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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 Clinical Trial: A biomedical or behavioral research study of human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new diagnostic procedures or therapeutic interventions are safe, efficacious, and effective.

3.3 Conflicting Interest: This is defined in the policy: Conflicts of Interest and Commitment; APS Number 5012. See COIC website for more information.

3.4 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.

3.5 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

3.6 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.

3.7 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.

3.8 Faculty Advisor: Individual is ultimately responsible for monitoring all aspects of the student's research.

3.9 Finding of Non-Compliance: Non-Compliance in fact.

3.10 Human Research: Any activity that either:[1]

3.10.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or

3.10.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

3.11 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) information that is both Private Information and Identifiable Information. For the purpose of this definition:

3.11.1 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.

3.11.2 Interaction: Communication or interpersonal contact between investigator and subject.

3.11.3 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).

3.11.4 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).

3.12 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.

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

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

3.14 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.[2]

3.14.1 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.

3.15 Non-Committee Review: Any of the following:

3.15.1 Determination of whether an activity is Human Research.

3.15.2 Determination of whether Human Research is exempt from regulation.

3.15.3 Reviews of non-exempt research using the expedited procedure.

3.15.4 Determinations of which subjects can continue in expired research.

3.16 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.

3.16.1 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

3.17 Organizational Official: Associate Vice Chancellor for Research Integrity & Compliance.

3.18 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.

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

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

3.19.1 A sponsor of the research;

3.19.2 A competitor of the sponsor of the research;

3.19.3 A product or service being tested; or

3.19.4 A competitor of the product or service being tested.

3.20 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

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

3.21.1 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;

3.21.2 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

3.21.3 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.

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

3.23 Serious Non-Compliance: Non-Compliance that adversely affects the rights or welfare of subjects.

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[2] 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).

3.23.1 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.

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

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

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

3.26.1 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:

3.26.1.1 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.

3.26.1.2 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).

3.26.1.3 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.

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)

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, Organizational 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

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 Colorado the following meet the definition of a legally authorized representative and, thus, can give surrogate consent:

3.1.1.1 A court appointed guardian of the person

3.1.1.2 A health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) that specifies that the individual also has the power to make decisions of entry into research

3.1.2 For research outside Colorado, 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 Colorado all individuals under the age of 18 years are children. Contact legal counsel for more information.

3.2.2 For research outside Colorado, 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 to consent on behalf of the child to general medical care[1].

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

[1] This is the DHHS and FDA definition of "guardian"

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 to withdraw a submission from consideration, withdraw the submission.

5.2 If the item is a request for an approval or determination[1], follow "SOP: Pre-Review (HRP-021)."

5.3 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)."

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

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

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

5.4.1.2 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.

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

6 MATERIALS

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

6.2 SOP: New Information (HRP-024)

6.3 SOP: Pre-Review (HRP-021)

7 REFERENCES

7.1 None

[1] 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."

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 not Human Research.

1.2 The process begins when the IRB receives a request for approval.

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 None.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the request is for a study closure complete and send “TEMPLATE LETTER: Closure (HRP-511)”.

5.2 If the submission is a response to modifications required to secure approval:

5.2.1 Evaluate whether the investigator made the required modifications.

5.2.2 If the investigator made the required modifications, follow “SOP: Post-Review (HRP-052)” to issue an approval.

5.2.3 If the investigator did not make the required modifications or made unrequested modifications, contact the investigator. Offer the investigator the opportunity to correct the submission.

5.2.3.1 If the investigator will correct the submission, have the investigator resubmit and stop processing the current submission.

5.2.3.2 If the investigator will not correct the submission, continue processing.

5.3 For all other submissions, use “WORKSHEET: Pre-Review (HRP-308),” and for FDA-regulated studies complete “CHECKLIST: Pre-Review (HRP-401)” or revise, as needed, the previously completed “CHECKLIST: Pre-Review (HRP-401)”, and for all other studies complete the associated fields in the electronic system.

5.4 If the information is not complete, contact the investigator. Offer the investigator the opportunity to provide additional information.

5.4.1 If the investigator will provide additional information, have the investigator resubmit and stop processing the current submission.

5.4.2 If the investigator will not provide additional information, continue processing.

5.5 If according to “HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)” the research represents a type of research the organization does not conduct or oversee or where the organization relies on an external IRB, contact the investigator.

