

## **HSPP Standard Operating Procedures**

### **General**

- HRP – 001 Definitions
- HRP – 012 Observation of Consent Process
- HRP – 013 Legally Authorized Representatives, Children, and Guardians

### **Management of Incoming Information**

- HRP – 020 Incoming Items
- HRP – 021 Pre-Review
- HRP – 023 Emergency Use Review
- HRP – 024 New Information
- HRP – 025 Investigations
- HRP – 026 Suspension or Termination
- HRP – 027 Emergency Use Post-Review

### **Non-Committee Review**

- HRP – 030 Designated Reviewers
- HRP – 031 Non-Committee Review Preparation
- HRP – 032 Non-Committee Review Conduct

### **Committee Review**

- HRP – 040 IRB Meeting Preparation
- HRP – 041 IRB Meeting Conduct
- HRP – 042 IRB Meeting Attendance Monitoring
- HRP – 043 IRB Meeting Minutes

### **Review Process**

- HRP – 050 Conflicting Interests of IRB Members
- HRP – 051 Consultation
- HRP – 052 Post-Review
- HRP – 056 Financial Conflicts of Interest

### **Periodic Tasks**

- HRP – 060 Annual Evaluations of the HSPP
- HRP – 061 Monthly Evaluations of the HSPP
- HRP – 062 Daily Tasks
- HRP – 063 Expiration of IRB Approval

### **Records**

- HRP – 070 IRB Records
- HRP – 071 Standard Operating Procedures
- HRP – 072 IRB Records Retention

### **Committee Management**

- HRP – 080 IRB Formation
- HRP – 081 IRB Removal
- HRP – 082 IRB Membership Addition
- HRP – 083 IRB Membership Removal
- HRP – 084 IRB Meeting Scheduling and Notification

### **Investigator**

- HRP – 090 Informed Consent Process for Research
- HRP – 091 Written Documentation of Consent



## SOP: Definitions

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-001	8/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 4

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

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

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

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

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

3.3.5 Board or executive relationship, regardless of compensation.

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

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

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

3.9 Human Research: Any activity that either:<sup>1</sup>

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

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

3.10 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:

3.10.1 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.

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



SOP: Definitions				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-001	8/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	2 of 4

- 3.10.2 Interaction: Communication or interpersonal contact between investigator and subject.
- 3.10.3 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).
- 3.10.4 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).
- 3.11 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.
- 3.12 Immediate Family: Spouse, domestic partner; and dependent children.
- 3.13 Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.<sup>2</sup>
  - 3.13.1 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.
  - 3.13.2 When following Department of Defense regulations, the definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).
- 3.14 Non-Committee Review: Any of the following:
  - 3.14.1 Determination of whether an activity is Human Research.
  - 3.14.2 Determination of whether Human Research is exempt from regulation.
  - 3.14.3 Reviews of non-exempt research using the expedited procedure.
  - 3.14.4 Determinations of which subjects can continue in expired research.
- 3.15 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.
  - 3.15.1 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
- 3.16 Organizational Official: Also referred to as the Institutional Official. At MSU Denver, the Associate Vice President of Curriculum and Academic Effectiveness is designated as the Organizational Official and is the Signatory Authority on the University’s federalwide assurance with OHRP.
- 3.17 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.

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<sup>2</sup> The phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).



SOP: Definitions				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-001	8/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	3 of 4

- 3.17.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.
- 3.18 Related to the Research: A financial interest is Related to the Research when the interest is in:
  - 3.18.1 A sponsor of the research;
  - 3.18.2 A competitor of the sponsor of the research;
  - 3.18.3 A product or service being tested; or
  - 3.18.4 A competitor of the product or service being tested.
- 3.19 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 3.20 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:
  - 3.20.1 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;
  - 3.20.2 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
  - 3.20.3 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.
- 3.21 Restricted: Applies to investigators who are delinquent in meeting IRB requirements.
- 3.22 Serious Non-Compliance: Non-Compliance that adversely affects the rights or welfare of subjects.
  - 3.22.1 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.
- 3.23 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.
- 3.24 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.
- 3.25 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.
  - 3.25.1 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:
    - 3.25.1.1 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.
    - 3.25.1.2 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).
    - 3.25.1.3 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



## SOP: Definitions

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-001	8/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	4 of 4

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)



## SOP: Observation of Consent

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-012	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 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



<b>SOP: Legally Authorized Representatives, Children, and Guardians</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-013	3/25/14	F.Conte	Loretta Martinez, J.D.	1 of 1

**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 individuals meet this definition:
    - 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<sup>1</sup>. Before obtaining permission from an individual who is not a parent, contact legal counsel.

**4 RESPONSIBILITIES**

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

**5 PROCEDURE**

- 5.1 None

**6 MATERIALS**

- 6.1 None

**7 REFERENCES**

- 7.1 45 CFR §46.102, 45 CFR §46.402
- 7.2 21 CFR §50.3

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

SOP: Incoming Items				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-020	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-020	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

## 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 includes new or modified contact information, update the contact information.
- 5.2 If the item includes new or modified training information, update the training information.
- 5.3 If the item includes an updated list of study personnel:
  - 5.3.1 Send "TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)."
  - 5.3.2 If there are financial disclosures, follow "SOP: Financial Conflicts of Interests (HRP-055)".
- 5.4 If the item is a request to withdraw a submission from consideration, withdraw the submission.
- 5.5 If the item is a request for an approval or determination<sup>1</sup>, follow "SOP: Pre-Review (HRP-021)."
- 5.6 If the item is a notification of an emergency use of a test article in a life-threatening situation have a Designated Reviewer follow "SOP: Emergency Use (HRP-023)."
- 5.7 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)."
- 5.8 If the item does not fit into the above categories:
  - 5.8.1 If the item is a question, concern, or complaint:
    - 5.8.1.1 Document the nature of the question, concern, or complaint and the contact information of the person contacting the IRB.
    - 5.8.1.2 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.
  - 5.8.2 Follow "SOP: New Information (HRP-024)."

