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POLICY: 200-050385-026

Guidelines for Publishing Case Reports of Patients Receiving Clinical Care at Harbor-UCLA Medical Center

It is the policy of the Harbor-UCLA Medical Center that a case report does not constitute research and does not require Institutional Review Board (IRB) approval. All case reports prepared for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Any use or disclosure of PHI must be authorized by the patient, or, or if the patient is deceased, the patient's family. Publication of PHI is disclosure of PHI.

Definitions

A **Case Report** is a retrospective analysis of the clinical symptoms, signs, diagnosis, treatment, and outcome of an individual case. For purposes of this policy the reference to case report also applies to case series where up to three unique cases are described in the proposed publication.

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

Protected Health Information (PHI) is individually identifiable information relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for healthcare provided to an individual.

Background

This policy seeks to offer clarity surrounding the patient consent requirements for publishing case reports. As case reports are not classified as research, they are not required to be submitted to an Institutional Review Board.

Case reports which have all PHI removed or masked do not require the author to acquire patient consent prior to their publication by law. However, specific journals sometimes require documentation of patient consent or attestation that consent was obtained as they may believe that it is in the best interests of the patient, the author, and the Institution that a reasonable effort is made to acquire consent from the person or persons featured in the case report prior to publication. Accordingly, there is confusion regarding when patient consent is required by law versus when he may be requested of an author by publisher.

Procedure

The publishing requirements regarding consent for case reports differ from journal to journal. While the author must adhere to any rules and requirements mandated by the publisher, they should not assume that any given journal's requirements will fully protect themselves, their patient(s), or the Institution from risk. Accordingly, a

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Department Chair may elect to establish procedures to review case reports written by their respective faculty or residents prior to submission for publication to determine if patient consent should be obtained.

A. In all circumstances, Protected Health Information (PHI) should be removed or masked from a case report prior to publication. PHI must be removed or masked from all aspects of the case report, whether in writing or within a photograph.

B. The HIPAA Privacy Rule lists the following 18 identifiers. All of these identifiers must be removed or masked for a case report to be considered de-identified, and therefore not requiring the patient's consent:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)

C. Any questions regarding PHI should be directed to the Privacy Officer or designated HIPAA authority prior to submission of the case report to assure proper authorization was obtained.

D. If a case report contains one or more of the eighteen HIPAA Privacy Rule identifiers listed above, then the author must not publish the report without having acquired the patient's consent, or obtaining a Waiver of Informed Consent from an IRB.

1. A patient's consent to participate in research may not extend to consent for publication. Therefore, the patient should be informed of which periodical the case report will be published

in, how the case report can be accessed (print, online, etc.) and whom will be able to access it (medical practitioners, journal subscribers, the general public, etc.)

2. The patient should be informed that while a reasonable effort will be made to anonymize the case report, complete anonymity is not possible. If a patient can identify themselves in a case report, then it cannot be considered completely anonymous.
3. All aspects of consent must be explained to the patient in their own language, understood by the patient and agreed to verbally by the patient. This should then be recorded by making a documentation of the consent agreement in the patient's medical record.
4. In the event that a patient is deceased, consent must be attempted to be obtained from their next of kin or a legal representative. If the patient is a child, consent must be attempted to be obtained from their parent or legal guardian.
5. If after reasonable effort, the author is unable to obtain consent from the patient, they must submit their case report to their Departmental Program Director or Chair for approval prior to publication.

E. If consent is required, documentation of the patient consent should be made in the patient's medical record as a provider entry detailing the informed consent of the patient or by uploading a separate consent document signed by the patient into the patient's medical record.

References

Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule -

http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/

Guidance for Investigators HIPAA Requirements for Case Reports Office of Human Subjects Research - Institutional Review Board, John Hopkins Medicine

http://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/hipaa_case_reports.html

Informed Consent Columbia University Institutional Review Board Policy

http://www.cumc.columbia.edu/dept/irb/policies/documents/Informed_Consent_Policy102610Final.pdf

Case Reports: Single Case Reports – Limited Case Series - Duke University Health System, Health Research Protection Program

https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/Case%20Reports%20Policy%2005-30-2008.pdf