5.5.1 If the investigator withdraws the submission, stop processing the current submission.

5.5.2 If the investigator will not withdraw the submission, continue processing.

5.6 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.

5.6.1 If the investigator withdraws the submission, stop processing the current submission.

5.6.2 If the investigator will not withdraw the submission, continue processing.

5.7 Evaluate the most likely level of review:

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

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

6 MATERIALS

6.1 CHECKLIST: Pre-Review (HRP-401)
6.2 HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
6.3 SOP: Conflicts of Interest and Commitment (HRP-056)
6.4 SOP: New Information (HRP-024)
6.5 SOP: Non-Committee Review Preparation (HRP-031)
6.6 SOP: Post-Review (HRP-052)
6.7 TEMPLATE LETTER: Closure (HRP-511)
6.8 TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)
6.9 WORKSHEET: Pre-Review (HRP-308)

7 REFERENCES

7.1 None

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 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.

3.1.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.

3.2 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 "For IRB Use Only" section of "FORM: Reportable New Information (HRP-214)": *(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 manager.

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

5.4 If the answer is "no" to all questions, skip section 5.5.

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

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

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

5.5.1.2 If no, follow any other corresponding sections.

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

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

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

5.5.3 Non-Serious/Non-Continuing Non-Compliance

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

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

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

5.5.4.1 Confirm your decision with the IRB chair or IRB manager.

5.5.4.2 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.

5.5.4.3 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 manager 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 and send a "TEMPLATE LETTER: Information Item (HRP-519)" to the person submitting the information.

6 MATERIALS

6.1 FORM: Reportable New Information (HRP-214)

6.2 SOP: Investigations (HRP-025)

6.3 SOP: Suspension or Termination (HRP-026)

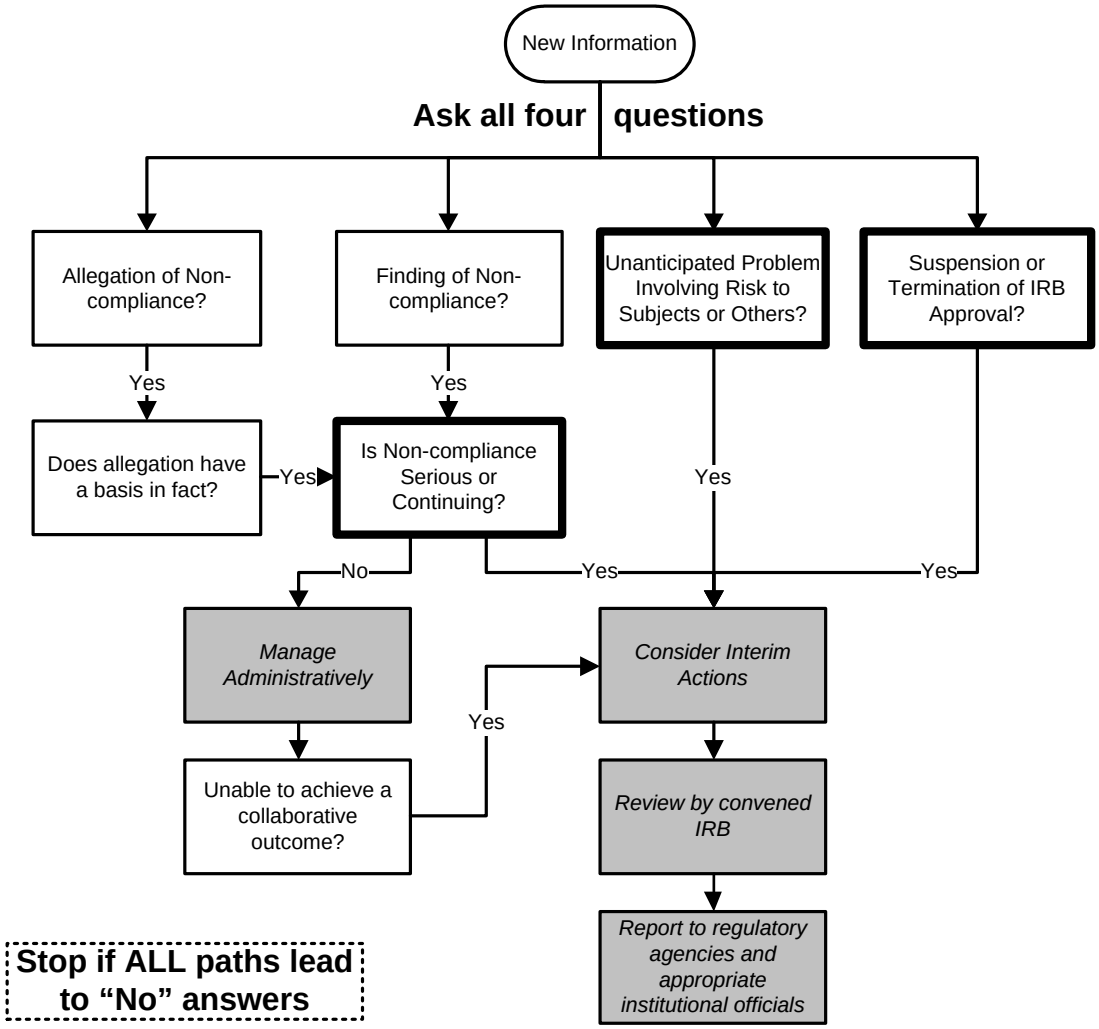
6.4 TEMPLATE LETTER: Information Item (HRP-519)