## 6 MATERIALS

- 6.1 SOP: Emergency Use (HRP-023)
- 6.2 SOP: Expiration of IRB Approval (HRP-063)
- 6.3 SOP: Financial Conflicts of Interests (HRP-055)
- 6.4 SOP: New Information (HRP-024)
- 6.5 SOP: Pre-Review (HRP-021)
- 6.6 TEMPLATE LETTER: Acknowledgement of Personnel Update (HRP-524)

## 7 REFERENCES

- 7.1 None

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<sup>1</sup> A "request for an approval or determination" includes approval of new research, response to modifications required to secure approval, continuing review of research, modification to previously approved research, request for study closure, or a determination whether an activity is exempt Human Research or is not Human Research. Submission of an updated list study personnel is not considered a modification of research and is therefore not a "request for an approval or determination."



<b>SOP: Pre-review</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-021	3/25/14	F.Conte	Dr. R. Shevalier	1 of 2

## 1 PURPOSE

- 1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.
- 1.2 The process begins when the IRB receives a request for 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 The addition of a previously approved protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites is considered a modification to previously approved research.

## 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

## 5 PROCEDURE

- 5.1 If the submission is a response to modifications required to secure approval received within 25 days of the IRB review date:
  - 5.1.1 Evaluate whether the investigator made the required modifications.
  - 5.1.2 If the investigator made the required modifications, follow "SOP: Post-Review (HRP-052)" to issue an approval.
  - 5.1.3 If the investigator did not make the required modifications or made unrequested modifications, contact the investigator. Offer the investigator the opportunity to correct the submission.
    - 5.1.3.1 If the investigator will correct the submission, have the investigator resubmit and stop processing the current submission.
    - 5.1.3.2 If the investigator will not correct the submission, continue processing.
- 5.2 For all other submissions, complete "CHECKLIST: Pre-Review (HRP-401)" or review the previously completed "CHECKLIST: Pre-Review (HRP-401)" and revise as needed, considering the items on "WORKSHEET: Pre-Review (HRP-308)" and note all remaining contingencies in the "Final Contingencies" section.
- 5.3 If the 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.
  - 5.3.1 If the investigator withdraws the submission, stop processing the current submission.
  - 5.3.2 If the investigator will not withdraw the submission, continue processing.
- 5.4 Evaluate the most likely level of review:
  - 5.4.1 If the study can be closed, complete and send "TEMPLATE LETTER: Closure (HRP-511)".
  - 5.4.2 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)."
  - 5.4.3 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 WORKSHEET: Pre-Review (HRP-308)



<b>SOP: Pre-review</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-021	3/25/14	F.Conte	Dr. R. Shevalier	2 of 2

- 6.3 HUMAN RESEARCH PROTECTION PROGRAM PLAN (HRP-101)
- 6.4 SOP: New Information (HRP-024)
- 6.5 SOP: Non-Committee Review Preparation (HRP-031)
- 6.6 SOP: IRB Meeting Preparation (HRP-040)
- 6.7 SOP: Post-Review (HRP-052)
- 6.8 TEMPLATE LETTER: Closure (HRP-511)

## **7 REFERENCES**

- 7.1 None



## SOP: Emergency Use Review

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-023	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

- 1.1 This procedure establishes the process to review notifications of:
  - 1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
  - 1.1.2 Compassionate use of an unapproved device without an IDE for a serious condition.
- 1.2 The process begins when the IRB receives a notification of a proposed or actual use.
- 1.3 The process ends when a Designated Reviewer has:
  - 1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and
  - 1.3.2 Notified the physician and IRB staff of the determination.

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.
- 3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device without an IDE for a serious condition.
- 3.3 Data obtained from uses covered by this procedure cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.

### 4 RESPONSIBILITIES

- 4.1 A Designated Reviewer carries out these procedures.

### 5 PROCEDURE

- 5.1 Use the "WORKSHEET: Emergency Use (HRP-322)" to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.
  - 5.1.1 If met, inform the physician that the physician can proceed with the use.
  - 5.1.2 If not met, inform the physician that if the physician proceeds with the use, the IRB will consider that action to be Non-Compliance.
- 5.2 For notifications after the emergency use of a test article in a life-threatening situation use the "WORKSHEET: Emergency Use (HRP-322)" to determine whether the circumstances met the regulatory and guidance criteria.
- 5.3 Inform IRB staff of the results of the evaluation.

### 6 MATERIALS

- 6.1 SOP: Definitions (HRP-001)
- 6.2 WORKSHEET: Emergency Use (HRP-322)

### 7 REFERENCES

- 7.1 21 CFR §50.23; 21 CFR §56.104(c).

SOP: New Information				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-024	3/25/14	F.Conte	Dr. R. Shevalier	1 of 3

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-024	3/25/14	F.Conte	Dr. R. Shevalier	1 of 3

## 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 5.7 and continue with section 5.8.
- 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.

