COLUMBIA UNIVERSITY
INSTITUTIONAL REVIEW BOARD/
PRIVACY BOARD
POLICY

CASE REPORTS

I. SCOPE OF POLICY:

This policy clarifies whether case reports require IRB and/or Privacy Office / HIPAA Compliance review and approval at Columbia University (the "University").

II. EFFECTIVE DATE: February 1, 2011

III. BACKGROUND:

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. Case reports used for internal educational or business activities within the organization do not require approval of the Privacy Office.

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. This Policy will address whether such activities require review by the University's IRB and/or Privacy Office.

REGULATORY REQUIREMENTS:

The federal regulations for the protection of human subjects, as codified in the U.S. Department of Health and Human Services regulations, 45 CFR 46, together with the Columbia Federalwide Assurances, require IRB review of all human research activities at the University. According to 45 CFR 46, "research" is defined as "a 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 exemption or approval.

The federal government implemented the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule") as a part of a broader federal law known as the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") [45 CFR 160 and 45 CFR 164, Subparts A and E]. The Privacy Rule provides for comprehensive federal protection for the privacy of identifiable health information ("protected health information" or" PHI"). The Privacy Rule's safeguards are overseen by the University's Privacy Office which informs researchers of the requirements to be compliant related to the disclosure of PHI in clinical and research settings. In addition, this department provides the information to train staff with respect to the University's privacy policies.

I. CASE REPORT ON SINGLE PATIENT:

A. IRB REQUIREMENTS:

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.

Clinicians 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 this Policy as evidence that the case report does not require IRB approval. Some journals may require that the institution provide written attestation that the authorization 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.

B. PRIVACY OFFICE REQUIREMENTS:

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).

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 may be identified upon presentation or 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.

II. CASE REPORT INVOLVING MORE THAN ONE PATIENT:

A. IRB REQUIREMENTS:

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.

B. PRIVACY OFFICE REQUIREMENTS:

A case report that describes more than one patient who is de-identified or that involves deceased patients may require patient authorizations, but would require submission of Form G or Form E. If patients are 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.

III. CONTACT FOR FURTHER INFORMATION:

For questions regarding 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.