



University at Buffalo

# Office of Research Compliance

Research and Economic Development

December 2, 2020

## University at Buffalo Institutional Review Board (UB IRB)

### Re: Case report policy

To whom it may concern:

Case reports submitted for publication do not strictly meet the criteria of research. Although case reports (defined as a retrospective analysis of one (1), two (2), or three (3) clinical cases) are illustrative, they do not meet the Federal Policy for the Protection of Human Subjects definition of Research, which require study intervention and/or 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 policy of the University at Buffalo is that a case report is not considered research that needs IRB review and approval.

Although there is no requirement for IRB review and approval for a case report, the HIPAA Privacy Rule does restrict 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), however they should consult their local privacy officer with any questions. It is the responsibility of the author to ensure that (i) no identifying photos or illustrations are included 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 to identify the patients from the case report.

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) they should consult their local privacy officer and obtain authorization from the patient 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.

If you have any questions, please feel free to contact the UB IRB (716) 888-4888.

Sincerely,

Richard Karalus, Ph.D.  
Director, Office of Research Compliance