HSIRB Case Study Policy

It is the practice of the CSUB Human Subjects Institutional Review Board (HSIRB) that a single case report or case series (three or fewer cases) does not constitute human subjects research requiring review and approval by the HSIRB. If an investigator wishes to have the project formally reviewed by the HSIRB to determine if the project meets the definition of a single case report or case series, the investigator must submit a new protocol application on the Cayuse IRB platform, requesting a Not Human Subjects Research (NRRS-NHSR) review. If the project qualifies, the HSIRB will send an acknowledgment letter to the investigator stating:
"The HSIRB received your request (dated 'x'), concerning a single case report or case series you wish to publish. The HSIRB has determined that a case report or case series involving three or fewer subjects does not produce generalizable knowledge, nor is it an investigation of an FDA-regulated product. HSIRB review and approval are not required for this activity."

NOTE: Case reports/series for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Any use or disclosure of PHI must be authorized by the subject, or, if the subject is deceased, the subject's family. Publication of a case report containing PHI is a disclosure of PHI.

- Under HIPAA, a case report is an activity to develop information to be shared for medical/educational purposes. Although the use of protected health information to prepare the paper does not require IRB review, the author of a case report must comply with HIPAA. Ideally, the author of the article will obtain the signed authorization of the subject, or the subject's legally authorized representative if the subject is deceased, to use the subject's information in the article. If it is not possible to obtain authorization, the author should be aware that one of the identifiers described by HIPAA as requiring written authorization is, "Any other unique identifying number, characteristic, or code…." Moreover, HIPAA requires that, at the time of publication, "[t]he covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information." (See: Definition of De-Identified Data.)
- Authors who remove HIPAA identifiers (including unique subject characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization.
- Investigators who wish to publish case report data with HIPAA identifiers will need to obtain from the subject a signed HIPAA compliant authorization. This authorization does not need to be submitted to the IRB for review. The appropriate authorization form for use with a single case report may be found on the HIPAA web site. See Privacy Rule Authorization Form.