THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Case Reports

Guidance

A *case report* for IRB purposes is an analysis of one, two, or three cases or experiences. Case reports merely report on an activity that will occur regardless of the report. Case reports should not involve manipulation of the environment so that the outcome can be assessed compared to a control population. This is 'research' and requires prospective IRB review.

In addition, the case is defined by the activity (e.g., a single person, a classroom, an institution). A *case report* that is composed of three or fewer cases typically does not constitute Human Research. This is because reporting on such a small series of cases is usually anecdotal and does not involve a systematic investigation, including defining a hypothesis that is then investigated prospectively and systematically, to develop or contribute to generalizable knowledge. It is possible, however, to have a research project with a sample size of 1. If the activity is a single case that could be research, please contact the Human Subjects Protection Program to discuss the details.

When do case reports require IRB review?

Submission of the *IRB Protocol for Determination* in eIRB is **required** when the case report involves the activities below, even though the case report may not be human research. This is because access to certain types of data, information, or specific populations may require increased protections above the regulatory definition of human research.

Review is required when the case report involves:

- Access to an electronic medical record;
- Use or disclosure of Protected Health Information (PHI);
- Requests for data or specimens from the Banner Clinical Research Data Warehouse (CRDW);
- The project is or will be supported by federal funds;
- The information will be used to support an application to the FDA or involves the use of a test article in a human;
- IRB certification for access to materials from the NIH dbGap; OR
- The project involves Native American/Alaskan Native or international indigenous populations.

What about a case series?

A *case series* (more than 3 cases) may meet the definition of *research* and would require IRB review. This is because when a larger series of cases is prepared for presentation or publication, ordinarily a specific research question is defined, manipulation of the environment may occur, and then a systematic collection of data occurs. Such a systematic investigation more closely resembles prospectively designed Human Research.

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What are HIPAA implications associated with publication of some case reports?

The use of or access to Protected Health Information (PHI) for a case report must comply with the Health Insurance Portability and Accountability Act (HIPAA, 45 CFR 164). The individual who is accessing the PHI must obtain from the patient a signed HIPAA compliant authorization if the report requires access to a medical record or PHI maintained by a Covered Entity (e.g., a hospital, health plan, health care clearinghouse or a provider who conducts electronic transactions).

Contact the Human Subjects Protection Program to determine if authorization to use protected health information is required.

Note: Access to patient information for PHI from Banner Health for a case report must also be reviewed by the Banner Non-Research Data Use Committee (NRDUC). Submit the *IRB Protocol for Determination of Human Research* in eIRB. The case report request will be forwarded to the NRDUC once the IRB has determined the activity is not human research. Please review our Collaborative Activities with Banner Health for more information.