7 REFERENCES

7.1 21 CFR §56.108(b)

7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)

7.3 Flowchart



University of Colorado Boulder

SOP: Investigations				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-025	5/1/2013	C. Dunne	J. Rosse	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 Organizational Official or designee.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 The Organizational 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.

4.1.4 Charges the investigative committee with a deadline.

4.2 Investigative committee members make their decisions based on a preponderance of the evidence.

4.3 Investigative committee decisions are made by majority vote.

4.4 Individuals being interviewed may have an advisor present. However, the advisor cannot address the investigative committee. The investigative committee by a vote of the majority may exclude the advisor when in the opinion of the investigative committee that person's presence is disruptive.

4.5 The Organizational Official may refer the investigation to the Standing Committee on research Misconduct (SCRM) in lieu of steps 4.1-4.4.

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 Repeat information gathering and interviews until a decision can be made.

5.5 The investigative committee provides a written report of the investigative committee's decision to the Organizational Official or designee.

6 MATERIALS

6.1 SOP: New Information (HRP-024)

6.2 APS Number: 1007; Misconduct in Research, Scholarship, and Creative Activities

7 REFERENCES

7.1 None

1 PURPOSE

1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.

1.2 The process begins when the Organizational Official 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 or IRB manager may institute a Suspension of IRB Approval when in the opinion of the IRB chair or IRB manager 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 Organizational 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

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 Verify that the IRB member is an Experienced IRB Member.

5.3 Update the "DATABASE: IRB Roster (HRP-601)" 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).

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 the IRB staff member notifies the Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 This SOP is to be completed within 5 business days.

3.2 IRB rosters are maintained using "DATABASE: IRB Roster (HRP-601)."

3.3 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in the "WORKSHEET: Review Materials (HRP-301)" according to their role: "Documents Provided to All IRB Members and Alternate IRB Members," "Additional Items Provided to Primary Reviewer," and "Additional Items Provided to Scientific/Scholarly Reviewer."

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Refer to "DATABASE: IRB Roster (HRP-601)" and select a Designated Reviewer.

5.1.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened IRB.

5.2 All information will be accessible to the Designated Reviewer in the electronic system.

5.3 For individuals who are provided hard copy materials to review, prepare and deliver the review materials using the "WORKSHEET: Review Materials (HRP-301)" and include all materials listed in the primary reviewer column along with:

5.3.1 CHECKLIST: Non-Committee Review (HRP-402).

5.3.2 Any relevant minutes or correspondence.

5.4 Notify the Designated Reviewer.

6 MATERIALS

6.1 CHECKLIST: Non-Committee Review (HRP-402)

6.2 DATABASE: IRB Roster (HRP-601)

6.3 WORKSHEET: Review Materials (HRP-301)

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)

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 an IRB staff member notifies the Designated Reviewer of the review.

