

When is IRB review of a project needed?

The IRB is required to review prospectively all projects that will engage the University at Buffalo or its affiliates in human subjects research. The following guidance is provided to help investigators determine whether IRB review is required for a given project or activity. Faculty, staff, or students at UB who have any doubt as to whether or not a planned project or activity will require prospective IRB review are strongly encouraged to contact an IRB administrator for consultation. Determinations regarding the need for IRB review will be provided upon request.

Regulatory Framework. IRBs are designated to review all “research” projects involving “human subjects” in order to help ensure that human participants are protected. The University at Buffalo has filed an assurance with the federal government agreeing to review research involving human subjects and to comply with all applicable federal regulations. The university has agreed in this assurance to ensure IRB review for not only federally-funded research projects, but all research involving human subjects that falls under the following categories (excerpted from the *UB Protection of Human Research Subjects Policy and Procedures Manual*):

The IRB will conduct initial and continuing review of all research involving human subjects if the project meets the federal definitions for both "research" and "human subject" and one or more of the following conditions apply:

- This institution sponsors the research.
- The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities.
- The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution.
- The research involves the use of this institution’s non-public information to identify or contact human research subjects or prospective subjects.
- The institution has an agreement in place to review a protocol from a non-institutional source.

Steps to Determine if IRB Review is Required. The SBSIRB provides the following as a guide for determining when any part of a project requires IRB review:

1. The project must fall under the federal definition of **research** provided in 45CFR46.102:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The SBSIRB is aware that some activities that take place at the university are systematic investigations but are not intended to contribute to generalizable knowledge. These activities typically do not fall under the federal definition of research. For instance, this can occur when:

- a. There is no intent to publish or otherwise disseminate (present) information obtained as a result of the activity. For example, class “practica” exercises used to teach students how to do research typically are not meant to contribute to generalizable knowledge. This is the case also when the data are to be used only for internal purposes by the organization (e.g. for quality control or employee evaluation).
- b. There is no intent to analyze or draw conclusions from the data (e.g., collection of oral histories for an archive solely to preserve the historical record).

The following activities, if they involved human subjects and otherwise met the definition of research, definitely would require review:

- a. A project to be used for a thesis, dissertation or other form of “capstone” project.
- b. A project for publication or presentation, if the university is to be listed as an author’s affiliated institution.
- c. A project that includes design contributions made by a university member through participation in the decision-making process for how a study will be carried out.
- d. Pilot testing of materials to be used in any of the above.

Unless undertaken for a **dual purpose** that includes research, the following activities most likely would not require review:

- a. A faculty member or student who acts as an expert consultant or in a community service or clinical capacity would not be performing research unless he or she intends to participate or assist in the publication or presentation of generalizable information obtained through his or her activities. When the intent to publish was not present at inception but arises after consultation has occurred or while the project is ongoing, the project should be submitted to the IRB for review at that time. In these cases, the IRB will determine whether the project data may be used for research purposes (e.g., publication) or if it may be used only for its originally intended purpose.
- b. A student or faculty member who is writing an article for a campus newspaper would not be considered to be engaged in research, but rather would be subject to the ethics of journalism, because purely journalistic activity is not intended to contribute to generalizable knowledge. However, if the student or faculty member is involved in a systematic investigation involving human subjects that is designed to contribute to generalizable knowledge, and the article is to present findings from that

activity, then the activity constitutes research and should have undergone IRB review prior to its onset.

2. The project must also fall under the federal definition of research with **human subjects** provided in 45CFR46.102:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.
Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

The federal definitions of intervention and interaction are sufficiently broad as to include interviews, surveys, participant and non-participant observations, as well as physical, psychological or environmental manipulations (real and virtual). Thus, it is a safe assumption that if a researcher receives information about an individual that did not come from a publicly available data archive, the project by definition involves human subjects.

The definition of what constitutes private information is based on an individual's reasonable expectation of privacy, and may be situation dependent. For example, internet postings where a password is required to access the site might reasonably be expected to remain private, whereas more accessible postings would be considered public. The definition of what is individually identifiable includes not only directly identifiable information but also information from which an identity can be ascertained indirectly by the investigator. In projects using a small sample of participants, simple demographic data such as race and gender may make an identity readily ascertainable. This is especially true when a researcher already is associated with study participants.

The following types of projects typically do not require review, because they do not involve federally-defined human subjects:

- a. When publicly available data are obtained without interacting with subjects, the project may be research, but this research does not involve

- human subjects (e.g. library research and most forms of internet research where there is no expectation of privacy related to archived materials).
- b. The use of existing completely de-identified data (e.g. review of secondary data provided to the investigator with no identifiers or links to identifiers, as long as the subjects' identities could not reasonably be determined). Note that if the data were not already in existence at the inception of the project, the project would constitute human subjects research, because some type of intervention or interaction with participants would be necessary in order to collect the data.
3. The university or its affiliates must be **engaged** in research through an individual's part in the project. The university becomes "engaged" when an individual, in his or her role as a faculty or staff member or student at the university, plays a professional role in human subjects research activities.

The following are common situations that would definitely engage the institution in research:

- a. Faculty and students conducting human subjects research for academic purposes.
- b. Faculty or students engaging in protocol-dictated communication or interpersonal contact such as conducting research interviews or obtaining informed consent.
- c. Faculty or students releasing individually identifiable private information or permitting investigators to obtain individually identifiable private information, without subjects' explicit written permission.

Unless undertaken for a **dual purpose** that includes research, the following activities most likely would not engage the institution in research and consequently would not require UB IRB review:

- a. A student who is serving in an internship or practical experience who is asked to collect data solely as a part of his or her employment. For example, a nursing student or resident performing routine blood draws as a part of his or her clinical experience would not be engaging the university in research, even if the blood is being collected for research purposes, unless the student were more actively involved as a collaborator in the research (e.g., by writing papers for publication).
- b. A student or faculty member engaged in an activity outside of his or her position as a member of the university (e.g., at a second job or a community organization) would not engage the university in research unless that person used material obtained or developed during this activity for a research purpose.

SBSIRB Guidance. The SBSIRB is cognizant of the possibility that overly broad application of the definitions could lead to the involvement of the IRB in areas with which it need not be concerned. The IRB is aware also that projects often are conducted with more than one purpose in mind. The SBSIRB therefore attempts to apply these

definitions in a judicious manner, so that all projects that reasonably fit the relevant definitions are reviewed, but those that clearly fall outside of these definitions are handled expeditiously by the IRB administrator, in consultation with the IRB chair when necessary.

Dual Purpose Projects. Regardless of any other motivation for a project, if any portion of the project engages the university or its affiliates in research with human subjects, the project must be reviewed prospectively by the IRB. Occasionally, the SBSIRB receives submittals for projects that are being carried out for dual purposes (E.g.: A project involving a new educational technique has the primary purpose of education and secondary purpose of research. A program evaluation survey used primarily for quality control and secondarily for research). For these projects, the ethical requirements of both purposes apply.

Sometimes the research portion can be considered to be separate from the other activities involved in a project. In these cases, the IRB is required to review the research portion but need not consider the other activities involved. In other situations, the research is sufficiently integrated with other procedures that review of the entire project is necessary. Occasionally the non-research purpose of a project and its intended implementation make it very difficult or impossible for the investigator to meet the ethical standards required for research with human participants. In these cases the investigator may have to choose which purpose the project will fulfill or may be not able to carry out a research component because the need to meet the other purpose leads to an ethical dilemma in using the project for research. For example, journalistic ethics might require the identifiable publication of material that would cause harm to a person's reputation, whereas the ethics of research would require that the material not be published if it would harm participants.