

"CASE REPORTING" AND RESEARCH LIMITED TO MEDICAL RECORDS

Background and Rationale

Clinical experiences are often the genesis of research questions and the design and development of clinical research protocols. In an academic medical center it is not unusual for unique and interesting clinical cases to 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(d)) defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. In general, the review of medical records for publication of "case reports" 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 one interacts 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. The boundaries between case reporting and formal medical records research may be unclear for a series of one's own patients. 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 is no prospective research plan 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.

Confidentiality: Patient confidentiality should be respected in all clinical situations involving identifiable medical information from patients. All clinicians are reminded of the following points:

- Names, dates of birth, social security numbers, and other "codes" or combinations of identifiers, which might easily allow someone to identify a subject, should never be used in publications or external presentations.
- Unique family trees or pedigrees should be masked or disguised when such information could identify individuals or kindreds.
- Photographs should be appropriately masked to preclude identification of subjects.
- Partner's Office of General Counsel strongly recommends that patients provide written consent to allow publication or electronic dissemination of pictures or other information (e.g. videos, voice recordings, transcripts), which might in any way identify them. Contact the Human Research or Public Affairs office, as appropriate, for sample research and non-research consent forms for use of identifiable material. When photographs will ONLY be used in confidential medical records or as part of direct clinical care of the patient (for example, photograph of a characteristic rash which would be retained in a record for documentation or shown to colleagues in the provision of clinical care), it is appropriate and acceptable to obtain and document verbal consent.

- Clinicians should be sensitive to the "small cell problem": the existence of individuals with such unique or unusual diagnoses or illnesses, that it might be possible for others (or patients and families themselves) to identify the individuals in case reports or medical text books based upon limited information, such as state or city of residence, age and diagnosis.

Formal Prospective Research Involving Retrospective Review of Medical Records

Formal, prospective medical records review to answer specific research questions DOES constitute systematic, prospective medical records research on identifiable human subjects, and does require IRB review and approval (Submit the Health/Medical Records form within the Humans module of [Insight](#).) Federal regulations state that if data is abstracted without retaining any link to specific individuals, some medical records research may be considered exempt from IRB review. The IRB, not the investigator, must make this determination. At BWH and MGH, institutional policy mandates that ALL systematic, prospective, formal records review requests are reviewed and approved by expedited IRB review mechanisms, rather than "exempted."

Investigators are reminded that they should abstract and retain only the minimum relevant clinical information. Investigators should discard links to human subjects when the research has been completed and published, or when relevant research goals requiring links to individuals are accomplished. Institutional and governmental policies on the duration of retention of research records vary and are discussed in a separate policy. Links to identifiable subjects may be maintained to be in compliance with these policies, but should not, in general, be retained indefinitely.

NB: This policy was created in part based upon information provided by Michael Carome MD at the December 2001 PRIMR/ARENA Meeting, Boston MA.