1.3 The process ends when the Designated Reviewer notifies an IRB staff member of the completion of the review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 This SOP is to be complete within 5 business days

3.2 The Designated Reviewer may not disapprove research.

4 RESPONSIBILITIES

4.1 The Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Review all materials.

5.2 Determine the required level of review. (Not Human Research, exempt Human Research, Human Research approved using the expedited procedure, or Human Research that requires review by a convened IRB.

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

5.4 Complete the review in the electronic system.

5.5 Check the accuracy of “CHECKLIST: Pre-Review (HRP-401)” and revise as needed, or complete the associated fields in the electronic system

5.6 When done notify the IRB staff and return all hard copy materials.

6 MATERIALS

6.1 CHECKLIST: Pre-Review (HRP-401)

6.2 SOP: Consultation (HRP-051)

7 REFERENCES

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).

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 14 days before a meeting date.
1.3 The process ends when IRB members are notified of the agenda.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

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

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.
5.2 Consult “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 Assign a primary reviewer to each agenda item.
  5.4.2 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 hard copy materials prepare and deliver the review materials using “WORKSHEET: Review Materials (HRP-301)” according to the individual’s role.
5.7 Notify IRB members of the agenda.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)
6.2 SOP: Consultation (HRP-051)
6.3 WORKSHEET: Review Materials (HRP-301).
6.4 WORKSHEET: Quorum and Expertise (HRP-305).

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(b)

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 may be reviewed for approval by an IRB staff member or Designated Reviewer..

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 that requirements for review of a specific item as defined in "WORKSHEET: Quorum and Expertise (HRP-305)" are not met.[1]

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 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, , 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.

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[1] "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.

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 or questions 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 on "CHECKLIST: Pre-Review (HRP-401)."

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, but if there is a management plan, it must return to the convened 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: Pre-Review (HRP-401)
6.2 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
6.3 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
6.4 CHECKLIST: Pregnant Women (HRP-412)
6.5 CHECKLIST: Prisoners (HRP-415)
6.6 CHECKLIST: Children (HRP-416)
6.7 CHECKLIST: Cognitively Impaired Adults (HRP-417)
6.8 CHECKLIST: Non-significant Risk Device (HRP-317)
6.9 SOP: IRB Meeting Preparation (HRP-040)
6.10 WORKSHEET: Review Materials (HRP-301)
6.11 WORKSHEET: Quorum and Expertise (HRP-305)
6.12 WORKSHEET: Criteria for Approval (HRP-314)
6.13 WORKSHEET: Advertisements (HRP-315)
6.14 WORKSHEET: Payments (HRP-316)
6.15 WORKSHEET: Short Form of Consent Documentation (HRP-317)
6.16 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
6.17 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.

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 <u>not</u> appropriately constituted for the review of that protocol.

5.3 When a member leaves the meeting room for any reason (including a <u>Conflicting Interest</u>) 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 <u>not</u> 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)

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 manager.

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 manager.
3.4 IRB members may make corrections to minutes.
3.5 The IRB writes minutes and makes them available for review within 15 business days of the meeting date.
3.6 The IRB reports its findings and actions to the institution through providing minutes to appropriate organizational officials.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Use the “TEMPLATE MINUTES (HRP-501)” to record observations at meetings.
5.2 Under “Attendance Table” 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 Record a summary of each business item that was discussed.
5.8 For each protocol reviewed record:
  5.8.1 Type(s) of review: Initial review, continuing review, review of modifications to previously approved research, or review of Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval.
  5.8.2 Protocol Title
  5.8.3 Investigator name.
  5.8.4 IRB identification number
  5.8.5 Funding Agency (indicate “none” if none)
  5.8.6 Grant Title (indicate “none” if none)
  5.8.7 Grant ID (indicate “none” if none)

5.8.8 IND or IDE (indicate “none” if none)

5.8.9 Documents reviewed

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

5.8.11 Consultant report: Summarize the key information provided the consultant. Delete if there was no consultant.

5.8.12 Controverted issues and their resolution. 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.”

5.8.13 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this.

5.8.14 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.

