



Human Subject Research Determination Worksheet

This is a determination guide to assist investigators to determine if their project is considered human subjects research as defined by the Department of Health and Human Services (DHHS) and would need IRB approval.

Section I

Federal regulations define RESEARCH as a **systematic** investigation designed to develop or contribute to **generalizable knowledge** [45 CFR 46.102](#)

Systematic investigation is an activity designed to test a hypothesis and to draw conclusions as described in a protocol that sets forth an objective and procedures to reach that objective.
(Note: activities such as **the practice** of social work, counseling, public health, or medicine are not research.)

Y N

Generalizable knowledge is information expressed in theories, principles, and statements of relationships that can be widely applied.
(for example: by publishing findings or presenting findings at a professional meeting also includes Graduate & Undergraduate Research Days)

Y N

Section II

Federal regulations define **HUMAN SUBJECTS** as a “living individual about whom an investigator conducting federal research obtains (1) data through intervention or interaction with an individual or (2) identifiable private information” [45 CFR 46.102](#)

Data includes information or specimens collected from living subjects.

Y N

About whom indicates the data must be personal information about an individual (the Whom”).
(The focus on the investigation is the opinions, characteristics, or behavior of the individual(s).)

Y N

Intervention includes physical procedures, manipulations of the subject, or manipulations of a subject’s environment for research purposes.
(for example: having a subject view a video or taking saliva or blood samples)

Y N

Interaction refers to communication between the investigator and the participant.
(for example: face-to-face, internet, mail, phone, etc.)

Y N

Individually identifiable means that the subject’s identity is or maybe ascertained by the investigator or others. (for example: name, address, telephone, email, or audio/video-recordings)

Y N

Private information includes information about behavior that occurs in a context in which the subject can reasonably expect that no observation or recording is taking place; or, information provided for specific purposes by the subject in which the subject can reasonably expect will not be made public. (for example: academic records, personal journals, medical records,)

Y N



Western Illinois University
Institutional Review Board

Section III

Is WIU engaged in the conduct of the Research when working with other institutions or organizations? (http://www.hhs.gov/ohrp/policy/engage08.html)	
WIU receives a direct award from sponsors, even where all activities involving human subjects are carried out by faculty, staff or other agents of another institution. <i>(For example: a grant, contract or cooperative agreement-- usually applies to Federal funding)</i>	Y <input type="checkbox"/> N <input type="checkbox"/>
WIU faculty, staff or other agents intervene for research purposes with any human subject of the research by performing invasive or noninvasive procedures. <i>(for examples: blood draws, administering counseling sessions, utilizing physical sensors or utilizing other measurement procedures)</i>	Y <input type="checkbox"/> N <input type="checkbox"/>
WIU faculty, staff or other agents intervene for research purposes with any human subject of the research by manipulating the environment.	Y <input type="checkbox"/> N <input type="checkbox"/>
WIU faculty, staff or other agents interact for research purposes with any human subject of the research. <i>(for example: conducting research interviews, or administering questionnaires)</i>	Y <input type="checkbox"/> N <input type="checkbox"/>
WIU faculty, staff or other agents obtain the informed consent of human subjects for the research.	Y <input type="checkbox"/> N <input type="checkbox"/>
WIU faculty, staff or other agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research. WIU is engaged even if the faculty or staff do not directly interact or intervene with human subjects. <i>(for example: observing or recording private behavior; using or analyzing for research purposes identifiable private information/specimens provided by another institution; or using or analyzing for research purposes identifiable private information/specimens already in the possession of the WIU faculty or staff.)</i>	Y <input type="checkbox"/> N <input type="checkbox"/>
There may be exceptions to the above statements. Contact the Compliance Specialist to discuss possible exceptions at 309-298-1191 or irb@wiu.edu	

Your responses to the above statement will assist in determining if the project is considered human subject research.

- Activities that **do** meet the definition of “human subject research” will require the submission of the *Human Subject Research- Initial Review Form*.
- Activities that **do not** meet the definition of “human subject research” do not require an IRB submission.

Continue to the next page to determine if you are required to submit the *Human Subject Research- Initial Review Form*.



Section I responses

RESEARCH response

If SYSTEMATIC INVESTIGATION is No → DO NOT complete or submit an IRB Initial Review Form

If GENERALIZABLE KNOWLEDGE is No → DO NOT complete or submit an IRB Initial Review Form

If SYSTEMATIC INVESTIGATION is Yes **and** GENERALIZABLE KNOWLEDGE is Yes → **Continue to next section**

Section II responses

DATA response

If No → DO NOT complete or submit an IRB Initial Review Form

If Yes → **Continue**

INTERVENTION or INTERACTION response

INDIVIDUALLY IDENTIFIABLE or PRIVATE INFORMATION response

If **ALL** four are NO → DO NOT complete or submit an IRB Initial Review Form

If INTERVENTION **or** INTERACTION is Yes → Submit an IRB Initial Review Form

If INTERVENTION **and** INTERACTION are No → Continue to next statement

If INDIVIDUALLY IDENTIFIABLE **or** PRIVATE INFORMATION is yes → Submit an IRB Initial Review Form

Section III responses

Is WIU engaged in the conduct of the Research?

If Section I & II above determine that your project is Human Subject Research, you are working with another institution or organization and you marked "yes" to any of the engagement statements then you will need to submit *Human Subject Research- Initial Review Form* for IRB review and approval of our project.

The following guidance documents available on the OHRP website may be helpful in determining whether research involves human subjects and also whether it is exempt: [OHRP Human Subject Regulations Decision Charts](#) (see [OHRP Guidance on Research Involving Coded Private Information or Biological Specimens](#))