



# Harvard University Area IRB Standard Operating Procedures

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SOP: Definitions				
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**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 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.

3.2 Ancillary Review: Ancillary reviews allow individuals, departments, offices, and other additional reviewers to give feedback, approval, and/or provide documentation on the submission in parallel with the IRB review. During IRB review, staff of the IRB office will manually select the reviewer or reviewing organization/department each time a review is needed or required. IRB staff can add ancillary reviewers to a study, modification, or continuing review.

3.3 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.

3.4 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.

3.5 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.

3.6 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.

3.7 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.

3.8 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:

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

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

3.8.3 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.

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

3.8.5 Board or executive relationship, regardless of compensation.

3.8.6 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.

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

3.9 Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

3.10 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews. For the purpose of non-committee reviews, IRB staff who meet the definition of an Experienced IRB Member conduct the review.

3.11 ESTR: The Electronic Submission, Tracking, and Reporting system that automates the IRB submission and review process for the Harvard IRBs.



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- 3.12 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.
- 3.13 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.
- 3.14 Finding of Non-Compliance: Non-Compliance in fact.
- 3.15 Harvard University Area (HUA): Harvard University Area is comprised of the Cambridge and Allston campuses and include the Faculty of Arts and Sciences, as well as the following schools: John F. Kennedy School of Government, Harvard Graduate School of Education, Harvard Law School, Harvard Divinity School, Harvard Graduate School of Design, Radcliffe Institute for Advanced Study, Harvard School of Engineering and Applied Sciences, and the Harvard Business School.
- 3.16 Harvard University Area IRB (HUA IRB): The Harvard University-Area IRB, the Committee on the Use of Human Subjects (CUHS), is the IRB for the Cambridge and Allston campuses.
- 3.17 Human Research: Any activity that either:<sup>1</sup>
- 3.17.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
- 3.17.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.
- 3.18 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) identifiable private information. For the purpose of this definition:
- 3.18.1 Intervention: Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- 3.18.2 Interaction: Communication or interpersonal contact between investigator and subject.
- 3.18.3 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 which the individual can reasonably expect will not be made public (for example, a medical record).
- 3.18.4 Identifiable Information: Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
- 3.19 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.
- 3.20 Immediate Family: Spouse, domestic partner; and dependent children.
- 3.21 Institutional Official: The University Chief Research Compliance Officer.
- 3.22 Institutional Profile: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborate Studies or Multi-Site Studies.
- 3.23 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 procedures(s) involved in the research.
- 3.23.1 If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
- 3.23.2 See "WORKSHEET: LARs, Children, and Guardians (HRP-013)" for who may serve as a Legally Authorized Representative at this institution.

<sup>1</sup> The terms "Human Subject Research," "Research Involving Human Subjects," "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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- 3.24 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.<sup>2</sup>
- 3.24.1 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.
- 3.24.2 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).
- 3.25 Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.
- 3.26 Non-Committee Review: Any of the following:
- 3.26.1 Determination of whether an activity is Human Research.
- 3.26.2 Determination of whether Human Research is exempt from regulation.
- 3.26.3 Reviews of non-exempt research using the expedited procedure.
- 3.26.4 Determinations of which subjects can continue in expired research.
- 3.27 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.
- 3.27.1 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
- 3.28 Participating Site (pSite): An institution that participates in a Single IRB (sIRB) Study.
- 3.29 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.
- 3.29.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.
- 3.30 Related to the Research: A financial interest is Related to the Research when the interest is in:
- 3.30.1 A sponsor of the research;
- 3.30.2 A competitor of the sponsor of the research;
- 3.30.3 A product or service being tested; or
- 3.30.4 A competitor of the product or service being tested.
- 3.31 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 3.32 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:

<sup>2</sup> 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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- 3.32.1 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 in the course of medical practice;
- 3.32.2 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
- 3.32.3 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.
- 3.33 Restricted: Applies to investigators who are delinquent in meeting IRB requirements.
- 3.34 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; or damage or compromise the scientific integrity of research data.
  - 3.34.1 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.
- 3.35 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.
- 3.36 SMARTIRB: An online reliance system to request, track, and document reliance agreements between institutions.
- 3.37 Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional 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.
- 3.38 Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official, or designee of the Institutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.
- 3.39 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.
  - 3.39.1 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:
    - 3.39.1.1 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.
    - 3.39.1.2 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).
    - 3.39.1.3 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 actually occurred.



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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 None

**7 REFERENCES**

- 7.1 45 CFR §46.102.
- 7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)



<b>SOP: Observation of Consent</b>				
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**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, Institutional Official, 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 None

**7 REFERENCES**

- 7.1 None





<b>SOP: Legally Authorized Representatives, Children, and Guardians</b>				
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**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.
  - 3.1.1 When research is conducted in Massachusetts, the following individuals meet this definitions:
    - For research that involves medical treatment:
      - 3.1.1.1 A “health care agent” as defined in M.G. L. c. 201D. with authority to make health care decisions pursuant to a health care proxy; or
      - 3.1.1.2 In instances in which no health care proxy has been executed, a “responsible party” designated by a health care provider under common law principles.
      - 3.1.1.3 A “guardian” as defined in M.G.L. c. 190B § 5-101; however, the health care decision of a health care agent takes precedence over that of a guardian.
    - For minimal risk non-medical research:
      - 3.1.1.4 A “guardian” as defined in M.G.L. c. 190B, § 5-101. (“a person who has qualified as a guardian of a minor or incapacitated person pursuant to court appointment and includes a limited guardian, special guardian and temporary guardian, but excludes one who is merely a guardian ad litem.”)
      - 3.1.1.5 In light of existing statutory and case law, it is unclear whether the IRB may approve a study that involves consent by a legally authorized representative for an incapacitated adult to participate in non-medical research in Massachusetts that presents more than minimal risk. For all such determinations, before approving the study, the IRB should consult with legal counsel to determine that the individuals proposed to serve as legally authorized representatives meet the federal definition of “legally authorized representative.”
  - 3.1.2 For research outside Massachusetts, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.
- 3.2 DHHS and FDA’s Subpart D applies to all research involving children.
  - 3.2.1 When research is conducted in Massachusetts, all individuals under the age of 18 years are children. Massachusetts law recognizes two instances when teenagers under the age of 18 may have the legal capacity to consent to medical treatment. These are the emancipated minor and mature minor rules. Note that these rules concern individuals in their capacity as patients, not as subjects in research, and also that they apply only to persons in Massachusetts. Contact legal counsel for more information.
  - 3.2.2 For research outside Massachusetts, a determination of who is a child is to be made with consultation from legal counsel.
- 3.3 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



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to consent on behalf of the child to general medical care<sup>1</sup>. Before obtaining permission from an individual who is not a parent, contact legal counsel.

**3.4 Massachusetts Uniform Statutory Will Act (the “Will Act”) and Parents or Guardians of Minor Children**

3.4.1 In general, and as more fully explained below, parents and guardians may provide consent to participation in research for their minor children or wards. The definition of who is a parent or guardian differs in some respects under federal and Massachusetts laws. The Massachusetts Uniform Statutory Will Act (the “Will Act”) indirectly defines “parent” in its definition of “child.” See M.G.L. c. 191B, § 1(1). Under this law, the “parent” is the biological or adoptive mother or father of a child. However, a father of a child who is not married to the child’s mother may not always be considered a parent; his status would depend on whether he openly treats the child as his offspring or on whether a court has made a paternity determination. Under the Will Act, the term “parent” does not include step-parents who have not formally adopted the child, foster parents, grandparents or other relatives. In general, the term “guardian” is widely understood to mean a person lawfully invested with the power, and charged with the duty, of taking care of and managing the property and rights of someone who is considered incapable of administering his or her own affairs. This definition includes a person who legally has responsibility for the care and management of the person or estate or both of a child during his or her minority. Parents are usually considered the guardians of their minor children under Massachusetts law. For example, with respect to children, the Department of Mental Retardation defines “guardian” in its regulations concerning research as “a natural or adoptive parent, or the individual or agency with legal guardianship of the person.” 115 CMR 10.02.

3.4.2 Legal guardianship in Massachusetts usually is created through a court process, most often through the Probate Court, M.G.L. c. 201 § 2, although parents may designate another adult to be a guardian without having to invoke a court proceeding. This kind of guardian, once appointed, is also referred to as a “standby proxy,” whose authority becomes enforceable when the parent dies, becomes incapacitated or is unavailable to care for the child. M.G.L. c. 201 §§ 2B – 2D. The Department of Social Services (DSS) or other state agencies may become the legal guardian of children it takes into custody. The IRB will make a determination based on the risk/benefits to determine whether to accept DSS, or other agency consent for children in their custody.

