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I. PURPOSE

The purpose of this standard operating procedure is to describe IRB review processes, including pre-review, review, and post-review procedures.

II. POLICY STATEMENT

The CHOP IRB reviews research involving human subjects via full board review procedures, expedited review procedures, or exempt determinations. Any non-exempt human subjects research must be reviewed and approved by the IRB prior to any intervention or interaction with human subjects, including recruitment procedures.

III. SCOPE

These policies and procedures apply to all IRB staff, members and alternates.

IV. DEFINITIONS


Consultants: When the IRB determines that additional expertise is required for an IRB review, an individual with the appropriate expertise is asked to assist with a review of a proposal. Consultants are selected based on education, training, and experience with the research topic, the subject population to be recruited, the research test article, and/or the research intervention. Consultants may not provide expertise or advise when they have a conflict of interest.

Exempt Determinations: Research activities that involve no greater than minimal risk and meet applicable criteria set forth by the federal regulations (45 CFR 46.104(d)). For research not subject to FDA regulations or federally funded, CHOP's expanded exempt categories will apply.

Full Board Review: Review of proposed research at a convened Full IRB meeting at which a majority of the membership of the IRB is in attendance, including at least one member whose primary concerns are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those members attending the meeting.

Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen a device is used. Under the FDA regulations and guidance, a human subject may include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical

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device research.

Human Subjects Research: Research involving human subjects.

Primary and Secondary Reviewers: An IRB member or alternate selected for each full board protocol review (including Initial, Amendment, Reportable Event, and Continuing Review) who is responsible for providing an in depth review of all submitted materials (described in **SOP 301**) prior to the meeting, documenting the review on the appropriate evaluation form, presenting the review to the full board, highlighting potential issues for IRB consideration, and making a recommendation for action by the IRB.

Review Using Expedited Procedures: Review of proposed research by the Chair, CPHS or their designee. The designee must be an experienced IRB member/alternate.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l)). Under FDA regulations, research (clinical investigation) means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects.

V. PROCEDURES

A. Determination of Need for Consultation


The Chair determines whether the review of the research requires expertise beyond that available on the IRB. For research that requires additional expertise, the Chair invites an individual with additional expertise to serve as a consultant and assist the IRB in its review as described in **SOP 201**.

1. Consultants are encouraged to attend IRB meetings; however, when attendance is not feasible, the consultant may participate via telephone conference or confer with the assigned Primary Reviewer(s) or Chair prior to the IRB meeting.
2. If the consultant presents at the meeting, the minutes will document key information provided by the consultant. If the consultant provides a written report, the report will be included in the IRB records.
3. Consultants who attend IRB meetings will not count toward a quorum.
4. Individuals with a Conflict of Interest may not serve as consultants to the IRB.


B. Review Processes

The IRB ensures that all research submissions receive substantive review.

1. The IRB Office will ensure that all submissions are complete and generally available to all IRB members and alternates (members) and consultants no later


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- than five (5) days prior to the scheduled convened meeting. The Chair or the Director, HSR may permit agenda items on shorter notice.
2. When the research will involve prisoners, it will be scheduled for a meeting in accordance with **SOP 503**.
 3. Members are responsible for disclosing any conflicting interests they may have with any research under review in accordance with **SOP 903**.
 - (a) Once disclosed, members with a Conflict of Interest may remain in the IRB meeting to answer questions related to the research at the invitation of the Chair but will recuse themselves for the deliberation and vote.
 - (1) IRB meeting minutes will document the name of each recused IRB member, and will document that a Conflict of Interest is the reason for the absence.
 4. Studies that must be reviewed by the convened IRB will be placed on the next available committee agenda for review.
 - (a) The IRB Analyst, in consultation with the IRB Chair, selects primary reviewers for each submission based on the relevant expertise and availability of the members. New studies are usually assigned a primary and secondary reviewer. At least one reviewer has the appropriate scientific and scholarly expertise to review the research.
 - (b) Members are expected to review the materials (described in **SOP 301**) in sufficient depth to be familiar with and prepared to discuss the information at the convened meeting. All IRB members have access to the complete submission; those who are not reviewers must review, at a minimum the application, protocol summary and consent document(s).
 5. Primary and secondary reviewer(s) responsibilities include:
 - (a) Presenting their findings regarding the proposed research activities, including the scientific merit of the research, at the convened IRB meeting.
 - (b) Reviewing and ensuring that the content and format of the informed consent document(s) (and assent document, when applicable) meet all regulatory requirements and are consistent with the information in the study protocol.
 - (c) Completing and submitting all reviews in writing using the electronic IRB system.
 - (1) The primary reviewer is generally responsible for completing the

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written review of the protocol.