5.8.14.1 For: Voting for the motion.

5.8.14.2 Against: Voting against the motion.

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

5.8.14.4 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”

5.8.14.5 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”

5.8.14.6 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)”

5.8.15 Level of risk determined by the convened IRB: Minimal Risk or more than Minimal Risk.

5.8.16 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, Prisoners, or cognitively impaired adults, include one of more of the “Determination/Protocol Specific Findings” tables in the “TEMPLATE MINUTES (HRP-501)” or enter “See IRB records for this protocol” and ensure that the corresponding completed checklist is in the IRB records. Otherwise delete.

5.8.17 Rationale for a significant/non-significant device determination: Describe the rationale for the determination. Otherwise delete.

5.8.18 Modifications required to secure approval: If this is the motion, complete the table with the required changes and corresponding reasons. Otherwise, delete.

5.8.19 Deferral/disapproval reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.

5.8.20 Suspension/termination reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.

5.8.21 Tabled reason: If the protocol was tabled, provide the reasons. Otherwise, delete.

5.9 Record the meeting end time.

5.10 Within 7 business days revise minutes for accuracy and provide them to the IRB chair or IRB manager for review and approval.

5.11 Once approved by the IRB chair or IRB manager, email them to:

5.11.1 Organizational Official or designee.

5.11.2 IRB members.

5.12 IRB members have 7 business days to review the minutes.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)

6.2 TEMPLATE: Minutes (HRP-501)

7 REFERENCES

7.1 21 CFR §56.115(a)(2)

7.2 45 CFR §46.115(a)(2)

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 Organizational 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: Pregnant Women (HRP-412)" or "CHECKLIST: Children (HRP-416)."

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.

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 (HRP-314)." and "CHECKLIST: Pregnant Women (HRP-412)" or "CHECKLIST: Children (HRP-416)."

4 RESPONSIBILITIES

4.1 The Organizational 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:

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.

6 MATERIALS

6.1 CHECKLIST: Pregnant Women (HRP-412)

6.2 CHECKLIST: Children (HRP-416)

6.3 WORKSHEET: Criteria for Approval (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

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).

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)

1 PURPOSE

1.1 This procedure establishes the process for communications after a protocol is reviewed.

1.2 The process begins when:

1.2.1 A Designated Reviewer has completed a Non-Committee Review and notified the IRB staff; OR

1.2.2 An IRB meeting has adjourned and the IRB chair or IRB manager 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 These reporting procedures are to be completed within 14 days of the IRB meeting or 31 days following 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 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 Check the accuracy of the electronic system and revise as needed.

5.3 Refer to “WORKSHEET: Approval Intervals (HRP-302)” to calculated approval intervals.

5.4 Affix all newly approved consent materials with the approval date.

5.5 Refer to “WORKSHEET: Communication of Review Results (HRP-303)” and send all applicable letters.

5.5.1 Send the letter to the inside addresses and cc list as directed by the letter.

5.5.2 If not available electronically, attach all dated consent materials.

6 MATERIALS

6.1 CHECKLIST: Pre-Review (HRP-401)

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

6.3 WORKSHEET: Communication of Review Results (HRP-303)

6.4 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

7.2 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

University of Colorado Boulder

SOP: Conflicts of Interest & Commitment				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-056	5/1/2013	C. Dunne	J. Rosse	1 of 1

1 PURPOSE

1.1 This procedure establishes how the IRB handles research personnel conflicts of interest and commitment.

1.2 The process begins when the Compliance Director for Conflicts of Interests and Commitment identifies a potential individual conflict of interests.

1.3 The process ends when the IRB has determined how the conflict will be managed in the protocol.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The organization applies the Conflict of Interest and Conflict of Commitment Disclosure and Review policy to all sponsored and non-sponsored Human Research.

3.2 Individuals subject to this policy are required to have a Disclosure of External Professional Activities (DEPA) on file and report any conflicts of interest to the IRB:

3.2.1 On submission of an initial review.

3.2.2 At least annually on submission of continuing review.

3.2.3 Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new conflict of interest

4 RESPONSIBILITIES

4.1 The IRB office carries out these procedures.

5 PROCEDURE

5.1 Apply Conflict of Interest and Conflict of Commitment Disclosure and Review policy to evaluate and manage the individual financial interest.

5.2 If the individual financial interest is determined to be a conflict of interest, provide the IRB staff of the reviewing IRB with the written management plan so the IRB can make the final decision as to whether the financial interest and its management, if any, allows the research to be approved.