SOP: New Information				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-024	3/25/14	F.Conte	Dr. R. Shevalier	2 of 3

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-024	3/25/14	F.Conte	Dr. R. Shevalier	2 of 3

- 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.
- 5.6 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).”
- 5.7 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:
- 5.7.1 Confirm that the subject is currently a Prisoner.
- 5.7.1.1 If the subject is currently not a Prisoner no other action is required.
- 5.7.2 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.
- 5.7.2.1 If the subject’s involvement in the research cannot be stopped for health or safety reasons, do one of the following:
- 5.7.2.1.1 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.
- 5.7.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.
- 5.7.2.2 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,
- 5.7.3 For Department of Defense (DOD) research promptly report all decisions to the Department of Defense (DOD).
- 5.7.4 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a prisoner.
- 5.8 Take any additional actions required to resolve any concerns or complaints associated with the information.
- 5.9 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.

5.10

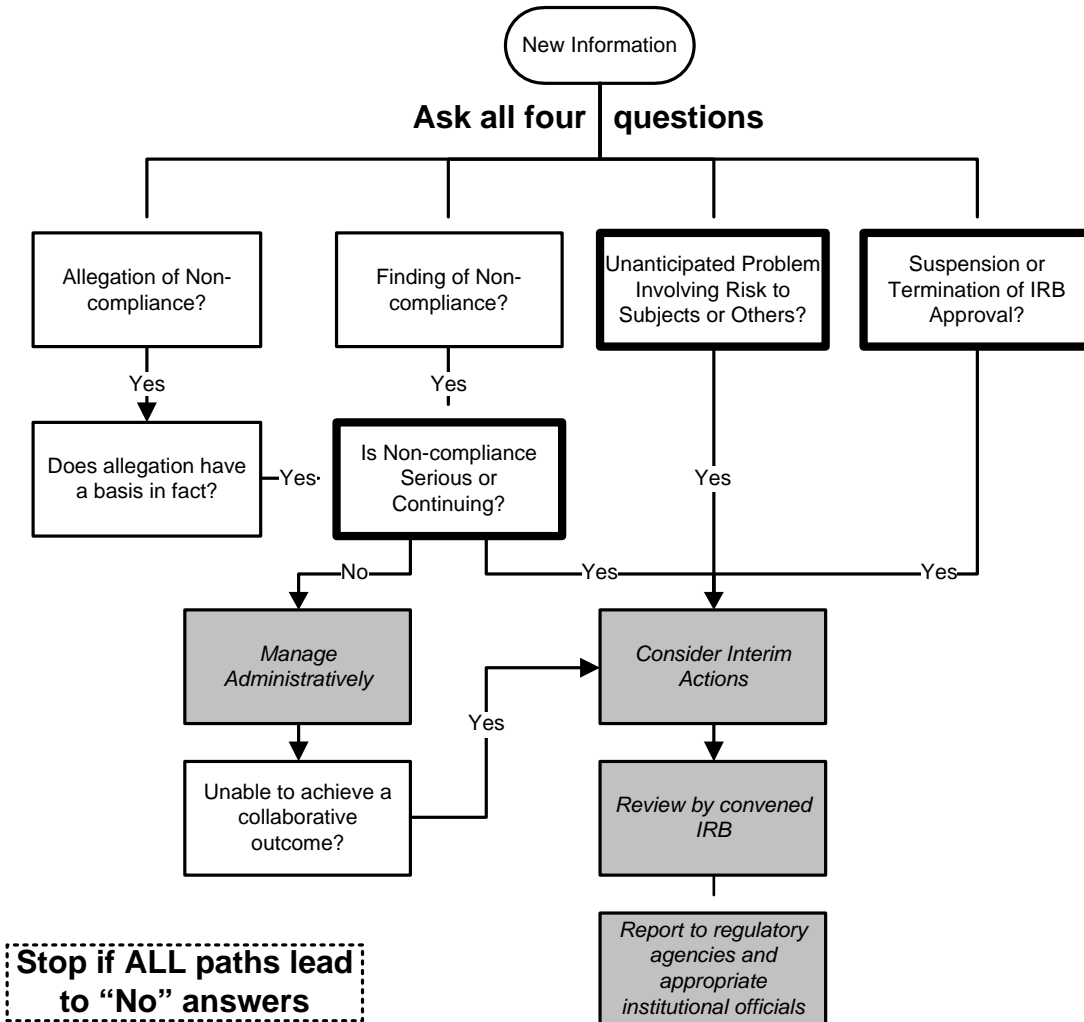
## 6 MATERIALS

- 6.1 FORM: Reportable New Information (HRP-214)
- 6.2 SOP: Investigations (HRP-025)
- 6.3 SOP: Suspension or Termination (HRP-026)
- 6.4 SOP: Post-Review (HRP-052)
- 6.5 TEMPLATE LETTER: Information Item (HRP-519)

SOP: New Information				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-024	3/25/14	F.Conte	Dr. R. Shevalier	3 of 3

**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





SOP: Investigations				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-025	3/25/14	F.Conte	Dr. R. Shevalier	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.
- 4.2 The investigative committee carries out these procedures within 60 days.
- 4.3 Investigative committee members make their decisions based on a preponderance of the evidence.
- 4.4 Investigative committee decisions are made by majority vote.
- 4.5 Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person's presence is disruptive.

**5 PROCEDURE**

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

**6 MATERIALS**

- 6.1 SOP: New Information (HRP-024)

**7 REFERENCES**

- 7.1 None



## SOP: Suspension or Termination

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-026	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

- 1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.
- 1.2 The process begins when the 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, Alternate IRB Chair, HSPP Coordinator, President or Provost and Vice President for Academic Affairs may institute a Suspension of IRB Approval when in the opinion of the IRB chair or HSPP Coordinator 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, or the Convened IRB 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





## SOP: Emergency Use Post-Review

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-027	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

- 1.1 This procedure establishes the process to communicate the review of:
  - 1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.
  - 1.1.2 Compassionate use of an unapproved device without an IDE for a serious condition.
- 1.2 The process begins when the Designated Reviewer has notified IRB staff of whether an actual or proposed use has followed or will follow FDA regulations and guidance.
- 1.3 The process ends when the IRB staff has communicated the results to the physician and if necessary initiated the non-compliance process.

