

## MEDSTAR HIPAA GUIDANCE FOR CASE REPORTS

In medicine, **a case report** is a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient intended to be shared for medical or educational purposes. As such, case reports do not meet DHHS's definition of human subject research under the purview of an IRB. Even when the use of protected health information (PHI) to prepare a case report does not require IRB review, the author must still comply with HIPAA.

HIPAA requires written authorization from the patient in order to use or disclose 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 a minor or deceased, to publish the patient's PHI in the article.

When it is not possible to obtain authorization, the patient's PHI must be de-identified in accordance with HIPAA before the case report is submitted to a journal or before any other type disclosure. This includes sharing PHI with any collaborators or contributors to the case report who are not a part of MedStar's workforce and were not part of the patient's treatment team.

To properly de-identify the PHI, the following identifiers<sup>1</sup> must first be removed from the case report:

- 1. Names;
- 2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes;
- 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death;
- 4. Telephone 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

Of note is identifier 18 - Any other unique identifying number, **characteristic**, or code; a unique characteristic would include a case so unique and unusual that it might be possible for others to identify the patients in the case reports. HIPAA also 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 summary, HIPAA authorization is not required if the author removes all 18 identifiers including unique patient characteristics from the data prior to publication.

Authors who wish to publish a case report with some or all of the 18 identifiers will need to have the patient sign the Case Report authorization form found here (IRB.O-004.02.FM4). The patient should be provided a copy of the form and the form should be uploaded to the patient's medical record.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> These identifiers are listed in 45 C.F.R. §164.514(a) with more detail on dates as it relates to age and zip codes

<sup>&</sup>lt;sup>2</sup> Forward the signed and dated form to the Health Information Management Department of the MedStar Entity where the patient was seen who will scan and upload the form to the appropriate folder in the patient's record.