5.3 If additional requirements to the protocol are warranted to manage the conflict these will be determined by the IRB.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 42 CFR §50

7.2 45 CFR §94

1 PURPOSE

1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.

1.2 The process begins the first business day of each June.

1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The human research protection program is evaluated annually.

3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making the document "BROCHURE: Should I Take Part in Research (HRP-104)" available to the subject population.

4 RESPONSIBILITIES

4.1 IRB staff ensures completion of these procedures.

5 PROCEDURE

5.1 Have the Organizational 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 Organizational 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 Organizational Official or designee to modify the IRB structure.

5.3 Have the IRB chair or IRB manager evaluate the knowledge, skills, and performance of each regular and alternate IRB member.

- 5.3.1 Provide a copy of the evaluation to the Organizational 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 Use the "WORKSHEET: IRB Composition (HRP-304)" to evaluate whether the composition of the IRB meets regulatory and organizational requirements.

- 5.4.1 Provide a copy of the evaluation to the Organizational Official or designee.
- 5.4.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the Organizational Official or designee to modify the IRB composition.

5.5 Check when the last time each IRB was registered. If more than 2 years, update the registration.[1]

5.6 Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 2 years, update/renew the federalwide assurance (FWA).[2]

6 MATERIALS

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

6.2 TEMPLATE LETTER: IRB Member Appreciation (HRP-562)

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[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

[2] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

6.3 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

7.1 None

University of Colorado Boulder

SOP: Monthly HRPP Evaluations				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-061	5/1/2013	C. Dunne	J. Rosse	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 achieve 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 The QA coordinator ensures 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 manager and Organizational Official or designee.

5.4 If the results of any evaluations demonstrate high variability or are outside performance targets, work with the IRB manager and Organizational 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 4 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

University of Colorado Boulder

SOP: Monthly and Daily Tasks				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-062	5/1/2013	C. Dunne	J. Rosse	1 of 1

1 PURPOSE

1.1 This procedure establishes the process to complete monthly and daily tasks required to monitor the research review process.

1.2 The process begins the first of the month for monthly tasks and each business day for daily tasks.

1.3 The process ends when the tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The institution relies on CITI to automatically check for individuals whose training will lapse and sends a notification.

4 RESPONSIBILITIES

4.1 IRB staff members are responsible for carrying out this procedure.

5 PROCEDURE

5.1 Monthly check for protocols whose continuing review progress report is due in 60 days or 30 days and complete and send “TEMPLATE LETTER: Continuing Review Reminder (HRP-530)”

5.2 Daily check for protocols that have expired due to lack of continuing review:

5.2.1 Complete and send the “TEMPLATE LETTER: Expiration of IRB Approval (HRP-533).”

5.2.2 Follow “SOP: Expiration of IRB Approval (HRP-063)”

6 MATERIALS

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

6.2 TEMPLATE LETTER: Continuing Review Reminder (HRP-530)

6.3 TEMPLATE LETTER: Expiration of IRB Approval (HRP-533)

7 REFERENCES

7.1 None

University of Colorado Boulder

SOP: Expiration of IRB Approval				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-063	5/1/2013	C. Dunne	J. Rosse	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

1 PURPOSE

1.1 This procedure establishes the process to maintain IRB records.
1.2 The process begins when records are received or created.
1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB records are to include:
- 3.1.1 Protocol files.
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all correspondence between the IRB and the investigators.
- 3.1.4 Current and all previous IRB member rosters.
- 3.1.5 Current and all previous IRB member files.
- 3.1.6 Current and all previous policies and procedures.