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.
- 3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device without an IDE for a serious condition.
- 3.3 Data obtained from uses covered by this procedure cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.

### 4 RESPONSIBILITIES

- 4.1 IRB staff carry out these procedures.

### 5 PROCEDURE

- 5.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:
  - 5.1.1 Complete a "TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)" and send to the physician.
  - 5.1.2 Set a 5 day deadline for receipt of the 5 day report.
- 5.2 If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, complete a "TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)" and send to the physician.
- 5.3 If the Designated Reviewer has indicated that the actual use followed FDA regulations
  - 5.3.1 Complete a "TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)" and send to the physician.
  - 5.3.2 For uses of drugs and biologics, set a 25 day deadline for receipt of a protocol, if applicable.
- 5.4 If the Designated Reviewer has indicated that the proposed use did NOT follow FDA regulations:
  - 5.4.1 Complete a "TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)" and send to the physician.
  - 5.4.2 Manage under "SOP: New Information (HRP-024)" as Non-Compliance.

### 6 MATERIALS

- 6.1 SOP: New Information (HRP-024)
- 6.2 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met (HRP-571)
- 6.3 TEMPLATE LETTER: Review of Emergency Use - Criteria Met (HRP-572)
- 6.4 TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met (HRP-573)
- 6.5 TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met (HRP-570)
- 6.6 WORKSHEET: Emergency Use (HRP-322)

### 7 REFERENCES

- 7.1 21 CFR §50.23; 21 CFR §56.104(c).



## SOP: Designated Reviewers

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-030	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

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

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

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

### 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

### 5 PROCEDURE

- 5.1 Obtain from the IRB chair the name of the IRB member designated to conduct Non-Committee Reviews.
- 5.2 Verify that the IRB member is an Experienced IRB Member.

### 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).



## SOP: Non-Committee Review Preparation

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-031	3/25/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

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

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 IRB rosters are maintained using "DATABASE: IRB Roster (HRP-601)."
- 3.2 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in the "WORKSHEET: Review Materials (HRP-301)" according to their role: "Documents Provided to All IRB Members and Alternate IRB Members," "Additional Items Provided to Primary Reviewer," and "Additional Items Provided to Scientific/Scholarly Reviewer."

### 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

### 5 PROCEDURE

- 5.1 Add to the review materials:
  - 5.1.1 CHECKLIST: Non-Committee Review (HRP-402).
  - 5.1.2 Any relevant minutes or correspondence.
- 5.2 Use text from "TEMPLATE LETTER: Designated Reviewer Materials (HRP-540)" to notify the Designated Reviewer in IRBNet within three business days of receipt of a complete submission.

### 6 MATERIALS

- 6.1 CHECKLIST: Non-Committee Review (HRP-402)
- 6.2 DATABASE: IRB Roster (HRP-601)
- 6.3 TEMPLATE LETTER: Designated Reviewer Materials (HRP-540)
- 6.4 WORKSHEET: Review Materials (HRP-301)

### 7 REFERENCES

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



## SOP: Non-Committee Review Conduct

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-032	8/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

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

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 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 "CHECKLIST: Non-Committee Review (HRP-402)."
- 5.5 Submit all materials and attach completed checklists in IRBNet within 5 business days of receipt of materials.

### 6 MATERIALS

- 6.1 CHECKLIST: Non-Committee Review (HRP-402)
- 6.2 SOP: Consultation (HRP-051)

### 7 REFERENCES

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



## SOP: IRB Meeting Preparation

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-040	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 2

### 1 PURPOSE

- 1.1 This procedure establishes the process to prepare for a convened IRB meeting.
- 1.2 The process begins when the agenda is closed, approximately 10 days before a meeting date.
- 1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

### 3 POLICY

- 3.1 At least one IRB member or consultant is responsible for scientific/scholarly review of research.
- 3.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.
- 3.3 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.
- 3.4 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.
- 3.5 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.
- 3.6 Review materials are provided to all IRB members at least 5 business 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 materials (IRB members, scientific/scholarly reviewers, consultants)
  - 5.6.1 Prepare review materials using "WORKSHEET: Review Materials (HRP-301)" according to the individual's role.
  - 5.6.2 Ensure review materials are available in the submission using "WORKSHEET: Review Materials (HRP-301)."
  - 5.6.3 Assign review materials in IRBNet within 5 business days of the scheduled meeting.



## SOP: IRB Meeting Preparation

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-040	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	2 of 2

### 6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 SOP: Consultation (HRP-051)
- 6.3 SOP: Definitions (HRP-001)
- 6.4 WORKSHEET: Review Materials (HRP-301).
- 6.5 WORKSHEET: Quorum and Expertise (HRP-305).

### 7 REFERENCES

- 7.1 45 CFR §46.108(b)
- 7.2 21 CFR §56.108(b)



## SOP: IRB Meeting Conduct

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-041	3/25/14	F.Conte	Dr. R. Shevalier	1 of 3

### 1 PURPOSE

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

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

### 3 POLICY

- 3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.
- 3.2 The IRB chair votes as a regular member.
- 3.3 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.
- 3.4 Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.
- 3.5 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.
- 3.6 The worksheets and checklists described in “WORKSHEET: Review Materials (HRP-301)” and listed below in “Section 6: MATERIALS” are provided to IRB members in advance of meetings per “SOP: IRB Meeting Preparation (HRP-040)” to conduct meetings and meet regulatory requirements.

