

## Case Report Guidance

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Many journals now require a letter, or other acknowledgments, from an IRB before publication of a case report. Specifically, they wish to confirm whether IRB approval was obtained or not required for the described case. The HU IRBs offer the following guidance regarding case studies/reports:

### Definitions:

1. **Case Report:** A case report is a retrospective analysis of one, two, or three clinical cases. It describes an interesting treatment, presentation, or outcome.
2. **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, current or future payment for healthcare provided to an individual.

Federal regulations for the protection of human subjects define “research” as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

- If an individual develops a case report with *no prior research intent, and the report does not meet the regulatory definition of research*, the HU IRB does not require a review.

When a case report or case study meet **ALL** criteria in the bulleted list below, it does not meet the HHS definition of “research” and therefore, IRB review **IS NOT** required for this scholarly activity.

- The project proposes to examine **three** patients/records or less;
- A case report involving three or fewer patients containing PHI that is presented outside the institution or submitted for publication does not constitute “research” under the HIPAA Privacy Rule, and therefore, does not qualify for a waiver of the HIPAA requirement for specific authorization of the patient.
- The project is a case report, case study, or multi-chart review reporting patient condition, treatment, outcome, or presentation that draws conclusions only about that participant or group, and only in that specific context;
- The project does **not** involve the investigation of a United States Food and Drug Administration (FDA) regulated product;
- The project does **not** involve confidential information, identifiers that could place a participant at risk if disclosed, or sensitive topics;
- The project does **not** involve persons from vulnerable populations;
- The project does **not** include data manipulation to include the use of statistical methods such as subgroup comparison or compilation of observations in such a manner that might allow for generalization to a larger population;

- The project does not involve an experimental intervention or a case series that incorporates statistics;
- The project does not offer incentives to participants; and
- The project does not include any added interventions to enhance the case study.

**If your activity meets all the above criteria, it does not meet the HHS definition of *research*, and therefore, IRB review is not required.\*\***

\*\*Although IRB review and approval are not required for case reports as described above, specific HIPPA Privacy Rule requirements may apply.

- If a case report involving three or fewer patients containing PHI, is presented as part of an educational program conducted outside of the US or affiliated institutions; then the activity is not considered part of standard health care operations under HIPAA, and may be presented only with a HIPAA-compliant specific authorization of the patient. Also, if the patient is deceased or otherwise unable to consent, the explicit authorization of the patient's legally authorized representative is required.
- If a case report involving three or fewer patients containing PHI will be submitted for a publication, this activity is not part of standard health care operations and requires the specific authorization of the patient. Also, if the patient is deceased or otherwise unable to consent, the specific authorization of the patient's legally authorized representative is required before submission for publication.
- A case report involving three or fewer patients containing PHI that is presented outside the institution or submitted for publication does not constitute "research" under the HIPAA Privacy Rule, and therefore, does not qualify for a waiver of the HIPAA requirement for specific authorization of the patient.
- While HIPAA authorization may not always be required, there may be instances in which authorization from the patient may be needed to use their health information.

If you are unclear or have questions, please contact the ORRC through the following means:

- Telephone: 202-865-8597
- Email: theorrc@howard.edu