**4 RESPONSIBILITIES**

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

**5 PROCEDURE**

5.1 None

**6 MATERIALS**

6.1 None

**7 REFERENCES**

7.1 45 CFR §46.102, 45 CFR §46.402

7.2 21 CFR §50.3

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<sup>1</sup> This is the DHHS and FDA definition of “guardian”



SOP: Incoming Items				
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## 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: Cede Review (HRP-085).”
  - 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: Cede Review (HRP-085).”
- 5.2 If the item is a request for an approval or determination<sup>1</sup> by this institution’s IRB that does not include other pSites (“single-site” study), 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: Cede Review (HRP-085).”
- 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 includes an updated list of study personnel:
  - 5.7.1 If there are financial disclosures, follow “SOP: Financial Conflicts of Interests (HRP-055).”
- 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: Cede Review (HRP-085)

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<sup>1</sup> 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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- 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)

## **7 REFERENCES**

- 7.1 None



SOP: Pre-review				
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## 1 PURPOSE

- 1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, 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 Any change to a previously approved IRB protocol, including the addition of a previously approved protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites is considered a modification to previously approved research.

## 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

## 5 PROCEDURE

- 5.1 If the submission is a response to modifications required to secure approval received within 45 days of the IRB review date:
  - 5.1.1 Evaluate whether the investigator made the required modifications.
  - 5.1.2 If the investigator made the required modifications, follow "SOP: Post-Review (HRP-052)" to issue an approval.
  - 5.1.3 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.
    - 5.1.3.1 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.
    - 5.1.3.2 If the investigator will not correct the submission, have the investigator execute the "Submit Changes" activity to resubmit and continue processing.
- 5.2 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.
- 5.3 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.
  - 5.3.1 Continue processing once the investigator responds to the request for additional information.
- 5.4 Manage Ancillary Review for all applicable items.
- 5.5 If the request is for an initial approval and principal investigator is Restricted, contact the investigator. Explain that the investigator is Restricted, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research. Offer the investigator the opportunity to withdraw the submission pending removal of the Restricted status.
  - 5.5.1 If the investigator withdraws the submission, stop processing the current submission.



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- 5.5.2 If the investigator will not withdraw the submission, continue processing.
- 5.6 Evaluate the most likely level of review:
  - 5.6.1 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).”
  - 5.6.2 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.

## 6 MATERIALS

- 6.1 WORKSHEET: Pre-Review (HRP-308)
- 6.2 HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
- 6.3 SOP: New Information (HRP-024)
- 6.4 SOP: Non-Committee Review Preparation (HRP-031)
- 6.5 SOP: IRB Meeting Preparation (HRP-040)
- 6.6 SOP: Post-Review (HRP-052)

## 7 REFERENCES

- 7.1 None



SOP: New Information				
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## 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.
- 1.3 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 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Institutional Official for further action.
- 3.2 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.
  - 3.2.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.
- 3.3 The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.

## 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 If you are unable to answer a question, consult the IRB chair or IRB Director.
- 5.3 If the IRB chair and IRB Director 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,



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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.
- 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 (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 Take any additional actions required to resolve any concerns or complaints associated with the information.
- 5.8 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: Investigations (HRP-025)
- 6.2 SOP: Suspension or Termination (HRP-026)
- 6.3 SOP: Post-Review (HRP-052)





<b>SOP: New Information</b>				
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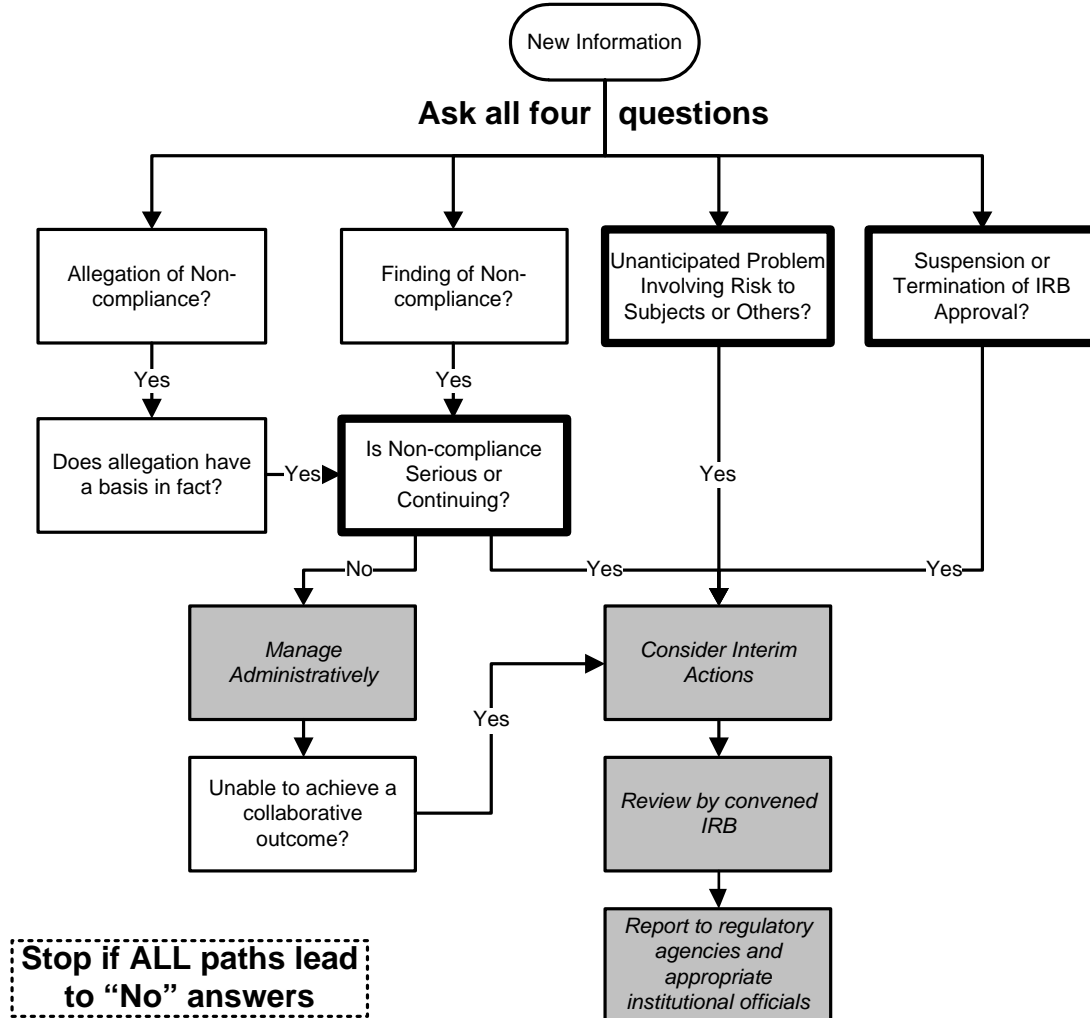
## **7 REFERENCES**

- 7.1 21 CFR §56.108(b)
- 7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)



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7.3 Flowchart





<b>SOP: Investigations</b>				
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HRP-025	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **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 or designee.

## **2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None.

## **3 POLICY**

- 3.1 None

## **4 RESPONSIBILITIES**

- 4.1 The Institutional Official or 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.
- 5.6 The investigative committee provides a written report of the investigative committee's decision to the Institutional Official or designee.

## **6 MATERIALS**

- 6.1 SOP: New Information (HRP-024)

## **7 REFERENCES**

- 7.1 None



SOP: Suspension or Termination				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-026	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 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 Institutional Official or 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 in conjunction with the IRB members and administration, as well as the Institutional Official or designee may institute a Suspension of IRB Approval when in their opinion subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.
- 3.2 The IRB Chair in conjunction with the IRB members and administration, as well as the Institutional Official or 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.

## 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 Making arrangements 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 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.
- 5.6 Complete and send to the investigator a "TEMPLATE LETTER: Suspension or Termination (HRP-515)."

## 6 MATERIALS

- 6.1 TEMPLATE LETTER: Suspension or Termination (HRP-515)

## 7 REFERENCES

- 7.1 21 CFR §56.108(b)(3), 21 CFR §56.113
- 7.2 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113



<b>SOP: Certificate of Confidentiality</b>				
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## **1 PURPOSE**

- 1.1 This procedure establishes the process to request, if applicable, and document a Certificate of Confidentiality (CoC) for a research study.
- 1.2 The process begins when the IRB requires that an investigator obtain a CoC is or when a CoC has already been obtained and is included with an IRB submission in ESTR.
- 1.3 The process ends when the CoC is documented in the ESTR study submission.

## **2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None.

## **3 POLICY**

- 3.1 The NIH Policy on Certificates of Confidentiality (CoC) applies to “all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information” that was commenced or ongoing after December 13, 2016.
- 3.2 If a NIH- funded activity falls within the scope of the NIH policy, CoCs are automatically granted as part of terms and conditions of the award and the requirements of such must be complied with. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the NIH policy and if the CoC is included as part of the terms and conditions of the award.
- 3.3 For all other HHS-funded (non-NIH) research, all other federal agency funded research, and non-federally funded research, researchers may request a CoC for their research or the IRB may request that the researcher obtain a CoC. These will only be issued on request.

## **4 RESPONSIBILITIES**

- 4.1 IRB staff carry out these procedures.

