What is Human Research?

Overview
Any ‘agent’ of the University of Arizona (e.g. faculty, staff or students) requires IRB oversight when the activity they are conducting is both ‘research’ that involves ‘human subjects.’ Please see the guidance on ‘principal investigator (PI) eligibility’ at the University of Arizona.

First, is the activity research?

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are 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).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Second, does the activity involve human subjects?

If the investigator is conducting ‘research’ as described above, and the project involves a human subject as defined below, then activity is ‘human research’ and requires IRB oversight.

Human subject means 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
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- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The definitions below will help frame and understand the terms listed in the definition of human subject above:

- **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
  *Note that if the private information is health information from a healthcare covered entity (CE) it may be subject to the HIPAA rules.*

- **Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
  *Note the biospecimen may be subject to the HIPAA rules if it is obtained from a healthcare covered entity (CE).*

What to do next?

If it is not clear whether the project is human research, then the investigator should complete the ‘determination of human research’ form found on the Human Subjects Protection Program website. Submit the completed form to the HSPP for review. The investigator will receive a formal letter of determination for their files.

If the project clearly IS human research, then the investigator should complete the ‘application for human research’ form found on the HSPP website. The HSPP will review the activity and submit it to the IRB for approval.