Case Report Policy

1) Purpose:

This is the policy of the Einstein IRB as to when Case Reports require IRB review and/or permission from the subject.

2) Background:

“Case Reports in Medicine are fundamentally individual patient stories generally describing unique or unexpected findings in terms of disease or treatment.”¹ Case reports describe (a) the course of medical treatment involving one or more patients and having a unique outcome, or (b) the handling of a unique clinical case. Treatment and/or case management will have been accomplished without any research intention (i.e. there was no prospective plan to systematically evaluate the outcome for purposes other than treating the particular patient(s)).

Case reports are commonly presented within the institution at clinical conferences involving faculty, residents, and students, for purposes of education, or as part of the planning and/or evaluation of patient care. Such case presentations are a routine part of care and teaching and do not require consent or IRB review.

Case reports may be prepared for publication in medical journals; or they may be presented at professional meetings within or outside of the institution that are unrelated to care of or teaching about the involved patient(s). Prior to presentation or publication, a journal or program sponsor may require documentation that IRB approval was obtained, or that the IRB determined that review was not required.

3) Regulatory Requirements:

Federal regulations for the protection of human subjects in research (45 CFR 46) and our Federalwide Assurances (FWA) require IRB review of all human research activities conducted under the auspices of Einstein/Yeshiva University, Montefiore Medical Center, and the North Bronx Healthcare Network. Under these regulations, Research is defined as, “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” A Human Subject is defined as, “a living individual about whom an investigator (professional or student) obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information.” All human subjects research activities must be submitted to the IRB for prospective review and approval or exemption.

In addition, the Health Insurance Portability and Accountability Act (HIPAA) provides for comprehensive protection for the privacy of “protected health information” (PHI). These regulations must be followed when individual medical cases are discussed or reported outside of the routine provision of care.

Definitions

1) Case report of an individual patient:

A case report of an individual patient does not meet the federal definition of human subjects research in that the information in the case report is not generalizable knowledge. Therefore, clinicians are not required to obtain IRB approval for such individual patient reports. If a publisher or presentation sponsor requires documentation of IRB approval, this policy document may be submitted (the IRB will provide written attestation if requested).

With respect to a case report of an individual patient:

The information presented in the case report must be fully de-identified as required under HIPAA (i.e. there can be no reference to: name; address; all elements of dates (except year) for dates directly related to an individual; telephone or facsimile numbers; email address; social security number; medical record number; health plan beneficiary numbers; hospital account numbers; certificate/license numbers; vehicle identifiers; device identifiers; web URLs; IP addresses; biometric identifiers; full-face photo images or comparable images; any other unique identifying number, characteristic or code.)

It may not be possible to fully de-identify the individual described in a case report, even if all HIPAA identifiers are deleted, since the unique character of the patient’s experience can serve as an identifier in its own right. Moreover, items such as the patient’s age and gender, in combination with diagnosis and course of treatment, the name of the treating physician who authored the case report, name of the institution and date of publication may cause others to be able to identify the patient. Therefore, the individual patient (or appropriate surrogate) should sign a HIPAA Authorization authorizing the use of the description of their individual case situation (see IRB website). Signed authorization must always be obtained if a potentially identifiable image of the subject is to be included in the report.

2) Case reports involving more than one patient (case series):

A case series has the characteristics of research in that it is systematic and has the potential to provide generalizable knowledge. Therefore, a research protocol, including a description of planned case selection, data extraction and analysis, and a plan for maintaining confidentiality of research data, must be submitted to the IRB for review and approval. This requirement includes the report of a single family, since more than one individual would be described.

   a) Prospective case series: Written consent and HIPAA authorization should be obtained from the involved patients (or appropriate surrogates). It may be permissible to request a waiver of consent and HIPAA authorization by the IRB when subjects with a common characteristic are identified prospectively, and all data are to be obtained through chart abstraction. Prospective case series generally qualify for expedited review (Category 5) as determined by the IRB.

   b) Retrospective case series: A request for waiver of informed consent and HIPAA authorization must be submitted as part of the application. Retrospective case series may qualify as exempt research (Category 4) as determined by the IRB.
3) Reports of a small number of cases: Under certain circumstances, there may be a limited number of 1st degree relatives of an individual patient who manifest similar findings; or a report based on a single individual may be enhanced by reference to a limited number of similar cases. Depending on the nature of the review undertaken, such situations may not meet criteria for systematic research and therefore do not require a research protocol or IRB approval. Final determination will be made by the IRB on a case-by-case basis. Investigators should contact the IRB and discuss these situations before undertaking the preparation of a report.

Policy Statement:

Any case report that involves more than one individual, thereby qualifying as a human subjects research activity, or any individual case report involving PHI, must be submitted to the IRB for prospective review for approval or exemption under federal regulations for the protection of human subjects in research (45CFR46). The submission must include a request for waiver of consent and/or HIPAA authorization when appropriate.

NB:

1. The IRB will not provide retrospective approval for case reports.
2. No case series database, even limited to the names and/or record numbers of potential series members, should be created prior to review and approval by the IRB.
3. Any such database that may have been created prior to approval by the IRB must be destroyed; it may not be used as the basis for future research.