### 4 RESPONSIBILITIES

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

### 5 PROCEDURE

- 5.1 Call the meeting to order.
- 5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.
- 5.3 For each business item involving review of a protocol:
  - 5.3.1 Table the item when notified by IRB staff when requirements for review of a specific item as defined in “WORKSHEET: Quorum and Expertise (HRP-305)” are not met.<sup>1</sup>
  - 5.3.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference, be placed on hold or disconnect for discussion and voting.
  - 5.3.3 If there is a consultant present, ask the consultant to present his or her review to the IRB.
  - 5.3.4 If a consultant provided written information to the IRB, present that information to the IRB.
  - 5.3.5 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.
  - 5.3.6 Ask the primary reviewer to lead the IRB through a discussion of the criteria in the “WORKSHEET: Criteria for Approval (HRP-314)” and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or 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.

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<sup>1</sup> “Tabled” is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.

SOP: IRB Meeting Conduct				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-041	3/25/14	F.Conte	Dr. R. Shevalier	2 of 3

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-041	3/25/14	F.Conte	Dr. R. Shevalier	2 of 3

- 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.
- 5.3.8 Restate the IRB’s consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.
- 5.3.9 Make a motion for one of the following actions:
- 5.3.9.1 Approve (with a specific continuing review interval for initial or continuing review): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.
- 5.3.9.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review): Made when IRB members require specific modifications such that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the assigned primary reviewer restates the modifications required by the IRB members and the IRB member’s reasons for those changes
- 5.3.9.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member’s reasons for the decision and describes recommendation to make the research approvable.
- 5.3.9.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member’s reasons for the decision.
- 5.3.9.5 Suspension or Termination: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use the “WORKSHEET: Review of Information Items (HRP-321)” to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member’s reasons for the decision.
- 5.3.10 Open the floor for additional discussion.
- 5.3.11 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.
- 5.3.11.1 Ensure that the required modifications include all final contingencies 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.





## SOP: IRB Meeting Conduct

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-041	3/25/14	F.Conte	Dr. R. Shevalier	3 of 3

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 CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)
- 6.10 SOP: IRB Meeting Preparation (HRP-040)
- 6.11 WORKSHEET: Review Materials (HRP-301)
- 6.12 WORKSHEET: Quorum and Expertise (HRP-305)
- 6.13 WORKSHEET: Pre-Review (HRP-308)
- 6.14 WORKSHEET: Criteria for Approval (HRP-314)
- 6.15 WORKSHEET: Advertisements (HRP-315)
- 6.16 WORKSHEET: Payments (HRP-316)
- 6.17 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 6.18 WORKSHEET: Additional Federal Agency Criteria (HRP-318)
- 6.19 WORKSHEET: Criteria for Approval for HUD (HRP-323)
- 6.20 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.



## SOP: IRB Meeting Attendance Monitoring

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-042	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

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

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

### 3 POLICY

- 3.1 None.

### 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

### 5 PROCEDURE

- 5.1 At meetings consult the "WORKSHEET: Quorum and Expertise (HRP-305)" to determine that the meeting is appropriately convened by meeting the "QUORUM REQUIREMENTS" and notify the IRB chair when the meeting is appropriately convened.
- 5.2 Before each protocol consult the "WORKSHEET: Quorum and Expertise (HRP-305)" to determine that the meeting is appropriately convened by meeting the "EXPERTISE REQUIREMENTS" and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.
- 5.3 When a member leaves the meeting room for any reason (including a Conflicting Interest) consult the "WORKSHEET: Quorum and Expertise (HRP-305)" to determine that the meeting continues to be appropriately convened by meeting the "QUORUM REQUIREMENTS" and notify the IRB chair when the meeting is not appropriately convened.

### 6 MATERIALS

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

### 7 REFERENCES

- 7.1 45 CFR §46.108(b)
- 7.2 21 CFR §56.108(c)



SOP: IRB Meeting Minutes				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-043	3/25/14	F.Conte	Dr. R. Shevalier	1 of 4

**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 21 days of the meeting date.
- 3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.

**4 RESPONSIBILITIES**

- 4.1 IRB staff members carry out these procedures.

**5 PROCEDURE**

- 5.1 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)



**SOP: IRB Meeting Minutes**

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-043	3/25/14	F.Conte	Dr. R. Shevalier	2 of 4

- 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, neonates, 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.



SOP: IRB Meeting Minutes				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-043	3/25/14	F.Conte	Dr. R. Shevalier	3 of 4

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-043	3/25/14	F.Conte	Dr. R. Shevalier	3 of 4

- 5.9 Record the meeting end time.
- 5.10 Within 2 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 days to review the minutes.
- 5.13 Attach the following documents to the approved minutes:
  - 5.13.1 List of protocols granted approval using the expedited procedure.
  - 5.13.2 List research approved with modifications to secure approval and granted approval by the chair or designee after confirmation that the modifications were made.

**6 MATERIALS**

- 6.1 TEMPLATE MINUTES (HRP-501)

**7 REFERENCES**

- 7.1 21 CFR §56.115(a)(2)
- 7.2 45 CFR §46.115(a)(2)



SOP: Conflicting Interests of IRB Members				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-050	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-050	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

## 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).



## SOP: Consultation

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-051	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

- 1.1 This procedure establishes the process for the IRB to obtain consultants.
- 1.2 The process begins when the IRB staff or IRB member has identified the need for consultation.
- 1.3 The process ends when the consultant has provided additional expertise to the IRB.

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- 3.2 Consultants with a Conflicting Interest may not provide information to the IRB.