## **5 PROCEDURE**

- 5.1 For NIH-funded studies in which a CoC has been issued:
  - 5.1.1 Investigators are responsible for clearly representing in the IRB submission that a CoC is in place (e.g. as terms and conditions of an NIH award).
  - 5.1.2 For studies that are already underway, investigators must submit a Modification Request to the IRB, along with updated consent language (if applicable) when automatically issued under the NIH policy. This includes NIH funded studies that were approved by the IRB prior to December 13, 2016 and for which a CoC was issued retroactively.
  - 5.1.3 When reviewing research under a CoC, the IRB will evaluate whether the research protocol is consistent with the obligations to protect information and specimens under a CoC and whether the consent language, if applicable, discloses the CoC and appropriately describes the associated protections and limitations.
  - 5.1.4 Sample consent language is available in HRP-502- TEMPLATE CONSENT DOCUMENT.
- 5.2 For all other HHS-funded (non-NIH) research, all other federal agency funded research, and non-federally funded research or when the IRB requests a CoC:
  - 5.2.1 Investigators are responsible for clearly representing in the IRB submission that a CoC is in place, if a CoC application is pending, or that an application for a CoC has been submitted. When the CoC application is in process or pending, the IRB may condition final approval upon its receipt.



<b>SOP: Certificate of Confidentiality</b>				
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- 5.2.2 When non-NIH research is not under a CoC, the IRB may require an investigator to apply for a CoC if the research includes identifiable, sensitive information and the IRB determines that a CoC is necessary to minimize risks and adequately protect subjects' privacy and the confidentiality of subjects' information or specimens.
- 5.2.3 For studies that are already underway, investigators must submit a Modification Request to the IRB, along with updated consent language (if applicable), when a CoC is applied for.
- 5.2.4 When reviewing research under a CoC, the IRB will evaluate whether the research protocol is consistent with the obligations to protect information and specimens under a CoC and whether the consent language, if applicable, discloses the CoC and appropriately describes the associated protections and limitations.
- 5.2.5 Sample consent language is available in HRP-502- TEMPLATE CONSENT DOCUMENT.
- 5.2.6 The IRB staff will draft the CoC Assurance letter (HRP-565-LETTER: CoC Assurance for Non-NIH Funded Studies) to send to the Institutional Official for signature. Once signed by the Institutional Official, the document will be provided to the PI for submission to the appropriate CoC issuing body.

5.3 A copy of the Notice of Award or CoC is to be retained in the ESTR study record.

## **6 MATERIALS**

6.1 HRP-502- TEMPLATE CONSENT DOCUMENT

## **7 REFERENCES**

- 7.1 NIH Certificates of Confidentiality website at <https://humansubjects.nih.gov/coc/index>
- 7.2 301(d) of the Public Health Service Act (42 U.S.C 241)



<b>SOP: Designated Reviewers</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-030	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 1 PURPOSE

- 1.1 This procedure establishes the process for an IRB chair to designate IRB members who can conduct Non-Committee Reviews.
- 1.2 The process begins when the IRB chair instructs IRB staff 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 “DATABASE: IRB Roster (HRP-601).”

## 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.
- 5.3 Verify that the IRB member is an Experienced IRB Member.
- 5.4 Update the “DATABASE: IRB Roster (HRP-601)” to indicate that the IRB member is a Designated Reviewer.
- 5.5 Use the “Update Eligible Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.

## 6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)

## 7 REFERENCES

- 7.1 21 CFR §56.110(b).
- 7.2 45 CFR §46.110(b).



<b>SOP: Non-Committee Review Preparation</b>				
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HRP-031	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 1 PURPOSE

- 1.1 This procedure establishes the process to prepare for a Non-Committee Review.
- 1.2 The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.
- 1.3 The process ends when an Experienced IRB Member is assigned as the Designated Reviewer.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 POLICY

- 3.1 IRB rosters are maintained using “DATABASE: IRB Roster (HRP-601).”
- 3.2 All relevant materials are provided in ESTR. 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.”

## 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

## 5 PROCEDURE

- 5.1 Use the “Assign Designated Reviewer” activity and select a Designated Reviewer according to their role in the review (i.e., Primary Reviewer, Scientific/Scholarly Reviewer, etc.).
- 5.2 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.
- 5.3 Execute the “Assign Designated Reviewer” activity to send to the Designated Reviewer.

## 6 MATERIALS

- 6.1 WORKSHEET: Review Materials (HRP-301)
- 6.2 DATABASE: IRB Roster (HRP-601)

## 7 REFERENCES

- 7.1 21 CFR §56.110(b)
- 7.2 45 CFR §46.110(b)





<b>SOP: Non-Committee Review Conduct</b>				
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HRP-032	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **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 (according to their role), either 1) completes the review and returns the completed materials to an IRB staff member, or 2) completes the review and issues the determination in ESTR.

## **2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

## **3 POLICY**

- 3.1 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 Determine the required level of review. (Not Human Research, Human Research not Engaged, exempt Human Research, Human Research approved using the expedited procedure, or Human Research that requires review by a convened IRB.
- 5.3 If changes or additional information is needed, execute the "Request Clarification" activity.
- 5.4 If consultation is needed follow "SOP: Consultation (HRP-051)."
- 5.5 Manage Ancillary Review for all applicable items.
- 5.6 Execute "Track Harvard Determinations" and mark appropriately.
- 5.7 Upload any checklists at the time of Designated Review.
- 5.8 Once all outstanding items have been rectified, execute the "Submit Designated Review" or the "Assign to Committee Review" activity.

## **6 MATERIALS**

- 6.1 SOP: Consultation (HRP-051)

## **7 REFERENCES**

- 7.1 21 CFR §56.110(b).
- 7.2 45 CFR §46.110(b).



<b>SOP: IRB Meeting Preparation</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-040	01/19/2018	S. Sowards	A. Tahmassian	1 of 2

## 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 15 days 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 calendar 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 chair) will be present at the meeting.
- 5.2 Consult "DATABASE: IRB Roster (HRP-601)" 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
  - 5.4.2 Execute the "Assign Reviewers" activity in the meeting workspace to assign a scientific/scholarly reviewer to each agenda 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 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.



<b>SOP: IRB Meeting Preparation</b>				
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## **6 MATERIALS**

- 6.1 DATABASE: IRB Roster (HRP-601)
- 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)



SOP: IRB Meeting Conduct				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-041	01/19/2018	S. Sowards	A. Tahmassian	1 of 3

## 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 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.
- 3.4 Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
- 3.5 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by an Experienced Reviewer (i.e., the IRB chair or a designated individual).
- 3.6 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.

## 4 RESPONSIBILITIES

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

## 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 For each business item involving review of a protocol:
  - 5.3.1 Table the item when notified by IRB staff when requirements for review of a specific item as defined in “WORKSHEET: Quorum and Expertise (HRP-305)” are not met.<sup>1</sup>
  - 5.3.2 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, be placed on hold or disconnect for discussion and voting.
  - 5.3.3 If there is a consultant present, ask the consultant to present his or her review to the IRB.
  - 5.3.4 If a consultant provided written information to the IRB, present that information to the IRB.
  - 5.3.5 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
  - 5.3.6 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

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<sup>1</sup> “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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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.

- 5.3.7 For 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) 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.
- 5.3.8 Restate the IRB’s consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
- 5.3.9 Make a motion for one of the following actions:
  - 5.3.9.1 Approve (with a specific continuing review interval for initial or continuing review): 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.
  - 5.3.9.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review): 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
  - 5.3.9.3 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.
  - 5.3.9.4 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.
  - 5.3.9.5 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.
- 5.3.10 Open the floor for additional discussion.
- 5.3.11 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.
  - 5.3.11.1 Ensure that the required modifications include all final contingencies in the Pre-Review activity.
  - 5.3.11.2 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 in coordination with the School’s Conflict of Interest Officer. If there is a management plan put in place by the School’s



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Conflict of Interest Officer relating to the Human Research, a copy of the plan must be returned to the IRB for review.

- 5.3.12 Call for a vote.
  - 5.3.12.1 Only IRB members may vote.
  - 5.3.12.2 If a member and an alternate are both present, only one may vote.
  - 5.3.12.3 Consultants may not vote.
  - 5.3.12.4 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.)
- 5.3.13 Re-invite IRB members with a Conflicting Interest back into the meeting.
- 5.3.14 Provide any written information provided by a member or consultant to the IRB staff.
- 5.4 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-418)
- 6.10 CHECKLIST: Information Security Level Determination (HRP-442)
- 6.11 CHECKLIST: Use of Fresh Human Fetal Tissue in Research (HRP-445)
- 6.12 SOP: IRB Meeting Preparation (HRP-040)
- 6.13 WORKSHEET: Review Materials (HRP-301)
- 6.14 WORKSHEET: Quorum and Expertise (HRP-305)
- 6.15 WORKSHEET: Pre-Review (HRP-308)
- 6.16 WORKSHEET: Criteria for Approval (HRP-314)
- 6.17 WORKSHEET: Advertisements (HRP-315)
- 6.18 WORKSHEET: Payments (HRP-316)
- 6.19 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 6.20 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 6.21 WORKSHEET: Review of Information Items (HRP-321)

## **7 REFERENCES**

- 7.1 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
- 7.2 45 CFR §46.109, §46.116, §46.117.



