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I. PURPOSE

The purpose of this SOP is to outline the courses of action the IRB may take when reviewing and approving research involving human subjects.

II. POLICY STATEMENT

As a result of its review, the IRB may take any of the following courses of action including (1) to approve the proposed research activity, (2) to approve the activity with revisions required (specified changes to the proposed research), (3) to defer the action, (4) to disapprove the proposed research activity, or (5) to acknowledge receipt of non-material changes to previously approved research.

III. SCOPE

These policies and procedures apply to all non-exempt human subjects research submitted to the IRB for review.

IV. DEFINITIONS

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.


Material Change: A modification to the research-related documentation that alters the conduct of the research at sites overseen by CHOP or the assessment of the risks and benefits of the study. Non-material changes (e.g. staff changes) do not require IRB review or approval.

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

Effective Approval Date: The date of confirmation that all of the IRB's requested clarifications and modifications have been satisfactorily completed and that all ancillary approvals or other conditions for approval (e.g., evidence of FDA approval, etc.) have been met.

Human Subjects Research: Research involving human subjects.

Institutional Official: The individual identified on the Federalwide Assurance with OHRP as authorized leader of the Hospital's human subjects protection program.


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V. PROCEDURES

A. Determinations

Except when expedited review procedures are used, decisions will be based upon a simple majority of the members and alternates participating in the IRB meeting (**SOP 303**). The IRB may make one of the following determinations as a result of its review:

1. Approval: The protocol and accompanying documents are approved by the IRB as submitted.
 - (a) Approval will begin the day the study is approved by an action of the convened IRB or the Chair or designee (reviewer).
 - (b) The duration of the approval period is determined at the time of approval. For federally funded and FDA-regulated research the approval period will not exceed one (1) year. For minimal risk research funded by other mechanisms and not subject to FDA regulation, the approval period will not be greater than three (3) years.
 - (c) No research activities may be conducted until the IRB has issued its notification to the investigator of final approval, which will reflect the effective approval date.
2. Approval with Revisions Required: The protocol and accompanying documents are approved, provided the investigator concurs with the changes required by the IRB prior to release of final IRB approval. Examples include but are not limited to requested modifications to the eIRB application and acceptance of IRB requested revision to consent documents.
 - (a) Approval will begin the day the study is approved by an action of the convened IRB or the reviewer.
 - (b) The duration of the approval period is determined at the time of approval. For federally funded or FDA-regulated research the approval period will not be greater than one (1) year. For all other minimal risk research the approval period will not be greater than three (3) years.
 - (c) No research activities may be conducted until the IRB has issued its notification to the investigator of final approval, which will reflect the effective approval date.
3. Deferral: Substantive changes or clarifications are required for the IRB to determine that the research meets the regulatory criteria for IRB approval. This

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action applies to both research reviewed by a convened IRB and research reviewed using expedited procedures. If the risks of the research have been determined to be greater than minimal, the review of the requested modifications (e.g. application, protocol or consent form) must be performed at a convened meeting of the IRB. For research that is determined to be not greater than minimal risk, review may take place using expedited procedures.

4. Disapproval: The submission fails to meet one or more criteria required by the IRB for approval of research and no changes can be made to the protocol without major changes in the study design to make it approvable. The action to disapprove the research may only be taken by a convened meeting of the IRB.

5. Acknowledge Receipt: Submission of non-material changes to previously approved research that do not influence the conduct of the research at CHOP may be acknowledged by the IRB staff.


B. Notification of IRB Determinations

1. Documentation regarding the IRB's determinations will be provided to the Investigator in accordance with **SOP 105**.
2. Electronic copies of IRB meeting minutes will be available to the Institutional Official (IO) via the electronic IRB system. The IO will be notified of any suspensions, terminations, serious or continuing non-compliance, or unanticipated problem involving risks to subjects or others in accordance with SOP 907.
3. The Committees for the Protection of Human Subjects are a committee of the Medical Staff of The Children's Hospital of Philadelphia. Medical Staff committees will be responsible to the Executive Committee of the Medical Staff (ECMS). To inform the ECMS of IRB determinations, the minutes of the IRB committees will be forwarded to the Secretary to the ECMS President as requested.

C. Additional Conditions of Approval

At the discretion of the IRB, additional conditions for approval may be imposed. These may include third party verification of information including auditing of study records or observation of the consent process to provide additional protection for subjects. The criteria used to determine whether third-party verification is required may include:

1. Studies that involve a potential high risk to subjects;
2. Studies that involve vulnerable populations, particularly those studies that are greater than minimal risk;

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3. Studies that involve enrollment of a large number of subjects; and
4. The IRB's previous experience with the investigator or sponsor.
5. Studies selected at the discretion of the IRB.

VI. ROLES AND RESPONSIBILITIES


Title	Responsibility
Director, HSR	Director, Human Subjects Research is responsible for establishing processes and educating Analysts so they are knowledgeable in the processes for documentation of all IRB decisions; for ensuring that documentation of IRB determinations is forwarded to the Investigator and that electronic copies of IRB meeting minutes are forwarded to the Institutional Official and the ECMS.
Chair, CPHS	The Chair (or designee) is responsible for ensuring the appropriateness of all IRB decisions and actions.

VII. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.109	21 CFR 56.109
45 CFR 46.111	21 CFR 56.113
45 CFR 46.113	21 CFR 56.111

VIII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: Review Process	SOP 907: Reporting to Regulatory Agencies and Sponsors
SOP 303: IRB Meeting Administration	

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IX. ATTACHMENTS

Reviewer Forms that include checklists for recommended categories of action are embedded in the eIRB system.

IRB Minutes templates are contained and maintained within eIRB.

X. REVISIONS:

- 4-6-2009 Revised to clarify that protocols that require substantive modifications as well as studies that are deferred require review by the convened IRB. The revision also incorporates changes made to the approval dates for continuing reviews, which are now based on the date of the review instead of anniversary dates.
- 6-9-2010 Revisions were made to incorporate changes due to adoption of the eIRB electronic management system.
- 7-8-2010: Revised to reflect AAHRPP recommendations
- 9-27-2012: Revised to specify the process for acknowledging non-material changes and the expanded approval period for specific research.
- 9-25-2018 Revised for editorial changes and to address distribution of IRB meeting minutes.

XI. APPROVAL:

Director, Human Subjects Research

Date

Chair, Committees for the Protection of Human Subjects

Date