3.2 Protocol files are to include, as applicable:
- 3.2.1 All submitted materials.
- 3.2.2 Protocols.
- 3.2.3 Investigator brochures.
- 3.2.4 Scientific evaluations.
- 3.2.5 Recruitment materials.
- 3.2.6 Consent documents.
- 3.2.7 DHHS-approved sample consent document and protocol, when they exist.
- 3.2.8 Progress reports submitted by investigators.
- 3.2.9 Reports of injuries to subjects.
- 3.2.10 Records of continuing review activities.
- 3.2.11 Data and safety monitoring board reports.
- 3.2.12 Amendments.
- 3.2.13 Reports of unanticipated problems involving risks to subjects or others.
- 3.2.14 Documentation of non-compliance.
- 3.2.15 Correspondence between the IRB and investigator related to the protocol.
- 3.2.16 Significant new findings and statements about them provided to subjects.
- 3.2.17 For initial and continuing review of research by the expedited procedure:
  - 3.2.17.1 The specific permissible category.
  - 3.2.17.2 Description of action taken by the reviewer.
  - 3.2.17.3 Any findings required under the regulations.
- 3.2.18 For exemption determinations the specific category of exemption.
- 3.2.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.
  - 3.2.19.1 Waiver or alteration of the consent process.
  - 3.2.19.2 Research involving pregnant women and fetuses.
  - 3.2.19.3 Research involving Prisoners.
  - 3.2.19.4 Research involving children.
  - 3.2.19.5 Research involving adults unable to consent.
  - 3.2.19.6 Significant/non-significant device determinations.
- 3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review.

3.3 Protocol files are maintained electronically for all non FDA-regulated research. FDA-regulated are maintained in paper file system.

3.4 Policies and procedures include:

3.4.1 Checklists.
3.4.2 Forms.
3.4.3 SOPs.
3.4.4 Template minutes.

3.5 IRB member files include a resume for each IRB member.

4 RESPONSIBILITIES

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

5 PROCEDURE

5.1 Minutes of IRB meetings: File in minutes binder and the electronic system.
5.2 File correspondence related to a specific protocol in the protocol file.
5.3 File correspondence NOT related to a specific protocol in a file related to that person or topic.
5.4 IRB member rosters: File in IRB member roster folder.
5.5 IRB membership records (e.g., curricula vita and resumes): File in IRB member files.
5.6 Policies and procedures:
5.6.1 File current policies and procedures in polices and procedures folder.
5.6.2 File replaced policies and procedures in the policies and procedures history file.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 None

University of Colorado Boulder

SOP: Standard Operating Procedures				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-071	5/1/2013	C. Dunne	J. Rosse	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 manager or Organizational 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 manager 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 IRB website.
- 5.5.4 File the old document, if any, in the standard operating procedure files.
- 5.5.5 Post a notice on the IRB website informing affected individuals of the change.

6 MATERIALS

6.1 TEMPLATE: SOP (HRP-505)

7 REFERENCES

7.1 None

1 PURPOSE

1.1 This procedure establishes the process to retain IRB records.

1.2 The process begins twice a year in June and December.

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 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 three 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

1 PURPOSE

1.1 This procedure establishes the process to form or rely on a new IRB.

1.2 The process begins when the Organizational Official or designee determines the need for a new IRB.

1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated, 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 Organizational 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 Organizational 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 HSRBs are part of an AAHRPP accredited organization.

5.2.1.2 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.

5.2.1.3 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 Update the federalwide assurance (FWA) with the new IRB.

5.2.4 File the federalwide assurance (FWA).

5.2.5 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 manager when all individuals have completed training.

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).

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB.

1.2 The process begins when the Organizational Official or designee determines that an IRB is no longer needed.

1.3 The process ends when the IRB is unregistered with OHRP and the federalwide assurance (FWA) is updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB rosters are maintained using the "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 Organizational Official or designee, and send to the former IRB members.

5.1.2 Unregister the IRB with OHRP[1].

5.1.3 Remove the IRB from the federalwide assurance (FWA)[2].

5.1.4 Remove members from "DATABASE: IRB Roster (HRP-601)."

5.1.5 File:

5.1.5.1 DATABASE: IRB Roster (HRP-601)

5.1.5.2 Federalwide assurance (FWA)

5.1.5.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)

5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)

6.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).

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

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[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

[2] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

1 PURPOSE

1.1 This procedure establishes the process to add a new IRB member.

1.2 The process begins when the Organizational 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 Organizational 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 Organizational 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 Update "DATABASE: IRB Roster (HRP-601)":

- 5.4.1 Set the End Date and save.
- 5.4.2 Set the Start Date, make the End Date blank, update with the new member information, and save as a new file.

