Guidance on Patient Case Reports and When IRB and HIPAA Regulations Apply

Overview

HHS defines research at §46.102 as "a systematic investigation designed to develop or contribute to generalizable knowledge". The FDA defines research at §56.102 as any experiment that involves a test article and one or more human subjects.

Patient Case Reports (or Case Reports) do not typically meet the definition of research and do not typically fall under the jurisdiction of an Institutional Review Board (IRB) unless it meets the definition of research.

While a Case Report does not typically meet the regulatory definition of research, the author must still comply with applicable HIPAA regulations.

DFCI IRB Guidance

A Case Report that does not meet the definition of research may summarize one or more medical cases to report upon a discrete and unique instance of a disease or illness. The number of patients included in a Case Report is generally limited in number to one, two or three patients. However, it is the nature of the Case Report, not the absolute number of patients, which determines whether the activity involves human subject research.

The Case Report must not involve a systematic investigation characterized as developing or contributing to generalizable knowledge otherwise the human research regulations apply. A Case Report is limited to an account of an observation or a description of a disease process that is not subject to scientific analysis. It is not presented as a systematic investigation designed to contribute to generalizable knowledge. A Case Report must be presented in such a way that it is readily distinguishable from a research publication, which usually contains data with statistical analysis, or a systematic qualitative analysis, that substantiates the science and the conclusion and thus constitutes a contribution to generalizable knowledge.

Investigators seeking formal determination from OHRS whether their project meets the regulatory definition of research may submit a Non-Human Subject Research (NHSR) application in iRIS..

HIPAA Authorization

- A signed HIPAA authorization is not required if HIPAA identifiers are removed from the Case Report data prior to submission and publication.

- A signed HIPAA compliant authorization is required if the author wishes to include HIPAA identifiers in published Case Reports. Note that photographs and illustrations could identify a patient and should be considered when determining if HIPAA authorization is required.

- If HIPAA identifiers are stripped but one or more "unique characteristics" remain that would make it possible to identify the patient, the author should contact their Institutional Privacy Office or Privacy Officer to discuss required steps prior to authoring the Case Report and submitting it for publication. Note that the

distinctiveness of a case or combination of the case report with other information may lead to a patient being identified.

For additional information on the HIPAA Privacy Rule, please see the HIPAA Privacy Rule Info Sheet.

Patient Notification

OHRS strongly advises authors to first ask patients for their permission to be used in a Case Report because the distinctiveness of most Case Reports may lead to the inadvertent identification of the patient(s).

References:
Dana-Farber Cancer Institute Institutional Review Board: Policies and Procedures for the Protection of Human Subjects in Research.. (2023, Febuary).: http://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/IRB_Policies_and_Procedures_for_the_Protection_of_Human_Subjects.pdf

U.S. Food & Drug Administration. (2016, April 1). *CFR - Code of Federal Regulations Title 21.* Retrieved March 30, 2017, from U.S. Food & Drug Administration Web site: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3