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HRPP Guidance for Case Report Publication

Many journals and other publishing venues now require a letter, or other form of acknowledgement, from an IRB prior to publication of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the case described. The UIW (University of the Incarnate Word) Human Research Protection Program has adopted a policy to address the following questions.

Q: What constitutes a “case report”?

A case report for IRB purposes is a retrospective analysis of a maximum of three cases. If more than three cases are involved in the analytical activity, the activity will constitute “research.”

Q: Do UIW Principal Investigators who prepare a case report for publication require IRB approval prior to preparation?

No. A case report is a medical/educational activity that does not meet the DHHS definition of “research”. Research is defined as: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Therefore, a case report, as defined above, does not have to be reviewed by the UIW IRB. If uncertain contact the UIW HRPP.

Q: Can a UIW Principal Investigator request that the HRPP makes a formal determination that the case report is not research?

In certain cases, publishers may require a formal determination from the HRPP/IRB that a case report does not constitute research. Researchers seeking an official determination that a case report is not research should submit a not-human subjects research (NHSR) application through the ERM system.

The following steps should be followed when submitting a request for a formal determination:

- Create a new project within ERM and start a new IRB – Application Form
- In Section 1, select “Non-Human Subjects Research/NRR” as the review type
- Follow the prompts to complete the rest of the application
- Your proposal should include a description of the process for the de-identification of data or in the alternative the process for obtaining HIPAA authorization from the patient(s) if Protected Health Information may be included.

Q: Are there HIPAA implications associated with publication of case reports?

Yes. Under HIPAA, a case report is an activity to develop information to be shared for **medical/educational purposes**. Although the use of protected health information to prepare the paper does not require review by an IRB member, the author of a case report must comply with HIPAA. In addition, when the source of the protected health information is not a UIW Covered Entity and there is



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no Institutional Affiliate Agreement, a Data Use Agreement may also be required. Contact the UIW HRP if in doubt.

Ideally, the author of the case report will obtain the signed authorization of the subject, or the subject's legally authorized representative if the subject is deceased, to use the subject's information. If it is not possible to obtain authorization, 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." 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." (See: [Definition of De-Identified Data](#)).

- 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.
- Investigators 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. The appropriate authorization form for use with a single case report may be found on the HIPAA web site.
- If the author strips off all HIPAA identifiers, but the information associated with the subject of the article includes a "unique characteristic" which would make it identifiable to the subject, or the author has actual knowledge that the information about the subject could be used alone or in combination with other information to identify the subject, the author must contact the UIW HIPAA Privacy Officer to discuss the required steps to take prior to publication.

This guidance has been adapted from guidance developed at Johns Hopkins University. For recommendations to write a clinical case report, see this [National Library of Medicine](#) article.