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 Organizational Official or designee for review and approval:

- 5.7.1 FORM: IRB Member Information (HRP-202).
- 5.7.2 Résumé or curriculum vita.
- 5.7.3 Completed "TEMPLATE LETTER: IRB Member Appointment (HRP-560)"

5.8 If not approved, select another individual and restart at 5.2.

5.9 Once the appointment letter is signed:

- 5.9.1 Send the signed "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.[1]

5.10 File:

- 5.10.1 Old and new DATABASE: IRB Roster (HRP-601)
- 5.10.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)

5.11 Notify the IRB manager when the individual has completed training.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)

6.2 FORM: IRB Member Information (HRP-202)

6.3 TEMPLATE LETTER: IRB Member Appointment (HRP-560)

6.4 WORKSHEET: IRB Composition (HRP-304)

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[1] See http://www.hhs.gov/ohrp/assurances/. Use Web site: http://ohrp.cit.nih.gov/efile/.

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).

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 Organizational 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 manager 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 Update "DATABASE: IRB Roster (HRP-601)":

5.1.1 Set the End Date and save.

5.1.2 Set the Start Date, make the End Date blank, delete the member's information, and save as a new file.

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 Organizational Official or designee, and send to the individual.

5.4 Update the registration of all affected IRBs.[1]

5.5 File:

5.5.1 Old and new DATABASE: IRB Roster (HRP-601)

5.5.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)

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)

[1] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

University of Colorado Boulder

SOP: IRB Meeting Scheduling and Notification				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-084	5/1/2013	C. Dunne	J. Rosse	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 180 days of meetings on the current schedule.

1.3 The process ends when meetings are scheduled at least six 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 The Panel Coordinator carries out these procedures.

5 PROCEDURE

5.1 Create a schedule of meetings for each IRB.

5.2 Post the schedule on the organization's website.

5.3 Notify the following individuals of the updated schedule by posting an update on the organization's website:

5.3.1 IRB members.

5.3.2 Investigators and research staff.

5.3.3 Organizational Official or designee.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 ICH-GCP E6 3.3.2

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 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative

3.4 If the subject is an adult unable to consent:

- 3.4.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
- 3.4.2 Permission is obtained from a legally authorized representative.
- 3.4.3 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)."

3.5 If the subject is a child:

- 3.5.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
- 3.5.2 Permission is obtained from both parents unless:
  - 3.5.2.1 One parent is deceased, unknown, incompetent, not reasonably available;
  - 3.5.2.2 Only one parent has legal responsibility for the care and custody of the child; or
  - 3.5.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
- 3.5.3 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.

3.6 If the subject/representative cannot speak English:

- 3.6.1 The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak language that the subject understands.

3.7 Conduct all discussions in a private and quiet setting.

3.8 Any knowledgeable individual may:

- 3.8.1 Review the study with subject/representative to determine preliminary interest.
- 3.8.2 If the subject/representative is interested, notify an investigator.
- 3.8.3 If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

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 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. 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.

5.2.7 Through the interpreter explain the details in such a way that the subject/representative understand what it would be like to take part in the research study. When necessary provide a different or simpler explanation to make the information understandable.

5.2.8 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.

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. 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, as appropriate.

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 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

5.10 If the subject/representative agrees to take part in the research study:

5.10.1 If the subject is a child:

5.10.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.

5.10.1.2 Request the assent (affirmative agreement) of the child unless:

5.10.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.

5.10.1.2.2 The IRB determined that assent was not a requirement.

5.10.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.

5.10.2 If the subject is an adult unable to consent:

5.10.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.

5.10.2.2 Request the assent (affirmative agreement) of the adult unless:

5.10.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.

5.10.2.2.2 The IRB determined that assent was not a requirement.

5.10.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.

5.10.3 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

6.2 Short form of consent documentation:

6.2.1 Short consent form

6.2.2 Summary (same information as the English consent form used for long form of consent documentation)

6.3 Requirement for written documentation of the consent process has been waived by the IRB:

6.3.1 Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

6.4 SOP: 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

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 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:

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 is writing, offer the subject/representative the option to document his or her consent is writing.

5.3.1 If the subject/representative declines, take no further action.

5.3.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation

5.4 Place the signed and dated documents in the subject's binder.

6 MATERIALS

6.1 If the consent process will be documented in writing with the long form of consent documentation:

6.1.1 Consent document

6.2 If the consent process will be documented in writing with the short form of consent documentation:

6.2.1 Short consent document

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