<b>SOP: IRB Meeting Attendance Monitoring</b>				
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**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.

**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)



SOP: IRB Meeting Minutes				
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**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 or IRB Director.

**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 or IRB Director.
- 3.4 IRB members may make corrections to minutes.
- 3.5 A designated IRB staff member writes the minutes and makes them available for review within 7 calendar 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 Record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under "Attendance Table.")
  - 5.2.1 Name.
  - 5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, or alternate member.
  - 5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
  - 5.2.4 Whether the member was present by teleconference.
- 5.3 Record the total number of members on "DATABASE: IRB Roster (HRP-601)." Exclude alternate members in this count.
- 5.4 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 "DATABASE: IRB Roster (HRP-601)," then  $10/2 = 5$  and the next whole number is 6. If there 11 IRB members on the "DATABASE: IRB Roster (HRP-601)," then  $11/2=5.5$  and the next whole number is 6.
- 5.5 Indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions. Delete if no members were present by teleconference.
- 5.6 Record the meeting start time.
- 5.7 For each submission reviewed record in the "Submit Committee Review" activity or "Submit RNI Committee Review" activity, as appropriate:
  - 5.7.1 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.
  - 5.7.2 Risk Level: Minimal Risk or more than Minimal Risk.
  - 5.7.3 Last Day of Approval Period: Record the study expiration date.
  - 5.7.4 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."





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- 5.7.5 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.”
- 5.7.6 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.”
- 5.7.7 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.
- 5.7.8 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.
- 5.7.9 Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions
- 5.7.10 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.
- 5.7.11 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.
  - 5.7.11.1 For: Voting for the motion.
  - 5.7.11.2 Against: Voting against the motion.
  - 5.7.11.3 Abstain: Present for the vote, but not voting “For” or “Against.”
  - 5.7.11.4 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”
  - 5.7.11.5 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”
  - 5.7.11.6 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)”
- 5.7.12 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.
- 5.8 Record the meeting end time.
- 5.9 Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.



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- 5.10 When prompted to "submit" enter NO so that any further edits, if applicable, may be made.
  - 5.11 Once edits are complete, execute "Prepare Minutes" activity. When prompted to "submit" enter YES.
  - 5.12 Within 5 business days revise minutes for accuracy and notify the IRB chair or IRB Director for review and approval.
  - 5.13 Once approved by the IRB chair or IRB Director, and execute the "Close Meeting" activity.
  - 5.14 Minutes are included with the next scheduled IRB meeting agenda.
  - 5.15 Attach the following documents to the meeting workspace:
    - 5.15.1 List of protocols granted approval using the expedited procedure.
  - 5.16 The agenda is sent to all IRB members as well as the Institutional Official.
  - 5.17 IRB members have until the next scheduled IRB Meeting (approximately 30 days) to review the minutes.
  - 5.18 At the next scheduled IRB Meeting, members are asked if there are any revisions that are needed to the minutes.
    - 5.18.1 If revisions are needed, make revisions as necessary.
    - 5.18.2 If there are no revisions, execute the "Approve Minutes" activity
- 6 MATERIALS**
- 6.1 None
- 7 REFERENCES**
- 7.1 21 CFR §56.115(a)(2)
  - 7.2 45 CFR §46.115(a)(2)



SOP: Not Otherwise Approvable Research				
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## 1 PURPOSE

- 1.1 This procedure establishes the process for the organization to review research that is not otherwise approvable, but because the research is not subject to regulatory approval no government agency will conduct a review of this research to determine whether it can be approved.
- 1.2 This process begins when the IRB determines that research involving children, pregnant women, or fetuses as subjects is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subjects health or welfare.
- 1.3 The process ends when the Institutional Official or designee communicates a decision to the IRB.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

## 3 POLICY

- 3.1 When research is not otherwise approvable, but because the research is not subject to regulatory approval no government agency will conduct a review of this research to determine whether it can be approved, this organization will conduct its own review that parallels the regulatory process.
- 3.2 The criteria used to make a determination are:
  - 3.2.1 That the research in fact satisfies the conditions of IRB approvable research in "CHECKLIST: Non-Viable Neonates (HRP-413)," "CHECKLIST: Neonates of Uncertain Viability (HRP-414)," or "CHECKLIST: Children (HRP-416)," or "CHECKLIST: Pregnant Women (HRP-412)
  - 3.2.2 All of the following criteria are met:
    - 3.2.2.1 The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children or pregnant women, fetuses or neonates.
    - 3.2.2.2 The research will be conducted in accordance with sound ethical principles;
    - 3.2.2.3 Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects as required by "WORKSHEET: Criteria for Approval and Other Considerations (HRP-314)," "CHECKLIST: Non-Viable Neonates (HRP-413)," "CHECKLIST: Neonates of Uncertain Viability (HRP-414)," or "CHECKLIST: Children (HRP-416)."

## 4 RESPONSIBILITIES

- 4.1 The Institutional Official or designee carries out these procedures.

## 5 PROCEDURE

- 5.1 Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates to review the protocol.
- 5.2 Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.
- 5.3 Inform potential experts that they will be asked to provide individual written recommendations and that their reports, as well as their identities, will be publicly available during the public review and comment period.
- 5.4 Publish in a form accessible to the public:



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- 5.4.1 A request for written comments, including an Internet link to the protocol, relevant sections of grant applications, parental permission and assent documents, and relevant excerpts from the IRB minutes and correspondence.
- 5.4.2 The date and location of the expert panel meeting (to be held a minimum of 30 days after the notice is posted.)
- 5.4.3 Indicate that the panel meeting will be open to the public and that the public will be given an opportunity to comment at the panel meeting.
- 5.4.4 Note that written comments on posted materials must be submitted at least 7 days before the day of the panel meeting to be considered by the panelists (which will allow the public 21 days to comment on posted materials);
- 5.4.5 Indication that the panelists' reports/recommendations (see below) will be posted 14 days after the panel meets.
- 5.4.6 Invite comments for up to 30 days after the meeting of the convened panel for review and consideration by the panel.
- 5.5 Open the meeting to the public.
- 5.6 After the convened panel discussion occurs and public comments are received, have each panel member write an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.
- 5.7 Post panel reports on the organization's website for informational purposes for 30 days after the panel meeting.
- 5.8 Review the panel deliberations, reports, public comments, and make one of the following recommendations within 90 days of the convened panel meeting:
  - 5.8.1 The organization approves support of the research as submitted;
  - 5.8.2 The organization approves support of the research, but with required and/or recommended modifications; or
  - 5.8.3 The organization disapproves support of the research.
- 5.9 Inform the IRB and the investigator.
- 5.10 Post the decision on the organization's Website.
- 5.11 Create a record in ESTR to document communication, upload study documents, and record final determination.

**6 MATERIALS**

- 6.1 CHECKLIST: Pregnant Women (HRP-412)
- 6.2 CHECKLIST: Non-Viable Neonates (HRP-413)
- 6.3 CHECKLIST: Neonates of Uncertain Viability (HRP-414)
- 6.4 CHECKLIST: Children (HRP-416)
- 6.5 WORKSHEET: Criteria for Approval and Other Considerations (HRP-314)

**7 REFERENCES**

- 7.1 45 CFR §46.207, 45 CFR §46.407
- 7.2 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66



<b>SOP: Use of Human Fresh Fetal Tissue in Research and M.G.L. ch. 112, §12J</b>				
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**1 PURPOSE**

- 1.1 This procedure establishes a process by which to review research that involves fresh human fetal tissue according to Harvard University institutional requirements per M.G.L. ch. 112, §12J
- 1.2 The process begins when the IRB receives a request for the approval of the PI's acquisition of fresh human fetal tissue from a Harvard researcher.
- 1.3 The process ends when the Harvard Office of the General Counsel (OGC) has filed the necessary documentation with the Massachusetts Attorney General Office.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**3 POLICY**

- 3.1 All research conducted by Harvard agents involving the acquisition of fresh human fetal tissue must receive a written determination that such use does not violate M.G.L. ch. 112, §12J by a convened IRB according to Harvard University institutional requirements.
- 3.2 Only research using fresh human fetal tissue from a non-live fetus is permissible according to Harvard University institutional requirements. Experimentation on live human fetuses is not permissible.

**4 RESPONSIBILITIES**

- 4.1 IRB staff and IRB members carry out these procedures.

