

CASE STUDIES AND IRB REVIEW/HIPAA AUTHORIZATION

The IRB often receives questions concerning case studies and their need for IRB review or HIPAA involvement. This guidance will help clarify when or if IRB review is needed.

Are case studies research?

The answer to this question determines whether case studies are subject to research regulations. The federal definition of research from [45 CFR 46.102\(d\)](#) is:

“Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.”

Based on this definition, a single or even a few case studies in an article is not research by the federal definition. It is not a systematic investigation of many cases, and scientists would not expect to obtain generalizable knowledge from this type of anecdotal sharing of one or a few cases. It is a scholarly teaching activity that is part of the operations of an academic medical center such as Ochsner Health Systems and may be a valuable contribution to hypothesis-generation for future research.

Do case studies need IRB approval?

No, IRB approval is not needed for one or a few case studies, because they are not considered research. If you are presenting or publishing one or a few case studies there is no need to obtain an IRB determination. However, if a larger collection of case studies is compiled together, then it may be research according to the federal definition above. Certainly, if you are presenting/publishing more than a few case studies it would be prudent to receive an IRB exemption determination.

Do case studies need HIPAA authorizations?

HIPAA exempts teaching activities as a part of the Institution’s operations. Therefore, HIPAA authorizations are not needed for case studies that are not considered research. However, if there were a larger collection of cases compiled together met the federal definition of research, then yes, a HIPAA authorization or waiver would be required. To learn more about HIPAA authorizations and waivers for research [click here](#).

How do I get an IRB determination or HIPAA waiver for research?

To receive a determination the project must be submitted to the IRB via the eIRB submission portal. Submission and determination via [eIRB](#) will ensure durable documentation for your project.

Can case studies use personal information in the presentations?

If case studies do not fall under research IRB rules or HIPAA rules, common sense and basic ethical standards apply. There should be the minimum possible use of personal identifiers that is in keeping with the scholarly goals of teaching, the more de-identified the better.

Do case study publications require patient permission?

Many journals have revised their policies and will not publish a case study without signed patient consent. This reflects the fact that patients are increasingly sensitive to such uses of information about them without their knowledge, whether the author and journal believe the subject of the case report can be identified or not.

In one prominent case, the Lancet was subject to legal action from a patient who was able to identify herself in the case report (Smith, R. Informed consent: edging forwards (and backwards) *BMJ* 1998; 316:949951). Conditions reported in case studies are usually rare or atypical, making recognition even easier by friends, family, or self.

The best course of action is to assume that individual descriptions may be identifiable and to obtain informed consent for publication. This also serves the goal of maintaining a collaborative relationship with the patient and family. Physicians who have shown case reports to the patient in question have often received useful feedback (and almost always permission), including correction and clarification of what, after all, is fundamentally the patient's story.