- (2) The secondary reviewer is generally responsible for completing the written review of the consent documents.
 - (3) When only a primary reviewer is assigned, they will be responsible for written reviews of all of the submitted documents.
6. Research is reviewed by the convened IRB to ensure that the Investigator has satisfied all of the requirements stated in **SOPs 402 and 404**.
 7. After review and discussion of research, the IRB takes one of the actions described in **SOP 406** based on the regulatory criteria for IRB approval as described in **SOP 402**.
 8. For each submission, the IRB determines the frequency of continuing review, based on the risks of the research and experience of the Investigator.
 - (a) FDA-regulated research cannot be approved for more than 1 year.
 - (b) Minimal risk research that is not FDA-regulated and is eligible for expedited review (with the exception of categories 8(b) or 9) does not require continuing review unless determined and documented by the IRB.
 - (c) For other submissions, including amendments, the IRB will determine if the submission affects the risks of the research and if changes to the frequency of continuing review are necessary.
 9. When applicable, the IRB also makes the following determinations at the time of initial review of the research and may change these determinations during subsequent reviews:
 - (a) Pediatric Research Risk:Benefit Determination (described in **SOP 504**).
 - (b) Assent Requirements (described in **SOP 702**).
 - (c) Parental Permission (described in **SOP 702**).
 - (d) Device Risk Determinations (described in **SOP 409**).
 - (e) Waiver or alteration of the consent process and authorization (described in **SOPs 706 and 707**).
 - (f) Requirement for informed consent for screening, recruiting, or determining eligibility of subjects (described in **SOP 706**).
 - (g) Determinations related to research involving pregnant women, human fetuses, and neonates (described in **SOP 502**).

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- (h) Determinations related to research involving prisoners (described in **SOP 503**)
- (i) The IRB retains the authority to observe or have a third party observe the consent process and the research.
- (j) Determinations related to the need for verification from sources other than the investigators that no material changes have occurred since previous IRB review.

C. Post IRB Review

1. Following IRB review by the convened IRB, the IRB Analyst drafts the meeting minutes as described in **SOP 303**.
2. Once the meeting minutes have been reviewed and approved by the IRB Chair, the IRB Analyst provides documentation for the Investigator regarding the IRB's determinations.
 - (a) For IRB approvals the documentation includes the following information:
 - (1) IRB Approval and Expiration Dates, if applicable;
 - (2) Type of submission reviewed (for example Initial, Amendments or Continuing Review);
 - (3) The date or version number of the protocol; and
 - (4) Any conditions of approval and additional determinations.
 - (b) For IRB approvals made by the convened IRB with revisions required, the documentation includes a listing of the required changes and additional information that must be submitted for IRB review. Refer to categories of action **SOP 406**.
 - (1) The documentation will include the date of the IRB review (via convened IRB or expedited review) and the stipulations that must be addressed by the investigator.
 - (2) Responses to approval with revisions required may be designated for either review by the Chair or designee or administrative confirmation.
 - (3) Administrative confirmation may be performed by appropriately trained IRB staff members. If the required confirmations or changes were not made exactly as specified by the IRB, the responses will be sent for expedited review.

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- (4) When the responses do not comply with the IRB's required changes or do not confirm the IRB's understanding, the responses will be forwarded to the convened IRB for review unless they qualify for expedited review.
- (5) If unsolicited changes were made by the investigator they will be assigned depending on whether they require review by the convened board or can be reviewed using expedited procedures.
- (c) When the research is disapproved, the documentation will include the date of review, reasons for disapproval, and a description of how the Investigators may respond (either in person or in writing).
- (d) When the research is deferred, the documentation will include the date of review, reasons for deferral, and a description of how the investigator may respond. The responses require review by the convened IRB unless the research was determined to be minimal risk.


VI. APPLICABLE REGULATIONS AND GUIDELINES

45CFR46.109, 46.111

21 CFR 56.109, 56.111

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 201: Composition and Management of the IRB	SOP 502: Research Involving Pregnant Women, Fetuses and Neonates
SOP 301: Research Submission Requirements	SOP 503: Research Involving Prisoners
SOP 303: IRB Meeting Administration	SOP 504: Research Involving Children
SOP 402: Initial Review - Criteria For IRB Approval	SOP 702: Assent and Parental Permission
SOP 404: Continuing Review of Approved Research	SOP 706: Waiver of Elements of Consent and Waiver HIPAA Authorization
SOP 406: Categories of Action	SOP 707: Requirements for and Documentation of HIPAA Authorization
SOP 409: Determination of IND/IDE Requirement	SOP 903: Reporting Test Results and Incidental Findings

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VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures.
Chair, CPHS	Responsible for establishing and periodically reviewing and modifying (as appropriate) IRB standard operating policies and procedures and for delegating reviews, as required to a designee.
Designee	Responsible for conducting reviews or determinations as assigned by the Chair.

IX. ATTACHMENTS

XI: REVISIONS:

8-29-2006	Revision to section B(3)(b)(4)
2-14-2007	Revised to incorporate new IRB office staff responsibilities.
4-16-2008	Revised to incorporate AAHRPP recommendations, editorial and technical changes to document formatting, clarification that only a single, Primary Reviewer may be assigned for Continuing Review of Approved Research, listing of IRB reviewer forms available on the IRB's website.
6 -9-2010	Revision to reflect the change in review procedures due to transition to electronic IRB management system and updates to links to IRB Reviewer forms.
7-8-2010	Revisions to reflect AAHRPP's recommendations.
9-4-2012	Revisions to reflect the consequences and new options from "unchecking the box" on the FWA.
9-25-2018	Revised to include new CHOP logo, editorial changes and to reflect the updated definitions of "Human Subjects Research".
1-22-2019	Revised to address the 2018 Common Rule.

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X. APPROVAL:

 Director, Human Subjects Research

 Date

 Chair, Committees for the Protection of Human Subjects

 Date