

Help tool for determining if your activity qualifies as “Human Subjects Research”

Activity Information	
Provide a clear summary of the proposed activity. Include the purpose and aims of the activity.	Click here to enter text.
Describe all activities that will be performed by or conducted under the supervision of the UMKC faculty, staff, or students.	Click here to enter text.
Describe or list all procedures to be conducted related to participants (i.e., screening, recruitment, consenting, enrollment, etc.), types of data being collected, anonymous/identifiable information and how you will be obtaining data from or about study subjects (attach any survey, interview, focus group questions, etc., if applicable)	Click here to enter text.
Why are you seeking this determination?	Click here to enter text.
Determination of Research (45 CFR 46.102(d)) <i>“Research” is defined as a systematic investigation designed to develop or contribute to generalizable knowledge.</i>	
1. What is the purpose of your activity? 2. How generalizable will the results be? a. To whom? 3. What is the importance? 4. How will it contribute to the body of knowledge? If a claim is made that it is not generalizable, that claim should be justified here.	Click here to enter text.
5. When was/will the data be collected?	Click here to enter text.
Indicate whether the activity meets the following criteria:	
A. <input type="checkbox"/> The activity is a systematic investigation : an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question	
B. <input type="checkbox"/> The activity is designed to develop or contribute to generalizable knowledge : designed to draw general conclusions (i.e. knowledge gained from a study may be applied to populations outside of the specific study population) inform policy, or generalize findings.	

Intent to publish is one of several indicators that the data may be generalizable. Activities such as oral histories, quality assurance, and investigative journalism are generally not “research” as used here. Evaluation studies may be quality assurance or may be research depending, in part, on the funding agency.

If you did not check A or B, the activity is “not research”.

If you checked both A and B, the activity is “Research”.

Go to Section IV.

Determination of the involvement of Human Subjects (45 CFR 46.102(f))

“Human Subject” means a living individual about *whom* an investigator conducting research obtains data through intervention or interaction with the individual, **or** the use of identifiable private information.

- “About whom” = *the information being elicited for the activity is about the [living] individual (the whom). The focus on the investigation is the opinions, characteristics, or behavior of the individual(s).*

1. What is the source of the recruits?
2. What identifying information is available about the individuals?

Click here to enter text.

3. What is to be done to or with the people for purposes of your study or evaluation?

Click here to enter text.

4. What information is to be obtained and how is it to be maintained?
5. How identifiable is it when you get it?
6. Where are identifiers stripped?

Click here to enter text.

Indicate whether the research meets the following criteria:

C. The research involves **living individuals**

D. The investigator will obtain data information **about** those individuals

E. the investigator will obtain **EITHER** of the following:

E.1. Collect data through **intervention** or **interaction** with an individual, including interviews, surveys, physical procedures, manipulations of the subjects environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not).

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: *communication or interpersonal contact between investigator and subject*

E.2. Obtain, view or otherwise handle any *private information* which identifies individual subject(s) through the use of either *direct identifiers* (name, address, etc.) or *indirect identifiers* in the form of a code that links back to the identity of the subject through an existing key.

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 includes (but is not limited to)*
 - Medical records and charts, specimens, data or tissue repositories
 - Employment or educational records and observations of behavior which the subject could reasonably expect no observation to be taking place
 - Personal thoughts, feelings, opinions, attitudes, beliefs, etc.

Direct identifiers include (but not limited to) name, street address, audio/video-recordings, telephone, fax, email, SSN, medical record number (Other potential identifiers evaluated on a case by case basis)

If codes and key exist, submit correspondence from the holder of the key which states that researcher will not be given access to the key under any circumstances.

If “Yes” to C, D and either E.1 or E.2, the activities involve human subjects.

Determination - Is this activity Human Subjects Research?

Applicants Request

I assert that the proposed:

- activity(ies) are research
- activity(ies) are not research
- activity(ies) involve human subjects
- activity(ies) does not involve human subjects

Signature Date

Print Name