

A case report is 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” which are under the purview of the 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 or utilize the patient’s information.

If it is not possible to obtain authorization, the patient’s PHI must be de-identified in accordance with [HIPAA Regulations](#) 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. In these instances, 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. Additionally, 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.”

Keep in mind that if a patient has already expressed desire not to include their information as part of a case study, the researcher should honor this request regardless of any de-identification methods.

To summarize:

- Researchers 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
- Researchers who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed, HIPAA-compliant authorization. The UCR HIPAA authorization form for use can be found on the [Forms page](#). The completed authorization form should be included as part of that person’s medical records, as well.
- A unique case is one that may identify an individual to the public simply by describing the disease or the unique treatment received. Authorization from the patient is required prior to disclosing the information as part of a published article, meeting abstract, or **any** other form of public presentation.

For any additional questions regarding HIPAA as it applies outside of IRB requirements, (for those with less than 3 case studies) researchers should contact the [UCR Health Sciences Compliance Office](#).