

CASE REPORT GUIDANCE

The Wright State University Institutional Review Board (IRB) frequently receives inquiries regarding whether publishing a case report or case series constitutes human subjects research and therefore requires IRB review. Also, many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report.

The purpose of this guidance to:

- Clarify the regulatory requirements associated with presentation or publication of case reports and when they fall under the purview of the IRB
- Clarify for researchers additional HIPAA authorization processes in regards to case reports

DEFINITION OF CASE REPORT

A case report is a medical or educational activity involving the presentation or publication of information and analysis for the purpose of highlighting an interesting experience, observation, treatment, relationship, or outcome.

IRB REVIEW NOT REQUIRED

Research, as defined by DHHS at 45CFR46.102(d), means a "systematic investigation", including research development, testing and evaluation, designed to develop or contribute to "generalizable knowledge," such that conclusions will be drawn that can be applied to populations outside of the specific study population.

For IRB purposes, a single case report, case study, and/or case series is a retrospective analysis of one, two, or three clinical cases and generally does not meet the definition of "research". No predetermined hypothesis or research question guides case reports and publication of the information about the patients' medical care is not planned prior to or during the patients' treatment. In addition, case reports are usually prepared by clinicians who have personally provided care to those patients. Thus, a single case report, case study, and/or case series does not have to be reviewed by the IRB. Note: Your facility (Premier Health, VAMC, or WSP) may require submission of a request form (e.g. Premier Health Case Report Form) to the local facility research committee.

It should also be noted that teaching, and soliciting colleagues' advice on clinical care of a specific patient or groups of patients during presentation of a case at departmental conferences DOES NOT require IRB review. Generalized commentary by a clinician on the outcome of their clinical care of patients in accepted locations for discussion of clinical management is also not considered research requiring IRB review, if there is no prospective research plan, and no formal, systematic and prospective collection of information. This type of communication may occur at hospital or practice meetings, in continuing education venues, or in editorials, where the comments are explicitly identified as personal experience and not formal clinical research.

WHEN A CASE REPORT REQUIRES IRB REVIEW

When larger series of patients are being reported, investigators/authors usually begin to ask specific research questions and formal systematic collection of data occurs, moving these activities closer to prospectively designed research. If more than three cases are involved in the analysis, the activity will be considered "research" and requires the submission of a new protocol application for IRB review.

Unlike DHHS regulations, FDA regulations do not provide for exemption from IRB review when research involves existing data/specimens and the investigator records information without identifiers or linking codes. Nor do FDA regulations define "human subjects" with reference to the identifiability of the subject or of the subject's private information. As such, any case report, case study, and/or case series involving a subject participating in an FDA-regulated clinical trial requires IRB review.



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HIPAA REQUIREMENTS

Although a single case report may not require IRB review as a research project, those conducting such activities should be aware that certain HIPAA Privacy Rule provisions may apply. The use of protected health information to prepare a case report does not require IRB review for HIPAA Privacy Rule purposes. However, anyone who wishes to publish information that includes HIPAA identifiers or may allow identification of the patient because of a description of a unique disease, condition, or outcome will be required to obtain from the patient a signed informed consent and HIPAA authorization. Best practices recommend that all case study subjects sign an informed consent/HIPAA authorization.

If case reports require access to, and the use of, PHI, the author is expected to:

- Obtain informed consent and/or HIPAA authorization from the patient or patient's representative (e.g., if the patient is deceased), **OR**
- Ensure that all HIPAA-specific identifiers are removed from the case report so that there is no reasonable risk of patient identification in the case report. This means:
 - Removing the 18 identifiers specified in the HIPAA Privacy Rule; **AND**
 - Determining that no photo, image, or illustration in the case report could lead to identification of the patient; **AND**
 - Determining that the cases described are not so unique as to be identifiable if someone looked at public sources such as social media accounts.

Informed consent and HIPAA authorization templates are available on the Wright State IRB Website: [Templates](#). Please consult your facility Privacy Officer with any questions regarding written HIPAA authorizations and/or deidentification of case reports.

CARE GUIDELINES

The [CARE guidelines \(for CAse REports\)](#) were established by an international group of experts as a way of increasing the accuracy, transparency, and usefulness of case reports. The Wright State IRB supports and encourages the use of these guidelines in your case report project.