Case Reports and HIPAA Requirements

A case report (generally described as a retrospective analysis of one (1), two (2), or three (3) clinical cases) is intended to develop information to be shared for medical or educational purposes and not necessarily as "generalizable knowledge." As such, case reports do not meet the definition of "human subject research under the purview of an IRB." Although the use of protected health information (PHI) to prepare the case report does not require IRB review, the author of a case report must still comply with HIPAA.

HIPAA requires written authorization from the patient for certain disclosures of the patient's PHI, including publication of a case report. The author of the case report must obtain the signed authorization of the patient, or the patient's legal representative if the patient is deceased, to publish the patient's information in the article. The *use* of PHI to prepare the article, however, does not require a HIPAA authorization.

If it is not possible to obtain authorization, the patient's PHI must be de-identified in accordance with 45 C.F.R. §164.514(a) before the case report is submitted to a journal or before any other type of disclosure. To de-identify the PHI, 18 identifiers must first be removed from the case report (these are listed in §164.514(a), or contact the Privacy Office for further guidance). The author should be aware that one of the identifiers described by HIPAA as requiring written authorization is, "Any other unique identifying number, ***characteristic***, or code…." This would include a case so unique or unusual that it might be possible for others to identify the patients in the case reports. Moreover, HIPAA requires that, at the time of publication, "[t]he covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information."

IN SUM:

- Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization.

- Authors who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed, HIPAA-compliant authorization. This authorization does not need to be submitted to the IRB for review, but must be scanned into the patient's medical record (please forward the authorization to Health Information Services (HIS) Department to be scanned). The appropriate authorization form for use with a case report may be found on the Dartmouth-Hitchcock web site HERE.

If you have questions about whether the data in your case report may directly or indirectly identify a patient, please contact the Dartmouth-Hitchcock Privacy Office at (603) 653-0457 or PrivacyOffice@hitchcock.org.

In some instances, journals or conferences may request a letter from an IRB before accepting a case report for publication/presentation. This is a memorandum confirming the policy of the Dartmouth CPHS: Case reports are not considered to be human subject research under the purview of an IRB. Therefore, case reports do not require review by the Dartmouth CPHS office. In the event you need a formal letter related to your specific project, please contact: cphs.tasks@Dartmouth.edu.

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