**5 PROCEDURE**

- 5.1 The PI submits a new ESTR application.
- 5.2 The following information must be included in the ESTR application:
  - 5.2.1 Copy of the informed consent form used to collect the fresh fetal tissue
    - 5.2.1.1 The form of the consent must indicate that the donor has reached the age of majority (18 years old)
    - 5.2.1.2 The consent states that the donor consents to the use of the dead fetus or dead neonate for scientific, laboratory, research, or other experimentation or study.
  - 5.2.2 A copy of the contract with the supplier
    - 5.2.2.1 The contract must contain the statement that the clinic or other medical provider who will perform the abortion will not offer any consideration to the donor for undergoing the abortion, including the consideration that the fetal remains would be used for experimentation or other kind of research or study.
    - 5.2.2.2 The contract must also state that no person associated with the process shall knowingly sell, transfer, distribute or give away any fetus or neonate for a use which is in violation of section M.G.L. ch. 112, §12J
- 5.3 IRB Staff 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 Assign the submission to an agenda for convened IRB review.
- 5.5 At the meeting, the IRB members review the protocol taking the criteria found in "CHECKLIST: Use of Fresh Human Fetal Tissue in Research and M.G.L. ch. 112, §12J (HRP-445)" into consideration.



<b>SOP: Use of Human Fresh Fetal Tissue in Research and M.G.L. ch. 112, §12J</b>				
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- 5.6 Following the meeting, the IRB documents its findings using “TEMPLATE LETTER: Use of Fresh Human Fetal Tissue in Research and M.G.L. ch. 112, §12J (HRP-545)” and retains this written documentation in the study file.
- 5.7 Provide OGC with the determination letter and protocol required to ensure proper filing with the Attorney General’s Office.
- 5.8 A copy of the written determination, together with any attached protocol or other writing, will be filed with the MA Office of the Attorney General by the Harvard University Office of General Counsel.
- 5.9 IRB Staff should retain a copy of the package prepared for the MA Attorney General in Ancillary Review Activity of the ESTR record. (This may involve reopening the record by re-submitting Committee Review, if the determination letter has already been issued to the PI).

## **6 MATERIALS**

- 6.1 WORKSHEET: Pre-Review (HRP-308)
- 6.2 CHECKLIST: Use of Fresh Human Fetal Tissue in Research and M.G.L. ch. 112, §12J (HRP-445)
- 6.3 HRP-545 TEMPLATE LETTER: Use of Fresh Human Fetal Tissue in Research and M.G.L. ch. 112, §12J
- 6.4 HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
- 6.5 SOP: IRB Meeting Preparation (HRP-040)
- 6.6 SOP: Post-Review (HRP-052)

## **7 REFERENCES**

- 7.1 Experimentation on human fetuses, Massachusetts law, MGL Chapter 112C, § 12J



<b>SOP: Conflicting Interests of IRB Members</b>				
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## **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 meeting 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 21 CFR §56.107(e).
- 7.2 45 CFR §46.107(e).



<b>SOP: Consultation</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-051	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 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.
- 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 21 CFR §56.107(f)
- 7.2 45 CFR §46.107(f)





<b>SOP: Post-Review</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-052	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **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; OR
  - 1.2.2 An IRB meeting has 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 5 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 days from the recognition of a reportable problem.

## **4 RESPONSIBILITIES**

- 4.1 IRB staff members carry out these procedures.

## **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 calculated approval intervals.
- 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.

## **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)

## **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 §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66



<b>SOP: Institutional Conflicts of Interests</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-054	01/19/2018	S. Sowards	A. Tahmassian	1 of 2

## 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 Harvard Office of Technology Development 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 An institutional financial conflict of interests exists when any of the following might affect the design, conduct, or reporting of research:
  - 3.1.1 Licensing, technology transfer, patents
  - 3.1.2 Investments of the organization
  - 3.1.3 Gifts to the organization when the donor has an interest in the research
  - 3.1.4 Financial interests of senior administrative officials
  - 3.1.5 Other financial interests
- 3.2 As per the "[Harvard University Policy on Conflicts of Interest and Commitment for Senior Officers and Administrators](#)," senior administrative officials are required to disclose their financial interests directly to the Office of General Counsel
  - 3.2.1.1 When initially appointed or hired
  - 3.2.1.2 Every year
  - 3.2.1.3 When there are changes to financial interests
- 3.3 The Technology Transfer Office, Office for Sponsored Programs, legal counsel, and the Conflict of Interests Officer are to notify the Institutional Official or designee of any change in the institution's financial holdings not controlled by the institution's investment Directors related to:
  - 3.3.1 Licensing (e.g., licensing or technology transfer agreements)
  - 3.3.2 Investments of the organization
  - 3.3.3 Gifts to the organization when the donor has an interest in the research
  - 3.3.4 Financial interests of senior administrative officials
  - 3.3.5 Other financial interests
- 3.4 The fiduciary responsibility of the institution's investment Directors is to maintain a diversified portfolio of holdings that 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 similar to diversified mutual funds and not subject to disclosure under this policy.
- 3.5 The evaluation and management of an institutional conflict of interest may not vary by funding or regulatory oversight.
- 3.6 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 of Investigators and Research Staff (HRP-055)".

## 4 RESPONSIBILITIES

- 4.1 The Institutional Official or designee carries out these responsibilities.



<b>SOP: Institutional Conflicts of Interests</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-054	01/19/2018	S. Sowards	A. Tahmassian	2 of 2

**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 None

**7 REFERENCES**

- 7.1 None



SOP: Financial Conflicts of Interests				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-055	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

**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 Human Research or an institutional financial interest related to the Human Research.
- 1.2 The process begins when an investigator or research staff has reported a financial interest related to the Human Research or the IRB staff have received notification from the investigator or research staff of a financial interest related to the Human Research.
- 1.3 The process ends when the School's Conflict of Interest (COI) Officer has evaluated the reported interest, communicated the results of this evaluation to the IRB, and provided a copy of the COI management plan if required.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**3 POLICY**

- 3.1 Each School may have its own approach to implementation of a Conflict of Interest Policy. Each School's policy is outlined in a School Implementation Plan.
- 3.2 Individuals are considered to have an institutional responsibility and are subject to this procedure when they have a financial interest relating to the Human Research.
- 3.3 Violations of this procedure or proscribed conflict of interest management plans related to the Human Research can lead to:
  - 3.3.1 Loss or restriction of privileges to conduct Human Research
  - 3.3.2 Other employment actions as allowed by Human Resources Policies and Procedures for staff or School Policies for academic appointees.
- 3.4 Records related to disclosures and management of financial conflicts of interest are to be retained for at least three years from completion of the Human Research.

**4 RESPONSIBILITIES**

- 4.1 The IRB staff in coordination with the respective School COI Officer carries out these procedures in accordance with their respective School Implementation Plan.

**5 PROCEDURE**

- 5.1 Obtain a copy of the investigator or research staff member's disclosed Conflicting Interest in the "FORM: Financial Interest Disclosure Form (HRP-221)"
- 5.2 Forward the notification of the investigator or research staff member's Conflicting Interest to the appropriate School COI Officer via the Ancillary Review process.
- 5.3 Obtain Conflicting Interest approval and a copy of the management plan if Conflicting Interest requires management from the School COI Officer
- 5.4 Provide the reviewing IRB with a copy of the written management plan and coordinate any necessary revisions with the appropriate School COI Officer
- 5.5 Maintain a copy of determinations and management plans in the ESTR study record.

**6 MATERIALS**

- 6.1 FORM: Financial Interest Disclosure Form (HRP-221)

**7 REFERENCES**

- 7.1 42 CFR §50
- 7.2 45 CFR §94



<b>SOP: Annual HRPP Evaluations</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-060	01/19/2018	S. Sowards	A. Tahmassian	1 of 2

## 1 PURPOSE

- 1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.
- 1.2 The process begins no later than the first business day each October.
- 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 resources pertaining to research participation and rights of a human research subject available to the subject population on the Human Research Protection Program [website](#).

## 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.
  - 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 the IRB chair.
  - 5.4.1 Provide a copy of the evaluation to the Institutional Official or designee.
  - 5.4.2 Provide the IRB chair with a copy of his or her evaluation.
  - 5.4.3 If needed, work with the 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.



<b>SOP: Annual HRPP Evaluations</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-060	01/19/2018	S. Sowards	A. Tahmassian	2 of 2

- 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 Provide a copy of the evaluation to the Institutional Official or designee.
    - 5.7.2 If the subject outreach program is not meeting organizational goals, work with the Institutional Official or designee to modify the plan.
  - 5.8 Check when the last time each IRB was registered. If more than 2 years, update the registration.<sup>1</sup>
  - 5.9 Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 5 years, update/renew the federalwide assurance (FWA).<sup>2</sup>
- 6 MATERIALS**
- 6.1 TEMPLATE LETTER: IRB Member Appreciation (HRP-562)
  - 6.2 WORKSHEET: IRB Composition (HRP-304)
- 7 REFERENCES**
- 7.1 None

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<sup>1</sup> See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.

<sup>2</sup> See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.