### 4 RESPONSIBILITIES

- 4.1 For review by a convened IRB, IRB staff members carry out these procedures.
- 4.2 For Non-Committee Review, the Designated Reviewer carries out these procedures.

### 5 PROCEDURE

- 5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
  - 5.1.1 IRB members from other committees
  - 5.1.2 Other employees of the organization
  - 5.1.3 External consultants
- 5.2 Contact the consultant and determine availability for review.
- 5.3 Determine whether the consultant has a Conflicting Interest as defined in "SOP: Definitions (HRP-001)." If so, obtain another consultant.
- 5.4 Use "WORKSHEET: Review Materials (HRP-301)" to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.
- 5.5 For review by the convened IRB:
  - 5.5.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.
  - 5.5.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.
- 5.6 For Non-Committee Review:
  - 5.6.1 Directly obtain the information (oral or written) from the consultant.
  - 5.6.2 Document information received with the name of the consultant.

### 6 MATERIALS

- 6.1 SOP: Definitions (HRP-001)
- 6.2 WORKSHEET: Review Materials (HRP-301)

### 7 REFERENCES

- 7.1 21 CFR §56.107(f)
- 7.2 45 CFR §46.107(f)



## SOP: Post-Review

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-052	3/25/14	F.Conte	Dr. R. Shevalier	1 of 2

### 1 PURPOSE

- 1.1 This procedure establishes the process for communications after a protocol is reviewed.
- 1.2 The process begins when:
  - 1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR
  - 1.2.2 An IRB meeting 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 10 business days of the IRB meeting or receipt of the completed Non-Committee Review materials.
- 3.5 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others 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 If the title, principal investigator, or research staff for a protocol changed, update the list of protocols
- 5.3 Refer to "WORKSHEET: Approval Intervals (HRP-302)" to calculated approval intervals.
- 5.4 For approvals for initial or continuing review, set a deadline for receipt of the continuing review application 30 days before study expiration.
- 5.5 Stamp all approved long form consent documents with the approval date on the first and last page, and convert stamped consent documents into pdf format.
- 5.6 Refer to "WORKSHEET: Communication of Review Results (HRP-303)" and send all applicable letters within 30 business days.
  - 5.6.1 Have letter signed by the signatory in the template letter, when applicable.
  - 5.6.2 Upload letter to IRBNet and make available to the principal investigator and/or send the letter to the inside addresses and cc list as directed by the letter.
  - 5.6.3 Upload stamped consent documents to IRBNet and make available to the principal investigator.

### 6 MATERIALS

- 6.1 SOP: Non-Committee Review Preparation (HRP-031)
- 6.2 WORKSHEET: Communication of Review Results (HRP-303)
- 6.3 WORKSHEET: Approval Intervals (HRP-302)

### 7 REFERENCES





<b>SOP: Post-Review</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-052	3/25/14	F.Conte	Dr. R. Shevalier	2 of 2

- 7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.207, 45 CFR §46.306(2)(C), 45 CFR §46.306(2)(D), 45 CFR §46.407, 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research (November 1, 1996)
- 7.2 21 CFR §56.108(a)(1), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66



**SOP: Financial Conflicts of Interests**

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-055	08/20/14	M. Clemens	Dr. R. Shevalier	1 of 1

**1 PURPOSE**

- 1.1 This procedure establishes how the IRB handles investigator or research staff conflicts of interest.
- 1.2 The process begins when the IRB staff identifies that an investigator or research staff has a potential financial interest Related to the Research.
- 1.3 The process ends when the IRB has determined how the conflict will be managed in the research protocol.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**3 POLICY**

- 3.1 Conflicts of interest may apply to all sponsored and non-sponsored Human Research.
- 3.2 Individuals subject to this policy are required to disclose their institutional responsibility to conduct research and the financial interests Related to the Research:
  - 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 financial interest

**4 RESPONSIBILITIES**

- 4.1 IRB staff members carry out these procedures.

**5 PROCEDURE**

- 5.1 Review submission materials for financial interest disclosures for all research personnel involved in the design, conduct, or reporting of the protocol.
- 5.2 Potential financial conflicts of interest in Human Research should be referred to the Associate Vice President for Administration, Finance and Facilities/Controller.
- 5.3 If the principal investigator provides documented assurance that no research personnel have declared a related financial interest for the protocol continue to process the submission.
- 5.4 If the submission materials indicate that any research personnel have a related financial interest, an evaluation from the institution must be included 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.
  - 5.4.1 If additional requirements to the protocol are warranted to manage the conflicts these will be determined by the IRB.

**6 MATERIALS**

- 6.1 None

**7 REFERENCES**

- 7.1 42 CFR §50
- 7.2 45 CFR §94



## SOP: Annual HSPP Evaluations

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-060	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 2

### 1 PURPOSE

- 1.1 This procedure establishes the process to conduct annual evaluations of the Human Subjects 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 Subjects 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 student population and campus community.

### 4 RESPONSIBILITIES

- 4.1 IRB staff ensure 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 HSPP 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 Have the Organizational Official or designee evaluate the knowledge, skills, and performance of each IRB chair.
  - 5.4.1 Provide a copy of the evaluation to the Organizational Official or designee.
  - 5.4.2 Provide each IRB chair with a copy of his or her evaluation.
  - 5.4.3 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.
- 5.5 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.
  - 5.5.1 Provide a copy of the evaluation to the Organizational Official or designee.
  - 5.5.2 Provide each IRB staff with a copy of his or her evaluation.
  - 5.5.3 If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance.

