The University at Albany Institutional Review Board (IRB) reviews all research involving human subjects conducted under the auspices of the University at Albany, which is defined as follows:

a) Human subjects research activities that are conducted by, or under the direction of, University at Albany faculty, staff, administrator, or student, whether the project is funded (externally or internally) or receives no funding support;

and

b) said research activities are conducted in fulfillment of duties associated with the researcher’s University at Albany employment or in fulfillment of a University at Albany educational/degree requirement.

Not all activities that involve human subjects require IRB review and approval. In order to require IRB review, the activity must meet both tests of the federal regulatory definition in order to require IRB review:

The activity:

1- must be Research, and

2- must involve Human Subjects

Definitions:

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; OR obtains, uses, or analyzes individually identifiable private information or biospecimen (information that is not publicly available).

Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Interaction: Includes communication or interpersonal contact between investigator and subject (for example, interviews, focus groups, surveys – including mailed and on-line).

Intervention: Includes both manipulations of the subject or the subject's environment that are performed for research purposes (for example, placement in one of three learning conditions, use of a room with and without a mirror present) and physical procedures by which data are gathered (for example, weight measurement, blood sample).

Private information: Includes 1) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, 2) 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 school record), or 3) information provided specifically in response to data collection (for example, responses to a survey).

Confidential data: Data is confidential when the researcher can link it to a particular participant but will protect the privacy of the participant. Projects may collect data in a confidential manner but analyze and/or report it in an anonymous manner, or the data may be collected and analyzed on an anonymous basis. The consent information provided to participants should make these procedures clearly understood.
### Anonymous data:
Data that by virtue of the method of collection can never reasonably be connected with the person providing the data (for example, questionnaires that are returned by mail in envelopes with no return address or other identifying markers). There are no identifiers connected to the data and the researcher is unable to link data to any one individual.

### Identifiable data:
Information that could be used to identify an individual either directly or ascertained with a reasonable amount of effort given the totality of the data collected.

### De-identified human specimen:
To be considered not human subject research, the **human specimen** must meet one of the following standards:
- Exists without ANY personal identifiers or links to identifiers.
- Provided by a research repository (biological specimen bank, data bank, medical record system, etc.) which takes responsibility for removing any identifiers, including a code linked to identifiers, prior to providing the biological specimen or data to the researcher. Researcher cannot be one of the parties responsible for collecting or maintaining the source material.
- Provided by a supplier who maintains a firewall security preventing recipients from receiving access to identifiers.

### Discard human specimen:
A **discard human biological specimen** is that portion of a human specimen specifically collected for medical care (diagnosis, treatment, surgery) of a patient but remains after all such purposes have been met. To qualify as Not Human Subject Research, all the following criteria must be met.

- If research specimen is to be obtained prospectively at time of this IRB submission:
  - No excess specimen will be taken from the patient for research purposes at the time of specimen collection.
  - Surgeon or other medical personnel collecting the specimen for medical purposes cannot be an investigator on the study.
  - Specimen must be de-identified prior to research samples being provided to any of the investigators listed on this application.
  - If research specimen already exists ("on the shelf"), it resides without identifiers.
  - No commercial development will result from this research.
  - May include Autopsy Specimen if above criteria are met.

### Identifiable data:
Information that could be used to identify an individual either directly or ascertained with a reasonable amount of effort given the totality of the data collected.

### Publicly available:
Means available without restriction. “Publicly available” refers to sources such as telephone books and public records. Although there are organizations that make data sets broadly accessible at reasonable cost to the research community, these materials are not usually available to the public at large. If you obtain data from any of these sources, you should not assume that the source meets the definition of "publicly available."

### Research:
A **systematic investigation designed to develop or contribute to generalizable knowledge**. Research encompasses work that is conducted on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experimental methodologies, regardless of the content or routine nature of the topic and whether the work is preliminary in nature or a study proper. Research does not include activities conducted for Public Health Surveillance, Criminal Justice or Criminal Investigative Purpose or National Security Purpose.
**Systematic:** The implementation or utilization of specific methods of inquiry or data collection that is repeated with multiple participants. An activity that involves a prospective plan to incorporate data collection and data analysis to answer a question. Methodology alone does not determine the need for IRB review. Methods used in research (such as interviews or surveys) are often employed for reasons having nothing to do with research.

**Disseminate:** The sharing or distribution of results to those outside of the University via the web, poster presentations, conferences, library placement, or publication.

**Generalizable:** Designed to draw conclusions from the data; results are analyzed for predictive value; results can be applied to a larger population (i.e., applicability is not limited to the individual participants) or inform policy.

**Class Projects:** Student project/presentation conducted solely in fulfillment of educational requirement for a specific class. There will be no dissemination beyond the class. In this instance, class projects are not “generalizable” – IRB review is not required.

**Program Evaluation:** Program evaluation activities are those for which the primary purpose of the evaluation is to assess the program -- not to develop or contribute to generalizable knowledge. The evaluation is a management tool for monitoring and/or improving the program. In this instance, program evaluation projects are not “generalizable” – IRB review would typically not be required.

**Public Health Authority:** Means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

**Public Health Surveillance:** Activities limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

**Criminal Justice or Criminal Investigative Purposes:** Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order.

**National Security Purpose:** Authorized operational activities (as determined by each federal agency) in support of intelligence, homeland security, defense, or other national security missions.

If you are still unsure whether your activity constitutes research with human subjects requiring IRB approval, please complete the Screening Form. It is intended to assist researchers and the IRB in determining whether or not a project involves research with human subjects.

If you believe that your project does constitute research with human subjects requiring IRB review, do not complete this Screening Form. Instead, please complete an [IRB protocol submission form](#) or [IRB Exempt category application](#).