<b>SOP: Monthly HRPP Evaluations</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-061	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 1 PURPOSE

- 1.1 This procedure establishes the process to conduct quality improvement of the human research protection program.
- 1.2 The process begins the first business day of each month.
- 1.3 The process ends when all evaluations have been completed and if needed, acted upon.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 POLICY

- 3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieving targeted levels of quality, efficiency, and effectiveness of the HRPP.
- 3.2 Objectives of the quality improvement program are to:
  - 3.2.1 Improve compliance of investigators with their responsibilities.
  - 3.2.2 Improve compliance of minutes with regulatory compliance.
  - 3.2.3 Increase efficiency of recording and finalizing minutes.
- 3.3 The measures of the quality improvement program are defined in:
  - 3.3.1 CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)
  - 3.3.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)

## 4 RESPONSIBILITIES

- 4.1 IRB staff ensure completion of these procedures.

## 5 PROCEDURE

- 5.1 Review the results of "CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)" sent out the previous month, track the results, and examine for significant trends.
- 5.2 Complete "CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)" on the minutes of the previous month. Track compliance and the days required to complete minutes and examine for significant trends.
- 5.3 Send the results to the IRB Director and Institutional Official or designee.
- 5.4 If the results of any evaluations demonstrate high variability or are outside performance targets, work with the IRB Director and Institutional Official to implement an intervention.
- 5.5 Complete "TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)" and Send "CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)" to 10 investigators.

## 6 MATERIALS

- 6.1 CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)
- 6.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)
- 6.3 TEMPLATE LETTER: Investigator Quality Improvement Assessment (HRP-534)

## 7 REFERENCES

- 7.1 None



<b>SOP: Daily Tasks</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-062	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **1 PURPOSE**

- 1.1 This procedure establishes the process to complete daily tasks required to monitor the research review process.
- 1.2 The process begins each day.
- 1.3 The process ends when the tasks have been completed.

## **2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

## **3 POLICY**

- 3.1 None

## **4 RESPONSIBILITIES**

- 4.1 IRB staff members (via electronic system, ESTR) are responsible for carrying out this procedure.

## **5 PROCEDURE**

- 5.1 ESTR will check on a daily basis for studies due to expire (in 30, 60, 90 days) and automatically send email reminders to the PI and Primary Contact.
- 5.2 ESTR will check on a daily basis for studies that have lapsed and automatically send email notifications to the PI and Primary Contact.

## **6 MATERIALS**

- 6.1

## **7 REFERENCES**

- 7.1 None





<b>SOP: Expiration of IRB Approval</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-063	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **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 Communicate with the investigator using “TEMPLATE LETTER: Continuation of Subjects in Expired Research (HRP-532).”

## **6 MATERIALS**

- 6.1 TEMPLATE LETTER: Continuation of Subjects in Expired Research (HRP-532)

## **7 REFERENCES**

- 7.1 None



<b>SOP: NIH Genomic Data Sharing (GDS) Institutional Certification</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-064	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 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 Institutional Official 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 staff verifies for the Institutional Official 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-563)” or NIH Template Letter with submission-specific information. Pass the letter to the Institutional Official for review and certification.
- 5.3 Save a copy of the signed letter and Checklist in ESTR.
- 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-563)

## 7 REFERENCES

- 7.1 National Institutes of Health Final Genomic Data Sharing Policy ([http://gds.nih.gov/PDF/NIH\\_GDS\\_Policy.pdf](http://gds.nih.gov/PDF/NIH_GDS_Policy.pdf))
- 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) ([http://gds.nih.gov/pdf/PTC\\_for\\_IRBs\\_and\\_Institutions.pdf](http://gds.nih.gov/pdf/PTC_for_IRBs_and_Institutions.pdf))



SOP: IRB Records				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-070	01/19/2018	S. Sowards	A. Tahmassian	1 of 2

## 1 PURPOSE

- 1.1 This procedure establishes the process to maintain IRB records.
- 1.2 The process begins when records are to be filed.
- 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 Electronic application in IRB e-submission system, ESTR, which contains all study information, study documents, and follow-on submissions (Modifications, Continuing Review applications, and Reports of New Information).
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all correspondence between the IRB and the investigators.
- 3.1.4 IRB member rosters.
- 3.1.5 IRB member files.
- 3.1.6 Policies and procedures.

- 3.2 ESTR record includes:

- 3.2.1 Research protocols and all study documents.
- 3.2.2 Any policy-based or required Ancillary Approvals.
- 3.2.3 DHHS-approved sample consent document and protocol, when they exist.
- 3.2.4 Progress reports submitted by investigators.
- 3.2.5 Reports of New Information.
- 3.2.6 Continuing review submission(s).
- 3.2.7 Correspondence between the IRB and investigator/study team related to the protocol.
- 3.2.8 For initial and continuing review of research by the expedited procedure:
  - 3.2.8.1 The specific permissible category.
  - 3.2.8.2 Description of action taken by the reviewer.
  - 3.2.8.3 Any findings required under the regulations.
- 3.2.9 For exemption determinations the specific category of exemption.
- 3.2.10 Unless documented in the IRB minutes determinations required by the checklists supporting those determinations for:
  - 3.2.10.1 Waiver or alteration of the consent process.
  - 3.2.10.2 Research involving pregnant women, fetuses, and neonates.
  - 3.2.10.3 Research involving prisoners.
  - 3.2.10.4 Research involving children.
  - 3.2.10.5 Significant/non-significant device determinations.
- 3.2.11 For each protocol's initial and continuing review, the frequency for the next continuing review.

- 3.3 Policies and procedures are to 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/CV, "FORM: IRB Member Information (HRP-202)," and copy of appointment letter for each member.



<b>SOP: IRB Records</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-070	01/19/2018	S. Sowards	A. Tahmassian	2 of 2

#### **4 RESPONSIBILITIES**

4.1 IRB staff members are responsible to carry out these procedures.

#### **5 PROCEDURE**

5.1 All protocol-specific information including communications (for example, correspondence between the IRB and the investigator(s)), documents, and determinations are maintained in ESTR.

5.2 Minutes of IRB meetings: Retain electronically in ESTR and on office shared drive.

5.3 IRB member rosters: Retain electronically on shared drive.

5.4 IRB membership records: Retain electronically on shared drive.

5.5 Policies and procedures:

5.5.1 File current policies and procedures electronically on shared drive.

5.5.2 File replaced policies and procedures electronically on shared drive.

#### **6 MATERIALS**

6.1 None.

#### **7 REFERENCES**

7.1 None



<b>SOP: Standard Operating Procedures</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-071	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **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 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 date.
  - 5.5.2 File 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 the old document, if any, 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



<b>SOP: IRB Records Retention</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-072	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **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 Harvard University Records Management Services (RMS) policy and then destroyed.
- 3.2 All records not in protocol files are retained indefinitely.
- 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 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.
- 3.5 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.
- 3.6 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.

## **4 RESPONSIBILITIES**

- 4.1 IRB staff members carry out these procedures.

## **5 PROCEDURE**

- 5.1 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.
- 5.2 Destroy all other protocol files when the protocol has been closed, withdrawn, or terminated more than 7 years unless otherwise required by law.
  - 5.2.1 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 None



SOP: IRB Formation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-080	01/19/2018	S. Sowards	A. Tahmassian	1 of 2

## 1 PURPOSE

- 1.1 This procedure establishes the process to form or rely on a new IRB.
- 1.2 The process begins when the Institutional Official or IRB Director determines the need for a new IRB.
- 1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated (if needed), and all members have completed training.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 POLICY

- 3.1 IRB rosters are maintained using the “DATABASE: IRB Roster (HRP-601).”

## 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.
- 4.2 The Institutional Official or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.)

## 5 PROCEDURE

- 5.1 Determine from the Institutional Official 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 “DATABASE: IRB Roster (HRP-601).”

- 5.2 For external IRBs:

- 5.2.1 Ensure that one or more of the following are true:
  - 5.2.1.1 The IRB has been designated as the “sIRB” as per NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
  - 5.2.1.2 The IRB is the IRB of a participating institution of the SMARTIRB
  - 5.2.1.3 The IRB is the IRB of an AAHRPP accredited organization
  - 5.2.1.4 The organization’s investigator is a collaborator on Human Research primarily conducted at another organization and the investigator’s role does not include interaction or intervention with subjects.
  - 5.2.1.5 The organization is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)
- 5.2.2 If the research is federally funded or the relied upon organization requires an agreement or contract, arrange for an agreement or contract.
- 5.2.3 File the agreement or contract if one exists.

- 5.3 For internal IRBs:

- 5.3.1 Select:
  - 5.3.1.1 At least five individuals to serve as IRB members.
  - 5.3.1.2 Additional individuals to serve as alternate IRB members, if needed.
  - 5.3.1.3 At least one of the individuals to be the IRB chair.
- 5.3.2 Follow “SOP: IRB Member Addition (HRP-082)” for each IRB member.
- 5.3.3 Use “WORKSHEET: IRB Composition (HRP-304)” and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
- 5.3.4 Notify the IRB Director when all individuals have completed training.
- 5.3.5 Using the “Create Committee” SmartForm, create the new committee in the system.
- 5.3.6 Once training is completed, add committee members to the system with the Committee Member role.



<b>SOP: IRB Formation</b>				
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5.3.7 Assign any designees eligible to conduct non-committee reviews using the "Update Eligible Designated Reviewers" activity.

