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	Title: Determining when Activities Meet the Definition of Human Subjects Research	Effective Date: 7/20/2006 Revision Date: 09/25/2018

I. PURPOSE

The purpose of this SOP is to outline the procedures in place for determining if submissions meet the definition of human subjects research. Activities that may not meet the definition of human subjects research include, but are not limited to, case series, quality improvement activities and the use of data/specimens that are not readily identifiable.

II. POLICY STATEMENT

The IRB must review all activities that meet the definition of human subjects research but is not required to review activities that are (1) not research or (2) do not meet the regulatory definition of research involving human subjects. When an investigator is uncertain whether the federal research regulations apply, the investigator may request that the IRB issue a formal determination. Note: An activity not meeting the definition of Human Subjects Research, but meeting the criteria for Engagement of CHOP, as an institution, in human subjects research (as defined by OHRP's Guidance) requires a submission for IRB review.

III. SCOPE

These policies and procedures apply to any activity where the investigator is uncertain whether the activity meets the definition of human subjects research.

IV. DEFINITIONS

eIRB: The electronic IRB management system.

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.

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

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

1. Investigators who are uncertain if their proposed activities constitute human subjects research may submit a request to the IRB office for a determination in eIRB.
2. The Chair or designee will review the submission to determine if the proposed activities meet the regulatory definition of research and if they are determined to be research, if they also meet the definition of human subjects research.
 - (a) Any activities that meet both the regulatory definitions of research and human subjects are subject to IRB review and approval or an exempt determination before any research activities may commence.
 - (b) Activities that do not meet the definition of research (e.g. case series, quality improvement activities) do not require IRB review or an exemption determination.
 - (c) Research activities that do not meet the definition of human subjects (e.g. use of data/specimens that are not readily identifiable) do not require IRB review or an exemption determination. Note: An activity not meeting the definition of Human Subjects Research, but meeting the criteria for Engagement of CHOP, as an institution, in human subjects research (as defined by OHRP's Guidance) requires a submission for IRB review. SOP 106
3. The investigator will be notified of any determinations that the activities do not meet the definition of human subjects research or be provided with instructions to submit the human subjects research for IRB review and approval or an exemption determination.

VI. APPLICABLE REGULATIONS AND GUIDELINES

HIPAA Privacy Rule regulations

Hospital Patient Care Manual policy number IM-1-01 Privacy of Patient Information

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OHRP - Guidance on Engagement of Institutions in Human Subjects Research issued October 16, 2008
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

VII. REFERENCES TO OTHER APPLICABLE SOPS

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VIII. RESPONSIBILITIES

Title	Responsibility
Director, Human Subjects Research	Director, Human Subjects Research (or designee) is responsible for determining whether or not the proposed activity meets the definition of research subject to regulation.

IX. ATTACHMENTS

Appendix: Example activities that may be submitted for the IRB's determination.

The IRB's webpage provides additional information regarding which activities are considered by the IRB to meet the regulatory definition of research and which research activities meet the regulatory definition of human subjects research.

The IRB's webpage describing quality improvement versus research provides information and a worksheet to assist investigators determine whether their QI activity also meets the definition of human subjects research.

OHRP's *Guidance on Engagement of Institutions in Human Subject Research* provides guidance on which activities require t require IRB oversight. The document is available on OHRP's website.

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X. REVISIONS:

- 10/13/06 Revised SOP to remove IRB oversight for Case Report/Case Series that do not meet the definition of research.
- 3/2/2007 Revised due to changes in IRB office staff responsibilities.
- 3/11/09 Revised to remove need for investigators to obtain an IRB determination that a case report or case series, provided there are 5 or fewer subjects, does not meet the definition of research.
- 6/10/10 Revised to correct minor typographical errors.
- 12/13/11 Revised for minor updates to reflect updated processes with the electronic system and to correct typographical errors.
- 2/13/2013 Revised to expand the SOP from case reports and case series to include quality improvement activities and use of data/specimens that are not readily identifiable.
- 9/25/2018 Revised to update the definition of “human subjects” and other minor edits.

XI. APPROVAL:

Director, Human Subjects Research

Date

Chair, Committees for the Protection of Human Subjects

Date

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XII. APPENDIX: EXAMPLES OF ACTIVITIES THAT EITHER DO NOT MEET THE DEFINITION OF RESEARCH OR ARE NOT HUMAN SUBJECTS RESEARCH

Case Report: An unsystematic clinical observation based on a single case. A case report states the outcome or response of a single patient to a diagnostic strategy or treatment. The IRB does not consider illustrative reports of a single patient (case report) to meet the definition of research.

Case Series: An unsystematic retrospective clinical observation about more than one case. A case series sometimes reports on a variety of different diagnostic or therapeutic approaches. These will not be considered research provided that there are 5 illustrative cases or fewer. Case series with more than 5 illustrative cases must be submitted to the IRB in order for the IRB to determine whether or not the case series meets the definition of research.

Quality Improvement: Systematic, iterative, data-guided activities designed to bring about immediate improvements in health delivery in particular settings. Most QI activities do not meet the definition of human subjects research. When there is an overlap, the QI initiative must be reviewed by the IRB prior to initiation.

Secondary Use of De-Identified Data or Specimens: The use of existing data or biospecimens that have been collected for clinical or research purposes and which is not readily identifiable to the investigator does not meet the definition of human subjects research and is not subject to IRB review.