of MTAs. MTAs need to be signed by an authorized agent of LSUHSC-S.

4 RESPONSIBILITIES

- 4.1 The investigator should ensure these procedures are carried out to ensure safe and proper usage of repositories and banking of specimens/data.

5 PROCEDURE

- 5.1 The following procedure should be followed when establishing a repository at LSUHSC-S.
- 5.2 The investigator is to develop written policies and procedures on operating and managing the repository. The policies and procedures are to be provided to the IRB as part of the initial application.
- 5.3 The following documents must be included with the TEMPLATE PROTOCOL (HRP- 503).
 - 5.3.1 Purpose of the repository
 - 5.3.2 Specimen and data collection procedures
 - 5.3.3 Specimen and data storage/retention
 - 5.3.4 Specimen derivation and processing
 - 5.3.5 Specimen and data distribution
 - 5.3.6 Obtaining informed consent
 - 5.3.7 Procedures for protecting privacy and confidentiality (for example, anonymization of specimens/data, coding of specimens/data, encryption, limited access/secure storage)
 - 5.3.8 Confidentiality measures
 - 5.3.9 Procedures for return of research results (if and under what conditions)
 - 5.3.10 Repository oversight
 - 5.3.11 Model informed consents for subjects contributing to the repository
 - 5.3.12 Model agreements for investigators collecting tissues for the repository and for investigators receiving tissues from the repository. These agreements should address use of specimens/data, human subject protections, sharing of specimens with third parties, commercial use of specimens, biohazards, and indemnification.
 - 5.3.13 A plan for the disclosure of clinically relevant results/incidental findings including the mechanism for evaluating whether the results of research testing are clinically relevant and might warrant disclosure to the research participants. A mechanism for disclosure to participants of clinically relevant results/incidental findings to be included.
 - 5.3.14 A Certificate of Confidentiality, if needed. Certificates of Confidentiality are issued by the National Institutes of Health to protect identifiable research information from forced disclosure. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Additional information is available at the NIH Certificate of Confidentiality Kiosk web site.
- 5.4 If the experimental design allows it, all identifiers should be stripped from the stored samples or data, such that they can never be traced to the individual

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5.5 If the experimental design requires that the specimens/data be referable back to an individual subject, retention creates a durable confidentiality risk that must be both controlled and disclosed.

5.6 Storage with easily traceable identifiers such as patient names, initials, social security numbers, or medical record numbers is almost never appropriate. An additional safeguard for maintaining confidentiality while retaining a link is to use a code in place of identifiers and retaining a master list that provides a key to the code.

6 MATERIALS

6.1 TEMPLATE PROTOCOL (HRP-503)

7 REFERENCES:

7.1 NIH Certificate of Confidentiality Kiosk web site

7.2 AAHRPP II.3.

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