**6 MATERIALS**

- 6.1 DATABASE: IRB Roster (HRP-601)
- 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 §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).





<b>SOP: IRB Removal</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-081	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 1 PURPOSE

- 1.1 This procedure establishes the process to remove an IRB.
- 1.2 The process begins when the Institutional Official or IRB Director 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 "DATABASE: IRB Roster (HRP-601)."

## 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 Institutional Official or designee, and send to the former IRB members.
  - 5.1.2 Unregister the IRB with OHRP<sup>1</sup>.
  - 5.1.3 Remove the IRB from the federalwide assurance (FWA)<sup>2</sup>.
  - 5.1.4 Remove members from "DATABASE: IRB Roster (HRP-601)."
  - 5.1.5 Remove the individual's Committee Member role in ESTR.
  - 5.1.6 File:
    - 5.1.6.1 DATABASE: IRB Roster (HRP-601)
    - 5.1.6.2 Federalwide assurance (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. See SOP: Cede Review (HRP-085).

## 6 MATERIALS

- 6.1 SOP: Cede Review (HRP-085)
- 6.2 DATABASE: IRB Roster (HRP-601)
- 6.3 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).

<sup>1</sup> See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.

<sup>2</sup> See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.



<b>SOP: IRB Membership Addition</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-082	01/19/2018	S. Sowards	A. Tahmassian	1 of 2

## 1 PURPOSE

- 1.1 This procedure establishes the process to add a new IRB member.
- 1.2 The process begins when the Institutional Official or designee has appointed a new IRB member to an IRB. (This may be a completely new IRB member, or the addition of a previous member to another IRB.)
- 1.3 The process ends when the IRB registration is updated with OHRP 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 “DATABASE: IRB Roster (HRP-601).”

## 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.
- 4.2 The Institutional Official or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

## 5 PROCEDURE

- 5.1 Determine from the Institutional Official or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
- 5.2 Have the individual complete the “FORM: IRB Member Information (HRP-202).”
- 5.3 Obtain a copy of the individual’s résumé or curriculum vita.
- 5.4 Add the individual to the “DATABASE: IRB Roster (HRP-601).”
- 5.5 Complete “WORKSHEET: IRB Composition (HRP-304)” and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.6 Prepare a “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” for the individual.
- 5.7 Provide to the Institutional Official or designee for review and approval:
  - 5.7.1 FORM: IRB Member Information (HRP-202).
  - 5.7.2 Résumé or curriculum vita.
- 5.8 If not approved, select another individual and restart at 5.2.
- 5.9 If approved:
  - 5.9.1 Send the “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” to the individual.
  - 5.9.2 If the individual requires training, schedule the individual for training.
  - 5.9.3 Update the registration of all affected IRBs.<sup>1</sup>
- 5.10 File:
  - 5.10.1 DATABASE: IRB Roster (HRP-601)
  - 5.10.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.11 Notify the IRB Director when the individual has completed training.
  - 5.11.1 Assign individual the “Committee Member” role in the system.
  - 5.11.2 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

## 6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 FORM: IRB Member Information (HRP-202)

<sup>1</sup> See <http://www.hhs.gov/ohrp/assurances/>. Use Web site: <http://ohrp.cit.nih.gov/efile/>.



<b>SOP: IRB Membership Addition</b>				
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6.3 TEMPLATE LETTER: IRB Member Appointment (HRP-560)

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).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).



<b>SOP: IRB Membership Removal</b>				
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HRP-083	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 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 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 “DATABASE: IRB Roster (HRP-601).”

## 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

## 5 PROCEDURE

- 5.1 Remove the individual from “DATABASE: IRB Roster (HRP-601).”
- 5.2 Complete “WORKSHEET: IRB Composition (HRP-304)” to ensure that the IRB is appropriately constituted.
  - 5.2.1 If not, identify one or more replacement members and follow “SOP: IRB Member Addition (HRP-082).”
- 5.3 Prepare a “TEMPLATE LETTER: IRB Member Thank You (HRP-561),” have it signed by the Institutional Official or designee, and send to the individual.
- 5.4 Update the registration of all affected IRBs.<sup>1</sup>
- 5.5 File:
  - 5.5.1 DATABASE: IRB Roster (HRP-601)
  - 5.5.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.6 Remove individual’s “Committee Member” role in ESTR.
  - 5.6.1 If applicable, update the “Update Eligible Designated Reviewers” activity.

## 6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 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)
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)

<sup>1</sup> See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.



<b>SOP: IRB Meeting Scheduling and Notification</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-084	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## **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 6 months 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.

## **4 RESPONSIBILITIES**

- 4.1 IRB staff out these procedures.

## **5 PROCEDURE**

- 5.1 Create a schedule of meetings for each IRB.
  - 5.1.1 Execute the "Create Meeting" SmartForm in the system for each scheduled meeting.
- 5.2 Notify the following individuals of the updated schedule with an email providing a link to the IRB Web page with the schedule information.
  - 5.2.1 IRB members.
  - 5.2.2 Investigators and research staff on the IRB email list.
  - 5.2.3 Institutional Official or designee.

## **6 MATERIALS**

- 6.1 None

## **7 REFERENCES**

- 7.1 ICH-GCP E6 3.3.2



<b>SOP: Cede Review</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-085	01/19/2018	S. Sowards	A. Tahmassian	1 of 2

## 1 PURPOSE

- 1.1 This procedure establishes the process to determine whether reliance is appropriate between institutions that each hold a Federal Wide Assurance (FWA) and set forth the steps to designate Harvard University Area (HUA), FWA00004387, as either the Reviewing or Relying Institution.
- 1.2 This process may begin when an investigator inquires and/or submits a request for HUA to serve as either the Reviewing or Relying institution for multi-site non-exempt human research or is otherwise triggered by the Designated Reviewer.
- 1.3 This process ends when HUA has been designated as either the Reviewing or Relying Institution or the study is otherwise ineligible or inappropriate for reliance.

## 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 WHEN HARVARD UNIVERSITY AREA SERVES AS THE REVIEWING INSTITUTION (e.g., sIRB, Institution/IRB of Record)

- 5.1 Determine eligibility for HUA to serve as the Reviewing Institution, i.e., HUA is engaged in non-exempt human subjects research.
- 5.2 When applicable, advise the PI to “Create New Study” in ESTR, and submit necessary supporting documentation, including “FORM: IRB Cede Request (HRP-224)”. A modification may be submitted if this request occurs after initial review/approval.
- 5.3 Ensure that each relying institution has an active FWA.
- 5.4 If the request does not involve a SMARTIRB participating institution, execute an IRB Authorization Agreement (IAA) using “TEMPLATE: HUA IAA Template (HRP-509)”.
  - 5.4.1 Email draft IAA to the relying institution’s contact(s) for review and signature.
  - 5.4.2 When appropriate, obtain signature from the Harvard University Area Organizational Official or their designee.
- 5.5 If request involves a SMARTIRB participating institution, advise PI to submit a reliance request in the SMARTIRB system.
- 5.6 Provide Designated Reviewer with the necessary documentation, e.g., fully-executed IAA or SMARTIRB reliance request. Designated Reviewer to complete review as per SOP: Non-Committee Review Conduct (HRP-032).

## 6 PROCEDURE WHEN HARVARD UNIVERSITY AREA SERVES AS THE RELYING INSTITUTION (e.g., participating site)

- 6.1 Determine eligibility for Harvard University Area to serve as the Relying Institution (see “Institutional Review Board” section of HRPP Plan, HRP-101).
- 6.2 When applicable, advise the PI to “External IRB Submission” in ESTR.
- 6.3 Ensure that the reviewing institution has an active FWA.
- 6.4 If the request does not involve a SMARTIRB participating institution, execute an IRB Authorization Agreement (IAA) using “TEMPLATE: HUA IAA Template (HRP-509)”.
  - 6.4.1 Email draft IAA to the relying institution’s contact(s) for review and signature.
  - 6.4.2 When appropriate, obtain signature from the Harvard University Area Institutional Official or their designee.



<b>SOP: Cede Review</b>				
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- 6.5 If request involves a SMARTIRB participating institution, advise PI to submit a reliance request in the SMARTIRB system.
- 6.6 Provide Designated Reviewer with the necessary documentation, e.g., fully-executed IAA or SMARTIRB reliance request. Designated Reviewer to complete review as per SOP: Non-Committee Review Conduct (HRP-032).

**7 MATERIALS**

- 7.1 FORM: IRB Cede Request (HRP-224)
- 7.2 TEMPLATE: HUA IAA Template (HRP-509)
- 7.3 SOP: Non-Committee Review Conduct (HRP-032).
- 7.4 HRPP Plan (HRP-101)

**8 REFERENCES**

NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research,  
[http://osp.od.nih.gov/sites/default/files/NIH\\_sIRB\\_Policy\\_Multi\\_site\\_Research](http://osp.od.nih.gov/sites/default/files/NIH_sIRB_Policy_Multi_site_Research)



<b>SOP: Informed Consent Process for Research</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	01/19/2018	S. Sowards	A. Tahmassian	1 of 5

## 1 PURPOSE

- 1.1 This procedure establishes the process to obtain informed consent from subjects, the legally authorized representatives of adults unable to consent, or the parents or guardians of children.
- 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 legally authorized representative provides legally effective informed consent or declines to do so.

