What Type of Project Requires IRB Review and Approval?

The first determination a researcher must make is whether or not the proposed research falls under the federal regulations for research on human subjects. Use this Decision Tree and the definitions on the following pages to make this determination (Definitions are provided for all underlined words.)

Does this activity involve interaction or intervention with, or collection of information or specimens about, living individuals?  

No

Yes

This research does not involve human subjects. IRB review is not required and nothing needs to be submitted to the IRB.

IRB review and approval is not required, BUT you must submit the IRB Registration form identifying the criteria for waiver of review.

No

Yes

Does this activity meet the regulatory definition of research (a systematic investigation designed to develop or contribute to generalizable knowledge)?

No

Yes

IRB review is REQUIRED. Please review the Screening Questions on the IRB web site to determine if you must submit the standard IRB Application Form or if your research qualifies for an exemption. If an exemption is appropriate, an Exemption Request Form must be submitted.

No

Yes

Does the research involve interaction or intervention with the individuals?

No

Yes

Does the research involve the collection of information or specimens about, or interaction with, living individuals?

This research does not involve human subjects. IRB review is not required and nothing needs to be submitted to the IRB.

Does the research involve access to information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information.)

No

Yes

Does the research involve private information (i.e., about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, such as a medical or school record)?

No

This research does not involve human subjects. IRB review is not required and nothing needs to be submitted to the IRB.
Definitions

**Research** is defined as a systematic investigation designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or to contribute to generalizable knowledge in a particular field of study. Generalizable knowledge is knowledge that has implications for a broader group of people or that will be used to influence policy or practice. It is usually described in a formal protocol utilizing scientific methods that sets forth an objective and a set of procedures to reach that objective.

The following are typically considered research:

1. Any project, including student projects, conducted with intent to contribute to generalizable knowledge through publication and/or public presentation within an academic discipline. Presentation of a class assignment to the class and/or the writing of a class paper do not in themselves constitute public presentation or publication.

2. Graduate theses and dissertations are clearly understood as “research” and fall within IRB jurisdiction when “human subjects” are involved.

The following generally fall outside the federal definition of research under 45CFR46:

1. Normal educational activities that are designed to train students in research techniques and methods or to qualify students as researchers, when those activities are conducted as part of courses or in regular classroom settings. For such coursework, the class instructor should submit a Classroom Based Protocol application describing the general nature of student projects.

   However, individual student class projects involving vulnerable populations (children, mentally impaired, prisoners or individuals on probation) or collecting identifiable, sensitive, private information will require individual IRB review. The course instructor must review all proposed student research and insure that any student whose research project involves a vulnerable population or sensitive information submits an individual IRB application for review.

2. Contractual research such as organizational evaluations that involve surveying/interviewing individuals, if not to be disseminated beyond the organization, is not considered research subject to the regulations.

3. Medical care, quality assurance, quality improvement, certain aspects of public health practice such as routine outbreak investigations and disease monitoring, fiscal or program audits, journalism, biography, oral history.

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**Human Subject** means a living individual about whom and investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) individually identifiable private information.
**Intervention** includes both physical procedures by which data are gathered (for example, drawing blood, dispensing drugs, administering other treatments) and manipulations of the subject or the subject's environment (controlling environmental light or sound, presenting sensory stimuli, making voice, digital or image recordings) that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject through surveys, interviews, focus group meetings, etc.

Data that is **Individually Identifiable** includes, but is not limited to, names, social security numbers, medical record numbers, addresses, phone and fax numbers, email addresses, account numbers, license or certificate numbers, vehicle identifiers, codes which the researcher could reasonably use to identify a living individual, or combinations of information from which a person's identity could easily be determined.

Data is considered to be not individually identifiable if it has been stripped (by someone external to the research project) of all identifiers including, but not limited to, names, social security numbers, medical record numbers, student numbers, codes which the researcher could reasonably use to identify a living individual, or combinations of information from which a person's identity could easily be determined. Data could be from previously conducted surveys or interviews, or medical, educational or financial records.

**Private** data includes biological specimens and information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information or specimens provided for specific purposes which the individual can reasonably expect will not be made public (e.g., a medical or student record). Private data must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator or associated with the information, either directly or through a coded link) in order for obtaining the data to constitute involvement of human subjects.