HUMAN RESEARCH PROTECTION

Case reports – IRB oversight and HIPAA compliance

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Resource type GUIDANCE

This document provides guidance about oversight associated with presentation and/or publication of case reports. It may also be used by authors of case reports to document Hennepin Healthcare requirements for case reports – for example, as documentation for a journal submission. This guidance has been established by the Hennepin Healthcare Human Research Protection Office (HRPO) regarding IRB oversight and has been reviewed by the Hennepin Healthcare Compliance regarding HIPAA authorization.

Definitions

Case report: A case report is a medical or educational activity involving the presentation or publication of information and analysis for the purpose of highlighting an interesting experience, observation, treatment, relationship, or outcome. It may involve a prospective intervention or prospective collection of specimens or data that is not part of standard service or care.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Do case reports require IRB oversight?

Case reports do **NOT** require IRB review if they:

1. Are about less than five individuals, **AND**
2. Do not involve the use of an investigational drug or device that is subject to regulation by the Food and Drug Administration (FDA).

Such case reports do not meet the definition of "research" as interpreted by the Hennepin Healthcare Human Research Protection Program and as described in federal human subject regulations (45 CFR 46), and they are not subject to FDA regulation.

If a case report **does not** meet the above criteria, a Cayuse HE submission for research must be completed and approved by the IRB prior to any analysis and publication/presentation. IRB approval cannot be granted retroactively, i.e., after analysis and publication/presentation.

What are the HIPAA requirements for case reports?

Case reports that are not subject to IRB oversight must still comply with HIPAA Privacy Rule requirements for Protected Health Information (PHI). If a case report requires access to, and the use of, PHI, the clinician/author is expected to:

- Obtain HIPAA authorization from the patient or patient's representative (e.g., if the patient is deceased), using a clinical HIPAA authorization form, **OR**
- Ensure that all HIPAA-specific identifiers are removed from the case report so that there is no reasonable risk of patient identification in the case report. This means:
  1. Removing the 18 identifiers specified in the HIPAA Privacy Rule **AND**
  2. Determining that no photo, image, or illustration in the case report could lead to identification of the patient; **AND**
  3. Determining that the case(s) described is/are not so unique as to be identifiable if someone looked at public sources, for example, a social media account

It is the responsibility of the individuals conducting activities for case reports to contact Hennepin Healthcare Compliance/Privacy, as appropriate, to address any issues related to PHI.

The IRB assumes no responsibility for activities that are not subject to its jurisdiction.