



CASE REPORTS:
SINGLE CASE REPORTS – LIMITED CASE SERIES
05/30/2008

Federal regulations (45CFR46.102(d) and 45CFR164.501) define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The review of medical records for publication of a single case report or a case series involving data from two or three patients is not considered by the DUHS IRB to be research involving human subjects, and therefore such a report of medical cases does not require IRB review and approval. This is because reporting such a small series of patients does not involve a systematic investigation, including defining a hypothesis that is then investigated prospectively and systematically, to develop or contribute to generalizable knowledge. When a larger series of patients is being prepared for presentation or publication, ordinarily a specific research question is defined, and then a systematic collection of data occurs. Such a systematic investigation more closely resembles prospectively designed clinical research. While drawing such a “bright line” to distinguish non-research from research is admittedly arbitrary, it serves as a useful guide to those who would prepare case reports for presentation or publication. The DUHS IRB regards such limited case report preparation as an educational activity, and thus it is permissible under the Privacy Rule (HIPAA) as a part of health care operations (45CFR164.501). However, from both the Common Rule and the Privacy Rule perspective, a case series involving more than 3 cases does meet the definition of research, and such research requires IRB approval.

Whenever a member of the DUHS community considers using information about another person in an activity that may by someone be considered to be research, that DUHS colleague is expected to consult with the DUHS IRB for an authoritative determination of the boundary between the reporting of an interesting case or cases and formal medical records research. This expectation becomes more urgent when a caregiver considers reporting a series of patients for whom he/she has provided medical care, perhaps over many years, with no prior intent to generalize his/her observations. While IRB review of a formal protocol may not be required if the medical record review occurs in accord with 45CFR46.101(b)(4), only the IRB can determine this so as to protect both the patients whose records are reviewed and the reviewer who is vulnerable to serious sanction if such a review occurs improperly.

Note that medical education or medical consultation, such as occurs when a colleague presents a difficult case or case series at a teaching conference, does not require IRB review. Generalizing comments presented in an accepted educational setting by a caregiver who describes the outcome of his/her clinical care of a group of patients, such as commonly occurs in a conference on clinical

management, is also not considered research requiring IRB review if the generalizing is restricted to the specific local educational setting. A useful guide to distinguish this type of activity from research is to identify if the speaker prefaces the comments by "In my experience,". Such a presentation may occur outside the local setting, and even in published form, as in a regional meeting on continuing education, or in an editorial in a medical journal, as long as the comments are clearly identified as representing the personal experience of the presenter and not the result of formal clinical research. In such a case, a summary of the opinion may be offered, but specific supporting data would not be presented.

Investigators should inform the DUHS IRB if a journal editor does not accept the IRB's determination that reporting a case or a limited case series does not constitute research. The specifics of such a situation will be discussed by the IRB Chairs/Vice-Chairs, along with the Institutional Official and/or designee, and if needed for resolution, by a convened IRB.