Program for the Protection of Human Subjects (PPHS)
Icahn School of Medicine at Mount Sinai

Guidance for Investigators regarding a Case Report and Case Series

Background:

An investigator planning to retrospectively report on the clinical experience of one or more patients may ask whether this activity requires IRB review? The first step in answering this question is to consider whether the activity meets the regulatory definition of "research".

Research, as per Federal Regulation 45CFR46.102(d) and 45CFR164.501 is defined as:

"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

Does a single case report meet the above definition of research?
Does a case series of 2 or more patients constitute research?

The guidance below will help the investigator think through these questions.

1. **What constitutes a case report?**
   A case report is a retrospective analysis of a single clinical case.

2. **Do persons who prepare a case report for publication require IRB approval prior to preparation?**
   In most cases, NO.
   The majority of the time, a case report represents a medical/educational activity that does not meet the DHHS definition and does not require IRB review unless the case report contains unique information posing a likelihood for identification. When the identification of a case is in question, please contact the PPHS/IRB Office for further guidance.

3. **Are there HIPAA implications associated with publication of a single case report?**
   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 may not require IRB review, the author of a case report must comply with HIPAA. Ideally, the author of the article 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 in the article.

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 release form can be found here: Authorization for Release of PHI for Media Relations form.

Should the author eliminate 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 HIPAA Privacy Office by phone at 646-605-7130 to discuss the steps required prior to publication.

4. **Who makes the determination regarding whether a case report requires IRB review?**
   Who makes this determination is contingent on the number of cases within a report.
   A. For a **single case report**, the author may render a decision as to whether or not IRB review is required. Again, when the identification of a case is in question, contact the PPHS/IRB Office for further guidance.
   B. For a case report or case series involving **more than one case**, the decision as to whether IRB review is required must be made by the PPHS/IRB office.

5. **My case report does involve more than one case.**
   Please email the PPHS/IRB Office at: **irb@mssm.edu** with "Case Report/Case Series Information" in the subject line of the email message.

   Provide the following information within your email:
   1. Your name
   2. Your department
   3. Your contact Information (email and phone)
   4. Indicate whether your case report activity is a systematic investigation?
   5. Indicate whether your case report activity is designed to contribute to generalizable knowledge?
   6. Are the patients within your case report your own patients? Please specify patient source.

6. **What if the journal to which I am submitting my case report or case series asks for a letter or acknowledgement from the IRB indicating their determination of whether approval was required?**
   Upon request, the IRB can issue a formal letter to the investigator for provision to a journal editor. To receive this documentation, your case report/series information must first be entered into the electronic submission system for IRB review and PPHS tracking purposes.

7. **Do teaching activities, or my obtaining a colleague's advice on clinical care for a specific patient or cohort of patients during presentation of a case at departmental conference, require IRB review?**
   NO. IRB review is not required under these circumstances

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In summary, investigators are advised to consult with PHHS/IRB when uncertainty exists about whether an activity meets the definition of human research.