

TO: Whom It May Concern

FROM: Andreas K. Klein, MD 
IRB Chair

DATE: 09 February 2012

SUBJECT: Institutional Case Report Policy

Case reports submitted for publication do not strictly meet the criteria of research. Although a case report (defined as a retrospective analysis of one (1), two (2), or three (3) clinical cases) may be illustrative, it does not meet the Federal Policy for the Protection of Human Subjects definition of Research, which requires an investigation that contributes to generalizable knowledge about a disease or condition. Instead, a case report is intended to develop information to be shared for medical or educational purposes.

The institutional policy of Tufts Medical Center and Tufts University Health Sciences, therefore, is that a case report is not research that must be approved by the IRB.

Although there is no requirement for IRB approval for a case report, the HIPAA Privacy Rule restricts how protected health information (individually identifiable health information) may be used and disclosed.

An author may be exempted from obtaining a signed authorization from the patient discussed in the case report if all HIPAA identifiers are removed from the case report prior to disclosure (i.e., before the case report is submitted to a journal). It is the responsibility of the author to ensure that (i) no identifying photos or illustrations are included in the case report (e.g. facial pictures have eyes/identifiable features blacked out, tattoos should not be visible) and (ii) the case(s) described in the report are not so unique or unusual that it might be possible for others to identify the patients in the case reports.

If an author wants to publish a case report that is not completely de-identified pursuant to the standards set forth in HIPAA or if there is any concern that a patient could be identified or likewise could identify themselves or a family member (for example, because the condition or diagnosis is distinct or identifiable features appear in photographs) the institutional privacy officer or his/her designee should be consulted and explicit authorization from the patient must be sought for the use of identifiable information. If a patient is deceased, authorization for the use of identifiable patient information must be obtained from the personal representative of the patient's estate.