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Human Subjects Research Determination

This tool provides assistance for researchers who wish to determine whether their project meets the definition of human subjects research. Throughout the tool, answer the questions with your current project in mind.

If you have any questions, please reach out to Lauren.Weisner@illinois.gov.

Step 1: Is it Research?

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

1(a) My project meets the definition of **systematic investigation**. That is, it is a detailed or careful examination that has or involves an identified approach to the activity based on a system, method, or plan

- Yes
 No

1(b) My project meets the definition of contributing to **generalizable knowledge**. That is, the information is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:

- Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study

Example: An evaluation of a grant funded program attempting to use the results to improve that specific program is typically not designed to contribute to generalizable knowledge and would not meet this definition

- Yes
 No



Count the number of questions marked "Yes".

If two questions in this section are marked "Yes", move onto the next section to determine if your project involves human subjects.

If one or more questions in this section are marked "No", your project is not research. Please complete the Not Research application.



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Step 2: Does it Involve Human Subjects?

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

2(a) My project meets the definition of **living individual**. That is, it involves individuals who are alive according to applicable local and national regulations and laws

- Yes
- No

2(b) My project meets the definition of **about whom**. That is, the data or information being collected relates to the person. Asking what they think about something, how they do something, or similar questions is usually about the individuals. Factual questions would not fall under this definition

Example: A survey of teachers that asks them factual questions about class size, classroom features, and availability of classroom materials is not about the teachers and would therefore not involve human subjects unless they are also asked to provide information about themselves (such as "How long have you been teaching")

Example: Suppose you are asking program staff "How does your program handle referrals?" If you are seeking information about the program and are asking people who are in charge of referrals, then the question is not about the person being asked. If you are seeking to find out how often staff know the correct answer, then the question is about the staff

- Yes
- No



Count the number of questions marked "Yes".

If either question in this section are marked "No", your project does not involve human subjects. Please complete the Not Research application.

If both questions are marked "Yes", move onto the next section to determine if you must go through IRB review.



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2(c) My project obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens

Relevant definitions (note, this does not have to include identifiable or private information):

- **Intervention:** Physical procedures, or manipulations of the individuals or the individual's environment, that are performed for research purposes. Manipulations may be physical, social, psychological, or emotional. "Environment" includes an individual's social and virtual environments as well as physical environment
- **Interaction:** Communication or interpersonal contact between a member of the research team and the individual. Surveys, whether in person, by mail, email, phone or social media are an example of interaction between researchers and individuals
- **Obtain:** Record in any way (writing, video, email, voice recording, photography, etc.) for research purposes and retain for any length of time

Example: Conducting an online survey to determine rates of drug use in a sample of individuals released from prison.

Yes

No

2(d) My project obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Relevant definitions:

- **Private:** 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
- **Identifiable:** the identity of the individual may be readily associated with the information or biospecimen by a member of the research team or the research team could readily identify the individual through a combination of the data or information

Example: Conducting a study in which you utilize an existing data set that contains identifying information about individuals including names, DOB, social security number, etc.

Yes

No



Count the number of questions marked "Yes".

If at least one question is marked "Yes", then your project involves human subjects and you must go through IRB review.

If no questions in this section are marked "Yes", your project does not involve human subjects. Please complete the Not Research application.