Mass General Brigham

CASE REPORTS

Background and Rationale

Clinical experiences are often the genesis of research questions and the design and development of clinicalresearch protocols. In an academic medical center, it is not unusual for unique and interesting clinical casesto be written up as case reports for publication in medical journals or presentation at medical or scientific meetings. This policy is designed to provide guidance on when publication/presentation of case report(s) constitutes human-subjects research and requires prospective IRB approval.

Medical Case Reporting

The Federal Policy for the Protection of Human Subjects (45 CFR 46.102(l) defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. In general, a case report of typically three or fewer patients is not considered human-subject research and does not typically require IRB review and approval because case reporting on a small series of patients does not involve the formulation of a research hypothesis that is subsequently investigated prospectively and systematically for publication or presentation. Reporting or publication is not typically envisioned when oneinteracts clinically with the subject.

When larger series of patients are being reported, investigators usually begin to ask specific research questions and formal systematic collection of data occurs, moving these activities closer to prospectively designed research. Researchers are advised to consult with the IRB or submit larger case series reports for IRB review when uncertainty exists about whether formal and systematic collection of human subjects research is occurring.

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 venues for discussion of clinical management is also not considered research requiring IRB review, if there isno 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.

In certain cases, journals may require a formal determination from the IRB that a case report does not constitute research. Researchers seeking an official IRB determination that a case report is not research should submit a Not Human Subjects Research (NHSR) application.

HIPAA REQUIREMENTS

HIPAA requirements apply to the access, use, and disclosure of protected health information (PHI) in case reports. If the case report includes PHI, the patient may need to provide HIPAA Authorization. For any questions regarding HIPAA and its applicability to case reports, contact the Privacy Office at your hospital.

Version: April 27, 2023
(AAHRPP Element I.1.A)