## 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 Legally authorized representative 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 In this procedure, "interpreter" means a person who reads aloud (in a language other than English) materials written in English, or who conveys (in a language other than English) information that is spoken in English. The interpreter must be 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. When implementing the short form consent process, 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.
- 3.4 In this procedure, translate means converting materials written in English into materials written in another language. When the research will involve subjects who are not fluent in English, the recruitment, consent, and study tools must be translated or interpreted into a language understood by the subjects/representatives. The IRB does not require an investigator to use a specific translation service. A couple options include the following:
  - 3.4.1 Certified Translator. The American Translators Association maintains two online directories: Directory of Translators and Interpreters (individuals) and Directory of Language Companies (companies), both available at: <http://www.atanet.org/onlinedirectories/>
  - 3.4.2 Native speakers who have demonstrated proficiency in English, including knowledgeable members of the research team, academics at Harvard or other institutions, etc.
- 3.5 The IRB expects that the selected interpreter/translator ensure that the tone, meaning, and content of the interpreted/translated materials remain consistent with the IRB-approved English version. This includes ensuring that the interpreted/translated materials are linguistically accurate, at an appropriate reading level for the subject population, and culturally sensitive for the locale in which the research will be conducted.
- 3.6 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.
- 3.7 If the subject is an adult unable to consent:
  - 3.7.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.





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- 3.7.2 Permission is obtained from a legally authorized representative.
- 3.7.3 A legally authorized representative must be in the class or persons approved by institutional policy or the IRB. See "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)"
- 3.8 If the subject is a child:
  - 3.8.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
  - 3.8.2 Permission is obtained from both parents unless:
    - 3.8.2.1 One parent is deceased, unknown, incompetent, not reasonably available;
    - 3.8.2.2 Only one parent has legal responsibility for the care and custody of the child; or
    - 3.8.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
  - 3.8.3 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.
- 3.9 If the subject/representative cannot speak English:
  - 3.9.1 The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak language that the subject understands.
  - 3.9.2 The investigator is responsible for ensuring that all materials and information will be provided to subjects in a language understandable to them, and for ensuring that any translations and interpretations will accurately convey the information.
  - 3.9.3 The investigator should describe the translation or interpretation process, including any criteria that will be used to identify the translator or interpreter, e.g., use of a certified translator.
- 3.10 Conduct all discussions in a private and quiet setting.
- 3.11 Any knowledgeable individual may:
  - 3.11.1 Review the study with subject/representative to determine preliminary interest.
  - 3.11.2 If the subject/representative is interested, notify an investigator.
  - 3.11.3 If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.
- 3.12 The IRB approves and watermarks all English recruitment and consent materials.

**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.
  - 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



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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. 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.
- 5.2 If the consent process will be documented in writing with the short form of consent documentation:
  - 5.2.1 Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).
  - 5.2.2 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.
  - 5.2.3 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.
  - 5.2.4 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.
  - 5.2.5 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.
  - 5.2.6 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.
  - 5.2.7 Through the interpreter explain the details in such a way that the subject/representative understands 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.
  - 5.2.8 Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.
- 5.3 If the requirement for written documentation of the consent process has been waived by the IRB:
  - 5.3.1 Obtain the current IRB approved script.
  - 5.3.2 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.
  - 5.3.3 When possible provide a copy of the script to the subject/representative.



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- 5.3.4 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.
- 5.3.5 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.
- 5.4 Invite and answer the subject/representative's questions.
- 5.5 Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.
- 5.6 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.
- 5.7 Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:
  - 5.7.1 The subject/representative understands the information provided.
  - 5.7.2 The subject/representative does not feel pressured by time or other factors to make a decision.
  - 5.7.3 The subject/representative understands that there is a voluntary choice to make.
  - 5.7.4 The subject/representative is capable of making and communicating an informed choice.
- 5.8 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.
- 5.9 If the study is a clinical trial and the investigator above is not a physician or physician extender, a physician or physician extender must complete the following steps:
  - 5.9.1 Invite and answer the subject/representative's questions.
  - 5.9.2 Confirm that the following are true or repeat the above steps:
    - 5.9.2.1 The subject/representative understands the information provided.
    - 5.9.2.2 The subject/representative does not feel pressured by time or other factors to make a decision.
    - 5.9.2.3 The subject/representative understands that there is a voluntary choice to make.
    - 5.9.2.4 The subject/representative is capable of making and communicating an informed choice.
- 5.10 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.
- 5.11 If the subject/representative agrees to take part in the research study:
  - 5.11.1 If the subject is a child:
    - 5.11.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.
    - 5.11.1.2 Request the assent (affirmative agreement) of the child unless:
      - 5.11.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.
      - 5.11.1.2.2 The IRB determined that assent was not a requirement.



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- 5.11.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.
- 5.11.2 If the subject is an adult unable to consent:
  - 5.11.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.
  - 5.11.2.2 Request the assent (affirmative agreement) of the adult unless:
    - 5.11.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.
    - 5.11.2.2.2 The IRB determined that assent was not a requirement.
  - 5.11.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.
- 5.11.3 Obtain written documentation of the consent process according to "SOP: Written Documentation of Consent (HRP-091)"

## **6 MATERIALS**

- 6.1 Long form of consent documentation:
  - 6.1.1 Consent form (HRP-502)
- 6.2 Short form of consent documentation:
  - 6.2.1 Short consent form (HRP-507)
  - 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: Legally Authorized Representatives, Children, and Guardians (HRP-013)
- 6.5 SOP: Written Documentation of Consent (HRP-091)

## **7 REFERENCES**

- 7.1 21 CFR §50.20, 50.25
- 7.2 45 CFR §46.116



SOP: Written Documentation of Consent				
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**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.

**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 Legally authorized representative 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.

**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 If the IRB required written documentation of assent, note on the signature block one of the following:
    - 5.1.4.1 Assent of the child was obtained.
    - 5.1.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
  - 5.1.5 Have the person obtaining consent personally sign and date the consent document.
  - 5.1.6 If an impartial witness was part of the consent process:
    - 5.1.6.1 Print the name of the impartial witness on the consent document.
    - 5.1.6.2 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.
  - 5.1.7 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:



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- 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 the summary:
  - 5.2.3.1 Subject/Representative
  - 5.2.3.2 Person obtaining consent
  - 5.2.3.3 Impartial witness
- 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 in writing, offer the subject/representative the option to document his or her consent in 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.

**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 (HRP-502)
- 6.2 If the consent process will be documented in writing with the short form of consent documentation:
  - 6.2.1 Short consent document (HRP-507)
  - 6.2.2 Summary (same content as the long form of consent documentation)

**7 REFERENCES**

- 7.1 21 CFR §50.27
- 7.2 45 CFR §46.117



<b>SOP: ClinicalTrials.gov</b>				
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HRP-102	01/19/2018	S. Sowards	A. Tahmassian	1 of 1

## 1 PURPOSE

- 1.1 This procedure establishes the process to maintain Harvard University Area (HUA) ClinicalTrials.gov accounts.
- 1.2 The process begins when at least one of the following actions is required:
  - 1.2.1 Create and maintain user/administrator accounts.
  - 1.2.2 Ensure that problem records are addressed in a timely manner.
- 1.3 The process ends when the ClinicalTrials.gov Protocol Registration System (PRS) Administrator has taken the necessary action.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

## 3 POLICY

- 3.1 The ClinicalTrials.gov PRS is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. The IRB Director serves as the PRS Administrator for the HUA ClinicalTrials.gov account. The PRS Administrator is responsible for creating accounts for affiliated users and providing support to users/Responsible Parties prior to initial release and after record updates. The PRS Administrator serves as a point of contact for the ClinicalTrials.gov team.

## 4 RESPONSIBILITIES

- 4.1 The PRS Administrator is responsible for carrying out these procedures.

## 5 PROCEDURE

- 5.1 As prompted by requests from researchers, the PRS Administrator creates a new user for HUA's Clinicaltrials.gov account as needed.
  - 5.1.1 The Principal Investigator should be listed as "Responsible Party" by the study team.
- 5.2 Monthly protocol record review:
  - 5.2.1 Review protocol records the beginning of each month. Identify:
    - 5.2.1.1 Record owner issues
    - 5.2.1.2 US Public Law 110-85 (FDAAA) issues
    - 5.2.1.3 PRS Administrator issues
  - 5.2.2 Take appropriate action(s) to resolve outstanding issues. Follow-up directly with protocol record owner, Responsible Party, and/or PI to modify, update, complete, approve and/or release the record
    - 5.2.2.1 If the record remains outdated for longer than 45 days, the investigator will be considered Restricted by the HUA IRB. Notify the IRB/department-assigned IRB Staff Member of this status.

## 6 MATERIALS

- 6.1 None.

## 7 REFERENCES

- 7.1 None.