MedStar Health
Research Institute

Case Report Frequently Asked Questions

What is a case report?

In medicine, a case report is a detailed report of the symptoms, signs, diagnosis, treatment, and follow-up of an individual patient. Case reports may contain a demographic profile of the patient, but usually describe an unusual or novel occurrence.

What is the difference between research and a case report?

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(d)(pre-2018)/45 CFR 46.102(l)(1/19/2017).

A **case report** is usually a write up of a single or a few patients. A case report/case series of less than three (3) patient records is not considered a systematic investigation. Therefore, this does not meet the definition of research requiring IRB review.

A case report/case series reviewing records of three (3) or more living individuals would be considered research and does require IRB review prior to accessing these records.

Do I need IRB review of a case report?

No, so long as you are reviewing less than three (3) patients.

What if the journal where the case report is being published requires a letter from the IRB?

MHRI IRB's policy is to not require IRB review for case reports. A letter to this effect has been written for journals. Click here (IRB.O-004.02.FM5, Case Report Not Human Research Determination Letter) to download the letter to provide to journals.

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How does HIPAA relate to 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.

Do I need a signed HIPAA authorization from the patient before doing the case report?

If you are creating a completely de-identified case report, you do not need to obtain the patient's authorization. If you are creating the case report for presentation outside of MedStar Health, publication, or presentation within MedStar Health for a non-MedStar Health affiliated or employed audience, and there is information in the case report that could be used to identify the patient, then you must obtain a signed HIPAA authorization from the patient before you access the medical record for the creation of the case report. If you are unable to obtain a signed HIPAA authorization from the patient then the case report must have all patient identifiers removed, also known as de-identification.

If you are creating the case report for internal use only (discussion or presentation within MedStar Health and with only MedStar Health employed or affiliated persons present), then you do not have to obtain a signed HIPAA authorization.

If you have questions about the requirement to obtain a signed HIPAA authorization or would like further guidance on how to de-identify patient information, please review the MedStar HIPAA Guidance for Case Reports. You may also contact resarchcompliance@medstar.net or the MedStar corporate privacy office at privacyofficer@medstar.net.

Where can I find an authorization for the patient to sign for a case report?

MedStar Health has created a HIPAA authorization for case reports. You can find that document, IRB.O-004.02.FM4, Form, Case Report Authorization, on StarPort. You can also contact your MedStar Health Entity Compliance Officer to obtain a copy.

Do I need to give the patient any other information?

Yes, when you approach the patient to obtain permission and the signed authorization, you will need to take the time to explain what information you will be using and how it will be used prior to having the patient sign the authorization form.

What do I do with the authorization once it is signed?

A copy of the signed authorization should be given to the patient. The signed authorization must also be included in the medical record.