<b>SOP: Annual HSPP Evaluations</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-060	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	2 of 2

- 5.6 Use the “WORKSHEET: IRB Composition (HRP-304)” to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
  - 5.6.1 Provide a copy of the evaluation to the Organizational Official or designee.
  - 5.6.2 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.
- 5.7 Evaluate the subject outreach plan.
  - 5.7.1 Provide a copy of the evaluation to the Organizational Official or designee.
  - 5.7.2 If the subject outreach program is not meeting organizational goals, work with the Organizational Official or designee to modify the plan.
- 5.8 Check when the last time each IRB was registered. If more than 2 years, update the registration.<sup>1</sup>
- 5.9 Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 2 years, update/renew the federalwide assurance (FWA).<sup>2</sup>

## 6 MATERIALS

- 6.1 BROCHURE: Should I Take Part in Research (HRP-104)
- 6.2 TEMPLATE LETTER: IRB Member Appreciation (HRP-562)
- 6.3 WORKSHEET: IRB Composition (HRP-304)

## 7 REFERENCES

- 7.1 None

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

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



## SOP: Monthly HSPP Evaluations

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-061	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

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

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

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

### 4 RESPONSIBILITIES

- 4.1 IRB staff ensure completion of these procedures.

### 5 PROCEDURE

- 5.1 Review the results of "CHECKLIST: Investigator Quality Improvement Assessment (HRP-430)" sent out the previous month, track the results, and examine for significant trends.
- 5.2 Complete "CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)" on the minutes of the previous month. Track compliance and the days required to complete minutes and examine for significant trends.
- 5.3 Send the results to the IRB 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 10 investigators.

### 6 MATERIALS

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

### 7 REFERENCES

- 7.1 None

SOP: Daily Tasks				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-062	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 1

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-062	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 1

## 1 PURPOSE

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

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 POLICY

- 3.1 The institution relies on CITI to automatically check for individuals whose training will lapse and sends a notification.
- 3.2 The institution relies on IRBNet to automatically check for protocols where the continuing review progress report is due in 60 days or 30 days and notify the principal investigator using "TEMPLATE LETTER: Continuing Review Reminder (HRP-530)"
- 3.3 The institution relies on IRBNet to automatically check for protocols that have expired due to lack of continuing review and notify the principal investigator using "TEMPLATE LETTER: Expiration of IRB Approval (HRP-533)"

## 4 RESPONSIBILITIES

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

## 5 PROCEDURE

- 5.1 Check for protocols that have expired due to lack of continuing review:
  - 5.1.1 Consider placing the principal investigator on the Restricted list.
  - 5.1.2 Process the failure to submit as a Finding of Non-Compliance under "SOP: New Information (HRP-024)."
  - 5.1.3 Follow "SOP: Expiration of IRB Approval (HRP-063)"

## 6 MATERIALS

- 6.1 SOP: New Information (HRP-024)
- 6.2 SOP: Expiration of IRB Approval (HRP-063)
- 6.3 TEMPLATE LETTER: Continuing Review Reminder (HRP-530)
- 6.4 TEMPLATE LETTER: Expiration of IRB Approval (HRP-533)

## 7 REFERENCES

- 7.1 None



**SOP: Expiration of IRB Approval**

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-063	3/25/14	F.Conte	Dr. R. Shevalier	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



SOP: IRB Records				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-070	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 2

**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, fetuses, and neonates.
    - 3.2.19.3 Research involving Prisoners.
    - 3.2.19.4 Research involving children.
    - 3.2.19.5 Research involving adults unable to consent.
    - 3.2.19.6 Significant/non-significant device determinations.
  - 3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review.
- 3.3 Protocol files are maintained in chronological order with the latest information in front.
- 3.4 Policies and procedures include:





<b>SOP: IRB Records</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-070	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	2 of 2

- 3.4.1 Checklists.
- 3.4.2 Forms.
- 3.4.3 SOPs.
- 3.4.4 Template letters.
- 3.4.5 Template minutes.
- 3.4.6 Worksheets.
- 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 IRBNet.
  - 5.2 Store all protocol-specific information (communications, documents, determinations) in IRB Net.
  - 5.3 File correspondence NOT related to a specific protocol in a file related to that person or topic in the access-controlled HSPP folder in the network drive.
  - 5.4 IRB member rosters: File in the access-controlled HSPP folder in the network drive.
  - 5.5 IRB membership records (e.g., curricula vita and resumes): File in IRB member files in the access-controlled HSPP folder in the network drive.
  - 5.6 Policies and procedures:
    - 5.6.1 File current policies and procedures in the access-controlled HSPP folder in the network drive and make available on the IRB website.
    - 5.6.2 File replaced policies and procedures in the policies and procedures history file in the access-controlled HSPP folder in the network drive.
- 6 MATERIALS**
  - 6.1 None
- 7 REFERENCES**
  - 7.1 None



<b>SOP: Standard Operating Procedures</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-071	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	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 Send an email to affected individuals informing them of the change.

**6 MATERIALS**

- 6.1 TEMPLATE SOP (HRP-505)

**7 REFERENCES**

- 7.1 None



**SOP: IRB Records Retention**

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-072	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

**1 PURPOSE**

- 1.1 This procedure establishes the process to retain IRB records.
- 1.2 The process begins each year in June.
- 1.3 The process ends when records that no longer need to be retained are destroyed.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**3 POLICY**

- 3.1 Protocol files are to be retained as long as required by law 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



SOP: IRB Formation				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-080	3/25/14	F.Conte	Dr. R. Shevalier	1 of 2

**1 PURPOSE**

- 1.1 This procedure establishes the process to form or rely on a new IRB.
- 1.2 The process begins when the 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 (if needed), and all members have completed training.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None

**3 POLICY**

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

**4 RESPONSIBILITIES**

- 4.1 IRB staff members carry out these procedures.
- 4.2 The 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 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" 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.
  - 5.3.5 Once training is completed, add committee members to the system with the Committee Member role

**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)



<b>SOP: IRB Formation</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-080	3/25/14	F.Conte	Dr. R. Shevalier	2 of 2

## **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).



SOP: IRB Removal				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-081	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

**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<sup>1</sup>.
  - 5.1.3 Remove the IRB from the federalwide assurance (FWA)<sup>2</sup>.
  - 5.1.4 Remove members from "DATABASE: IRB Roster (HRP-601)."
  - 5.1.5 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).

