

## **GUIDELINES FOR CASE REPORTS**

Federal regulations (45 CFR 46.102) define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Case Reports often fall outside of that specific definition and as such, do not require IRB approval. The following guidelines can be used for determining what case report activities do and do not require IRB review at Broward Health.

### **1. Case Reports**

Broward Health IRB has determined that a descriptive report of observations on up to 3 people or organization(s), in which the observations were retrieved in a retrospective manner and no research questions/hypotheses are being tested, does not meet the definition of research, and may be considered a "case report". In such cases, Broward Health investigators are not required to obtain IRB approval prior to beginning the activity. However, investigators must make a reasonable attempt to protect the patient's/individual's privacy by removing identifiers (see HIPAA section, below).

Note: when a series of observations is compiled in such a way as to allow generalizing of the results to a larger, defined population, this does represent research and IRB review is likely required. Studies may meet the criteria for [exempt](#) or [expedited](#) categories of research.

### **2. HIPAA Regulations**

A case report that was not undertaken as a research project does not meet the HIPAA definition of "research." Rather, this would be an activity to develop information to be shared for medical/educational purposes. Medical/educational activities are allowed under HIPAA without individual authorizations. The use of protected health information to prepare the article does not require any additional review for HIPAA purposes. However, investigators must assure that the article does not contain any of the 18 PHI identifiers noted in the HIPAA regulations.

### **3. Publication**

Individuals asked by a journal to provide documentation of IRB approval prior to publication of a submitted case report should first provide a copy of this document to the publisher. If additional documentation is requested, contact the IRB at [irb@browardhealth.org](mailto:irb@browardhealth.org) or 954-355-4941 or 954-355-4358.