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IRB Review of Case Studies

Is it Research?

Case studies generally involve the description of medical treatment in a single patient or a few patients with a unique treatment, disease course, or outcome based on a retrospective review of medical records, or they can involve a description of a unique diagnostic finding or uncommon presentation. No predetermined hypothesis or research question guides case studies and publication of the information about the patients' medical care is not planned prior to or during the patients' treatment. In addition, case studies are usually prepared by clinicians who have personally provided care to those patients.

Case studies usually do not require IRB review since they do not meet the Common Rule definition of research. Research is defined as a systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(d)) A single retrospective case study that reports the observation of a single subject receiving the normal standard of care (no new or novel procedures) is generally not considered research assuming that there is no intent to test a hypothesis via systematic analysis, or add to a body of knowledge. However, when a series (more than one) of subject observations is compiled in such a manner that would allow possible extrapolation of the results to a larger population, this would likely represent research.

The question regarding when case studies constitute research is a complex one to address. Case studies involving more than three patients are more likely to meet the criteria for research and require IRB review. Although a single case study involving up to three (3) patients may not require IRB review, those conducting such activities should be aware that certain HIPAA Privacy Rule provisions may apply and ethical concerns can arise if identifiable information is published. The use of protected health information to prepare a case study does not require IRB review for HIPAA Privacy Rule purposes. However, anyone who wishes to publish information that includes HIPAA identifiers or may identify the patient because of a description of a unique disease, condition, or outcome will need to obtain from the patient a signed HIPAA authorization. This authorization does not need to be submitted to the IRB for review, but consultation with the PHS HIPAA Privacy Officer is recommended. Additionally, those publishing case studies are strongly encouraged to obtain consent from any patients about whom information will be published. In the case of deceased individuals, consent might be obtained from the next of kin.

Criteria for IRB Review

Regardless of the number of study participants, the activity is considered research and requires IRB approval if any of the following is present:

- Investigational drug(s) or device(s) are involved (off-label use of an approved drug or device for the sake of an individual patient does not constitute research).
- There is a clear intent before treating the patient to use systematically collected data that would not ordinarily be collected in the course of clinical practice in reporting and publishing the case study.
- There is a plan to perform the treatment on some individuals but not on others.

- There is intent to manipulate medications (even approved ones) to determine maximum effectiveness, or to test if they work consistently well.
- Extra tests are conducted for the sake of reportability.
- There is a protocol/study plan.
- Records or data sheets are maintained separate from clinical records (particularly with identifiers).
- The primary purpose is to answer a research question, not to provide care.
- There is a possibility that the treatment might yield a case series if it is effective in others (e.g., testing a hypothesis).
- There is intent to publish a report that is analytical not descriptive.

Many journals now require a letter or other acknowledgement from an IRB prior to publication of a single case study or a case series. Anyone asked by a journal to provide documentation of IRB approval prior to publication of a submitted case study or case series should contact the PHS Human Research Protections Office (HRPO), which will provide a letter confirming IRB review was not required per this guidance.

What to Do?

At PHS the initial decision regarding whether a proposed case study meets the definition of research should be made jointly with the HRPO and the IRB using the federal guidelines available at http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees/. For assistance, please contact the HRPO at 505-841-1436 or by email at PHSResearch@phs.org.