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

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

**SOP: IRB Membership Addition**

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-082	3/25/14	F.Conte	Dr. R. Shevalier	1 of 2

**1 PURPOSE**

- 1.1 This procedure establishes the process to add a new IRB member.
- 1.2 The process begins when the 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 Add the individual to the “DATABASE: IRB Roster (HRP-601).”
- 5.5 Complete “WORKSHEET: IRB Composition (HRP-304)” and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.6 Prepare a “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” for the individual.
- 5.7 Provide to the 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.<sup>1</sup>
- 5.10 File:
  - 5.10.1 DATABASE: IRB Roster (HRP-601)
  - 5.10.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.11 Notify the IRB 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)

**7 REFERENCES**

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

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



<b>SOP: IRB Membership Addition</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-082	3/25/14	F.Conte	Dr. R. Shevalier	2 of 2

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





## SOP: IRB Membership Removal

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-083	3/25/14	F.Conte	Dr. R. Shevalier	1 of 1

### 1 PURPOSE

- 1.1 This procedure establishes the process to remove an IRB member.
- 1.2 The process begins when an IRB member resigns or is removed from one or more IRBs. This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.
- 1.3 The process ends when the IRB registration is updated.

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 The 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 Remove the individual from "DATABASE: IRB Roster (HRP-601)."
- 5.2 Complete "WORKSHEET: IRB Composition (HRP-304)" to ensure that the IRB is appropriately constituted.
  - 5.2.1 If not, identify one or more replacement members and follow "SOP: IRB Member Addition (HRP-082)."
- 5.3 Prepare a "TEMPLATE LETTER: IRB Member Thank You (HRP-561)," have it signed by the Organizational Official or designee, and send to the individual.
- 5.4 Update the registration of all affected IRBs.<sup>1</sup>
- 5.5 File:
  - 5.5.1 DATABASE: IRB Roster (HRP-601)
  - 5.5.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)

### 6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 SOP: IRB Member Addition (HRP-082)
- 6.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 6.4 WORKSHEET: IRB Composition (HRP-304)

### 7 REFERENCES

- 7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5)
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)

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



## SOP: IRB Meeting Scheduling and Notification

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-084	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	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 four IRB meetings on the current schedule.
- 1.3 The process ends when meetings are scheduled for the upcoming academic year, approximately 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 30 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 IRB manager carries out these procedures.

### 5 PROCEDURE

- 5.1 Create a schedule of meetings for each IRB.
- 5.2 Post the schedule on the IRB website.
- 5.3 Notify the following individuals of the updated schedule with an email providing a link to the IRB Web page with the schedule information:
  - 5.3.1 IRB members.
  - 5.3.2 Investigators and research staff
  - 5.3.3 Organizational Official or designee.

### 6 MATERIALS

- 6.1 None

### 7 REFERENCES

- 7.1 ICH-GCP E6 3.3.2

<b>SOP: Informed Consent Process for Research</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 4

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	1 of 4

## 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 subject unable to speak English and a consent process in the 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.

SOP: Informed Consent Process for Research				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	2 of 4

#### 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

<b>SOP: Informed Consent Process for Research</b>				
<b>NUMBER</b>	<b>DATE</b>	<b>AUTHOR</b>	<b>APPROVED BY</b>	<b>PAGE</b>
HRP-090	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	3 of 4

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.
- 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:

<b>SOP: Informed Consent Process for Research</b>				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	4 of 4

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	08/19/14	F.Conte / M.Clemens	Dr. R. Shevalier	4 of 4

- 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



## SOP: Written Documentation of Consent

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-091	3/25/14	F.Conte	Dr. R. Shevalier	1 of 2

### 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 a 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 If an impartial witness was part of the consent process:
    - 5.1.5.1 Print the name of the impartial witness on the consent document.
    - 5.1.5.2 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.
  - 5.1.6 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 a language understandable to the subject/representative.



SOP: Written Documentation of Consent				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-091	3/25/14	F.Conte	Dr. R. Shevalier	2 of 2

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-091	3/25/14	F.Conte	Dr. R. Shevalier	2 of 2

- 5.2.2 Print the name of the following individuals on the short form consent document and the summary:
  - 5.2.2.1 Subject/Representative
  - 5.2.2.2 Person obtaining consent
  - 5.2.2.3 Impartial witness
- 5.2.3 Have the following individuals personally sign and date the short form consent document and the summary:
  - 5.2.3.1 Subject/Representative
  - 5.2.3.2 Person obtaining consent
  - 5.2.3.3 Impartial witness
- 5.2.4 If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:
  - 5.2.4.1 Assent of the child was obtained.
  - 5.2.4.2 Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
- 5.2.5 Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.
- 5.3 If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.
  - 5.3.1 If the subject/representative declines, take no further action.
  - 5.3.2 If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation
- 5.4 Place the signed and dated documents in the subject or study folder and maintain signed consent documents according to the IRB approved protocol.

## 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