**IRB/Privacy requirements for Case Reports**

A case report is a description of (a) the course of medical treatment with one or more patients that has a unique outcome or (b) the handling of a unique clinical case; which in either case did not involve the investigator having any research intent at the time of the intervention [i.e., no prospective plan to systematically evaluate the outcome for purposes other than treating the particular patient(s)].

Clinicians may have the opportunity to present unique clinical cases at professional meetings, to medical students or to colleagues within the institution. Many case reports are also published in medical journals. Prior to presentation or publication of a case report, some institutions or journals may require documentation from an IRB that IRB approval was obtained or was not required.

**Harlem Hospital** requires form 2423 to be completed in the primary language of the patient/parent. To obtain this form:

1. Open the Generations+/Northern Manhattan webpage
2. Click on "HHC Intranet Site" in the lower right corner
3. Click on "Forms Index" on the left side
4. Go to page 9 and select form HHC 2423 "Authorization to Disclose Health Information to the Media" in the appropriate language.
5. This form requires the patient/parent's signature

**Columbia University** requirements (http://www.cumc.columbia.edu/dept/irb/policies/docs/Case_Report_Policy.doc):

1. **Case report on a single patient:**

   A case report describing the treatment of a single patient does not meet the federal definition of human subjects research on the basis that the information in the case report is not generalizable knowledge. Therefore, clinicians at the University are not required to obtain IRB approval for case reports of a single patient.
Investigators who are asked by a journal or other entity to provide documentation from the IRB that such a case report was either approved by the IRB or did not require review by the IRB may present the Columbia University IRB/Privacy Board Policy on Case Reports as evidence that the case report does not require IRB approval. Some journals may require that the institution provide written attestation that the informed consent of the subject has been obtained prior to publication of the case report. Such written documentation can and should be provided by the Department with which the investigator is associated.

In most cases, the Privacy Office requires case reports to be de-identified, i.e., the presentation or article must not contain any of the 18 identifiers of an individual that are described in the Privacy Rule (name; addresses; all elements of date; telephone and facsimile numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers; device identifiers; web URLs; IP addresses; biometric identifiers; full face photographic images and any comparable images; any other unique identifying number, characteristic, or code).

If the case report involves a living person and the information is de-identified, an Investigator’s Certification for Research with De-Identified Data Form (Form G) must be submitted to the Privacy Office. If the case report involves a patient who is deceased, the investigator must instead submit an Investigator’s Certification for Research with Decedents’ Information (Form E). Both forms can be found on RASCAL under “HIPAA”. Neither form is required to be approved by the Privacy Board and formal approval letters are not generated.

In the situation of a case report including a facial photograph or other image showing a unique identifier, or of a report of a case that is so unique that the identity of
the subject would be readily known upon publication, the investigator should contact the Privacy Office before proceeding with the presentation or publication. In those cases, patient authorization will be needed prior to the presentation or publication.

2. Case report involving more than one patient:

A case report involving more than one living individual may meet the definition of human subjects research and may require IRB review. A brief summary describing the case, the type of information that will be included, and the safeguards for protecting confidentiality should be submitted to the IRB prior to abstracting patient data. The submission may be sent by e-mail to <irboffice@columbia.edu> with “Case Report” indicated in the subject line. The IRB will make a determination whether the activity is human subjects research requiring further IRB review, and will so notify the investigator.

A case report that describes more than one patient who is de-identified or that involves deceased patients does not require patient authorizations, but would require submission of Form G or Form E. If a patient is living and identifiers are used, the investigator should contact the Privacy Office before proceeding with the presentation or publication. In those cases, patient authorization would typically be needed. Such case reports would rarely, if ever, qualify for a waiver of authorization from the Privacy Board as it would be difficult to show that it would be impractical to obtain actual authorization from a small number of patients.

For questions regarding Columbia IRB review or requirements, please contact the **IRB office at (212) 305-5883**. For questions regarding HIPAA related matters, please contact the **Privacy Office at (212) 342-0059**.