I. PURPOSE

The purpose of this SOP is to outline the procedures in place for determining whether submissions meet the definition of human subjects research, including but not limited to case series, quality improvement activities or 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 or not the federal research regulations apply, the investigator may request the IRB to issue a formal determination.

III. SCOPE

These policies and procedures apply to any activity where the investigator is uncertain regarding whether or not the activity meets the definition of human subjects research.

IV. DEFINITIONS

**Human Subject (DHHS):** A living individual about whom an investigator conducting research (1) obtains data through an interaction or intervention or (2) collects identifiable private information about the subject for research purposes.

**Non-Human Subjects Research:** Research that does not meet the definition of human subjects research subject to review.

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

V. PROCEDURES

A. IRB Review

1. Investigators who are uncertain as to whether their proposed activities constitute either research or human subjects research may submit a request to the IRB office for a determination of non-human subjects research.

2. The Director, Human Subjects Research or designee, will review the submission to determine if the work proposed meets the regulatory definitions of research and
if it does, whether or not it meets the definition of human subjects research or non-human subjects research.

(a) Any proposals that meet the regulatory definition of human subjects research are subject to IRB review and approval before any research activities commence.

(b) Otherwise, the investigator will be notified of the IRB’s determination that the planned activities are non-human subjects research (i.e., do not meet the definition of research or human subjects research).

VI. APPLICABLE REGULATIONS AND GUIDELINES

| HIPAA Privacy Rule regulations | Hospital Patient Care Manual policy number IM-1-01 Privacy of Patient Information |

VII. REFERENCES TO OTHER APPLICABLE SOPS

| SOP 105: IRB Review Processes | SOP 106: Research That Must Be Reviewed by the IRB |

VIII. RESPONSIBILITIES

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<thead>
<tr>
<th>Title</th>
<th>Responsibility</th>
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<tr>
<td>Director, Human Subjects Research</td>
<td>Director, Human Subjects Research (or designee) is responsible for determining whether or not the proposed activity meets the definition of research subject to regulation.</td>
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IX. ATTACHMENTS

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

The IRB’s intranet page entitled *What Must be Reviewed by the IRB* 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 intranet page entitled 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 and which don’t require IRB oversight. The document is available on OHRP’s website.

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 investigator’s 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.

XI. APPROVAL:

______________________________  ________________________
Director, Human Subjects Research  Date

______________________________  ________________________
Chair, Committees for the Protection of Human Subjects  Date
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.