I. PURPOSE

Define the criteria and procedures by which the IRB can determine whether or not human subjects research is exempt.

II. POLICY STATEMENT

CHOP does not permit investigators to make their own independent determination as to whether or not their research qualifies as exempt; that role is reserved for the IRB. The determination that human subjects research qualifies as exempt will be made by a member of the IRB based on regulatory and/or institutional criteria. The basis for the determination will be documented.

III. SCOPE

These policies and procedures apply to investigators, study staff and the IRB members and IRB staff.

IV. DEFINITIONS

Exempt: 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 review categories will apply.

Expanded Exempt Review Categories: The procedures and categories of research not listed in 45 CFR 46.104(d) but that have been determined by the CHOP IRB to be exempt from the regulations under 45 CFR 46 due to their low risk level. This exemption provision does not apply to research that is funded by the federal government or to clinical investigations of FDA-regulated products.

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.

Limited IRB Review: IRB review limited to the determinations described in 46.111(a)(7) or 46.111(a)(8), which pertain to protections for privacy and confidentiality and broad consent.

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

1. Pre-review procedures to ensure completeness of the submission will be followed in accordance with **SOP 105.**

2. The Chair or designee (the reviewer) will have access to all materials submitted in the eIRB system as outlined in **SOP 301**.

3. The reviewer evaluates the application to determine if it qualifies for an exemption determination. The reviewer documents their review and determinations.

    (a) A limited IRB review will be conducted as required by the federal regulations (45 CFR 46.111(a)(8) or 45 CFR 46.111 (a)(7)).

    (b) Questions about the application or submitted materials will be sent to the investigator for response.

    (c) If the exemption is granted, the investigator will be notified.

    (d) If the exemption is not granted, the investigator will be notified that the submission does not meet the criteria and will be advised about how to proceed.

4. The electronic IRB management system accommodates both the investigators' request for exempt determination and the IRB review.

5. Expanded Exempt Categories:

Research that is not funded by the federal government, that is not FDA-regulated, and that includes one or more of the following categories of research is eligible for a determination of exemption.

    (a) In addition to research that qualifies as exempt under Category 2, research that involves interviews or questionnaires with adults will qualify as exempt even when the subject of the research is a child.

    (b) Interviews or questionnaires with adolescents (exempt under Category 2(i) or (ii)) where the IRB would otherwise waive the requirement for parental permission.

    (c) Benign behavioral interventions (exempt under Category 3(i)(A) or (i)(B) with adolescents where the IRB would otherwise waive the requirement for parental permission.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.104	21 CFR 56.104, 21 CFR 56.105

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Processes	SOP 301: Research Submission Requirements

VIII. RESPONSIBILITIES

Title	Responsibility
Chair, CPHS	Responsible for evaluating submissions that claim exemption or delegating review to designated committee member(s); authorized to make exemption determinations.
Designee (IRB Member)	Responsible for evaluating submissions that claim exemption; authorized to make exemption determinations.
IRB Staff	Responsible for pre-review of study application for completeness and for communicating queries and determination results to the investigator.

IX. ATTACHMENTS

X. REVISIONS:

07-07-2006 Initial approval date

12-26-2006: Revised to incorporate AAHRPP recommendations and changes in IRB staff responsibilities.

04-20-2007: Revision of document formatting.

04-24-2007: Updated principles, procedures sections.

11-10-2008: Updated to include the reviewer form used to make the determination of exemption and to accommodate the processes associated with the electronic management system.

06-09-2010: Revised to reflect that all submissions are now received via the eIRB electronic IRB management system.

07-07-2010: Revised to reflect AAHRPP recommendations.

02-28-2013: Revised to include expanded exempt categories.

05-22-2018: Revised to reflect updated CHOP logo and editorial changes.

01-22-2019: Common Rule Revisions

06-18-2021: Revised Expanded Exempt Categories to include questionnaires with adolescents (exempt under Category 2(i) or (ii)) where the IRB would otherwise waive the requirement for parental permission

06-09-2022: Revision of document formatting

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 06/09/22

Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS