1.0 Purpose:

1.1 To define when case reports require Institutional Review Board (IRB) oversight.

2.0 Definitions:

2.1 **Research** - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.0 Procedure:

3.1 From both the Common Rule and the Privacy Rule perspective, a case series involving more than 3 cases meets the definition of research, and such research requires IRB review and approval. Investigators are required to submit a Research Application Form.

3.2 It is the policy of Hartford HealthCare (HHC) that a "single" case report (three or fewer cases), does not meet the federal definition of research, and therefore does not require oversight by the IRB. Investigators are not required to submit a Research Application Form.

3.3 It is suggested that investigators check target journals' submission requirements for documentation from the IRB before proceeding.

3.4 If a physician/investigator wishes to have the activity assessed by the HHC HRPP to determine if it meets HHC's definition of a single case report, the investigator should complete and submit a "Request for Determination that a Proposed Activity is Not Research or is Not Human Subjects Research" Form.

3.5 Such requests will be reviewed by the HRPP Director or designee for a determination. If the project qualifies as a single case report, HHC's HRPP will send to the investigator a form letter that states:
"Your proposed activity entitled, "***[%study_title%]***" has been reviewed by the Human Research Protection Program. It has been determined that this does not meet the federal definition of research according to 45 CFR 46.102(l), does not produce generalizable knowledge, nor is it an investigation of an FDA regulated product and, therefore; does not require further review or oversight by the Institutional Review Board.

3.6 HIPAA Requirements for Case Reports

3.6.1 The HHC IRB regards such limited case report preparation as an educational activity, and thus it is permissible under the Privacy Rule (HIPAA) as a part of health care operations (45CFR164.501).

3.6.2 Investigators who remove HIPAA identifiers from the case report data prior to disclosure of the data (e.g., prior to submission of the case report to a journal) do not need to obtain a signed privacy authorization from the subject of the case report.

3.6.3 In addition to removing the 18 listed HIPAA identifiers, the investigator must determine that no photo or illustration in the case report could lead to identification of the patient, and that the case(s) described are not so unique as to be identifiable with reference to other public sources such as media accounts.

3.6.4 If the author strips off all HIPAA identifiers, but the information associated with the subject of the article includes a "unique characteristic" which would make it identifiable to the subject, or the author has actual knowledge that the information about the subject could be used alone or in combination with other information to identify the subject, the author must contact the HIPAA Privacy Officer to discuss the required steps to take prior to publication.

3.6.5 Investigators who wish to publish a case report that is **not completely de-identified** to the standards of the HIPAA Privacy Rule (i.e., that contains any direct or indirect identifiers), must first obtain each patient's signed HIPAA-compliant authorization. It is not necessary to submit this authorization form to the IRB for review.

4.0 Documentation:

4.1 Any documentation related to a formal determination by the HRPP will be maintained for three years.

5.0 References:

5.1 45 CFR 164.501 (Privacy Rule)

5.2 45 CFR 46.102(l)

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	CLG	7/1/11	New Issue
01	CLB	3/15/20	Updated the regulatory citation for the definition of research; added section 3.6 to detail HIPPA Privacy Rule requirements that investigators should be aware of.

Elements I.1.A. and III.1.A.