

SOP 106: Research That Must Be Reviewed by the IRB

I. PURPOSE

To provide guidance on the types of research activities that are subject to review and approval or determination of exemption by the Children's Hospital of Philadelphia Committees for the Protection of Human Subjects, which comprise the Institutional Review Boards (IRBs).

II. POLICY STATEMENT

It is the policy of Children's Hospital of Philadelphia IRBs to assert jurisdiction over all human subjects research subject to its Assurance.

III. SCOPE

These policies and procedures apply to all Children's Hospital of Philadelphia (CHOP) investigators and their staff, IRB members, and IRB staff.

IV. DEFINITIONS

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 device research.

Intervention: A manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies.

Not Human Subjects Research: Activities that do not meet the definition of human subjects research.

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Private Information: Includes information about data or behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving no subjects. This may include identifiable private information obtained from a primary subject about a third party.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(1)). 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 Human Subjects Research

1. When an investigator submits a new application, the Chair or designee will review the application and determine if the study meets the criteria for human subjects research.
 - a) If the submission meets the criteria of human subjects research, the application will be reviewed according to the applicable SOPs. The investigator will be notified and may be instructed to resubmit under an alternate review pathway.
 - b) If the submission does not meet the criteria of human subjects research, the investigator will be notified.

Note that a submission to the IRB for a determination of human subjects research is not required. The investigator is permitted to decide whether their activities meet the definition of human subjects research or not (without obtaining a determination from the IRB).

B. Review and Approval of Human Subjects Research

1. All research conducted at CHOP that meets the definition of human subjects research regardless of sponsorship or funding, must be reviewed and approved, or determined to be exempt, by an IRB. The CHOP IRB may designate another IRB to serve as the Reviewing IRB (see **IRB SOP 305**). An IRB must review all human subjects research if one or more of the following apply:
 - a) The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of CHOP in connection with his/her institutional responsibilities, without regard to the location of research;
 - b) The research is conducted by or under the direction of any employee or agent of this institution using any of its property or facilities;
 - c) CHOP receives a direct award and or contract to conduct human subjects research by the federal government, even where all activities involving human subjects are carried out by a subcontractor or collaborator; and/or
 - d) The research is conducted in accordance with an Assurance filed with the Office of Human Research Protections (OHRP) in which the CHOP IRB is designated as the Reviewing IRB through an established IRB reliance agreement. (**SOP 305**)
2. No research involving human subjects, including intervention, interaction, collection of private identifiable information, administration of test articles, advertising, recruitment, or screening, may begin until the CHOP IRB has reviewed and approved the research, issued an exempt determination, or accepted the oversight of an external Reviewing IRB.

C. Failure to Submit Human Subjects Research for IRB Review

1. Failure to obtain IRB approval or an exempt determination for human subjects research from the IRB is considered non-compliance.
2. The IRB will not grant post-hoc approval for research conducted without prior IRB review and approval.
3. The IRB will not grant post-hoc exempt or not human subjects research determinations for research already conducted at the time of the determination request.

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D. Human Subjects Research Review Not Conducted at CHOP

1. Research that involves either classified information or is excluded by **SOP 107** will not be conducted at CHOP. The IRBs at CHOP cannot provide oversight for this research.

VI. ROLES AND RESPONSIBILITIES

Title	Responsibility
Senior Director, Human Subjects Research	Responsible for working with the Chair or designee on determining whether a submission meets the definition of human subjects research.
Chair, CPHS	Responsible for working with the Senior Director, Human Subjects Research or designee on determining whether a submission meets the definition of human subjects research.
IRB	Responsible for reviewing proposed research activities in accordance with applicable IRB policies and procedures.

VII. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46	21 CFR 50 and 21 CFR 56
2008 OHRP Guidance on Engagement of Institutions in Human Subjects Research	

VIII. REFERENCES TO OTHER APPLICABLE SOPS

IRB SOP 105: IRB Review Processes	IRB SOP 107: Department of Defense
IRB SOP 305: Cooperative Agreements	IRB SOP 401: Expedited Review Procedures

IX. ATTACHMENTS

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XI: REVISIONS:

- 06-01-2006 Initial approval date
- 11-29-2006 Revised to incorporate two additional definitions (research and human subject).
- 06-09-2010 Revised to incorporate AAHRPP recommendations.
- 07-08-2010: Revised to reflect AAHRPP's recommendations.
- 05-29-2013: Revised to outline human subjects research reviews not conducted at CHOP and to include the link to the IRB intranet page
- 09-25-2018 Revised with updated CHOP logo, editorial changes, updated web links and revised definitions
- 03-21-2022 Editorial changes
- 11-18-2024 Revised to update job titles and make minor clarifications

X. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 11/18/24
Amy Schwarzhoff, Senior Director, Human Subjects Research and Barbara Engel, Chair, CPHS