I. PURPOSE

Define the criteria and procedures by which the IRB makes the determination of whether research is exempt from further IRB review.

II. POLICY STATEMENT

CHOP does not permit investigators to make an independent determination of exemption and reserves that role for the IRB. The determination of exemption will be made by a member of the IRB based on regulatory and/or institutional criteria and will be documented in the study file.

III. SCOPE

These policies and procedures apply to investigators, study staff and the IRB members and 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 46.101(b), 45 CFR 46.201(b), 45 CFR 46.301(a), 45 CFR46.401(b), and 21 CFR 56.104. For research not subject to FDA regulations or federally funded, CHOP's expanded exempt categories will apply.

V. PROCEDURES

1. After an investigator submits an application conforming to the requirements of IRB SOP 301, the IRB staff checks it for completeness, and returns incomplete applications with a request for changes outlining any identified deficiencies.
2. The application will be evaluated to determine whether or not it qualifies for exemption.
   (a) Questions about the application will be sent to the investigator for response.
   (b) If the exemption is granted, the investigator will be notified.
   (c) 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.
3. Expanded Exempt Categories:

Research that is not funded by the federal government, 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 is exempt under Category 2, research that involves interviews or questionnaires of adults is exempt even when the subject of the

research is a child.

(b) Interviews with adolescents where the IRB would otherwise waive the requirement for parental permission.

(c) In addition to research that is exempt under Category 4, research that involves the use of existing data, documents, records, pathological specimens, or diagnostic specimens collected during a previously approved research study may be eligible for a determination of exemption, provided that the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.101	21 CFR 56.104, 21 CFR 56.105

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Submission Requirements	

VIII. RESPONSIBILITIES

Title	Responsibility
Chair, CPHS	Responsible for evaluating submissions that claim exemption from IRB review or delegating review to designated committee member(s); authorized to make exemption determinations.
Designee (IRB Member)	Responsible for evaluating submissions that claim exemption from IRB review; 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 investigative team.

IX. ATTACHMENTS

All paper forms attachments are available on the IRB website in the forms section at https://intranet.research.chop.edu/display/cmtirb/IRB+Forms. The e-IRB system has application pages with equivalent sections for each of these forms.

X. REVISIONS:

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

4/20/2007: Revision of document formatting.

4/24/2007: 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.

6/9/2010: Revised to reflect that all submissions are now received via the eIRB electronic IRB management system.

7/7/2010: Revised to reflect AAHRPP recommendations.

2/28/2013: Revised to include expanded exempt categories.

XI. APPROVAL:

Director, Human Subjects Research _____ Date _____

Chair, Committees for the Protection of Human Subjects _____ Date _____