Human Research Determination Form

**Purpose:** If you are working on a student thesis/project, or a faculty, student, or staff publication, survey, qualitative study, pilot study, community assessment, or another planned inquiry, complete this form to determine whether your activity requires CSU Institutional Review Board (IRB) review in order to protect human subjects.

If you require assistance in completing this form, see your CSU College or Unit IRB representative for guidance.

 Answer each question in Section A. Then proceed as instructed.

1. Does your activity ***involve Human Subjects***?

*Human subject is defined by the Department of Health and Human Services as: “a living individual, about whom an investigator (whether professional or student) conducting research (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.”*

1. Yes No Not Sure Will data be gathered about living individuals or from biospecimens?

2. Yes No Not Sure Will data be collected through interventions or interactions with individuals or biospecimens?
*For example, physical procedures, such as venipuncture, or manipulations of those individuals or their environment. (Intervention); Communication or interpersonal contact with the individuals. (Interaction)*

3. Yes No Not Sure Will the data contain private information?
*For example, the data 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).*

4. Yes No Not Sure Will the data contain identifiable information or identifiable biospecimens?
*For example, the participant’s identity is or may be readily ascertained by the investigator, or will be associated with the information; the research involves the use of coded\* data/specimens*

 If your answer to any question in Section A is “Yes”, continue to Section B.

 If your answers to ***all*** questions in Section A are “No”, no IRB review is required.

 If your answer to any question in section A is “Not Sure”, obtain guidance from your CSU College or Unit IRB
 representative and continue to Section B.

1. ***Is the activity Research***?

*Is the activity a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?*

1. Yes No Not Sure Is the activity an investigation?
*Investigation: a searching inquiry for ascertaining facts; detailed or careful examination*

2. Yes No Not Sure Is the investigation systematic?
*Systematic: having or involving a system, method, or plan*

3. Yes No Not Sure Is the systematic investigation designed to develop or contribute to knowledge?
*Designed: done with purpose and intent. Develop: to elaborate or expand in detail. Contribute: to be an important factor in; help to cause. Knowledge: truths, facts, information.*

4. Yes No Not Sure Is the knowledge generalizable?
*Generalizable: universally applicable*

If your answer to ANY question in Section A is “Yes” and your answer to ANY question in Section B is “Yes”, then
(a) complete Sections C and D below and (b) you must submit an application for this activity to the CSU IRB for review and approval before obtaining information from the participants in the activity (i.e., human subjects).

If your answer to ALL questions in Section B is “No”, then the activity does not meet the definition of Human Subjects Research and no IRB review is required.

If your answer to any question in Section B is “Not Sure”, then contact your CSU College or Unit IRB representative for guidance, and complete Section C below.

1. Does your study or activity ***involve special populations that need protection***?

Does the activity intentionally focus on or include one or more of the following specific populations? Check all that apply:

 Children under the age of 14 years outside of an educational setting.

 Neonates/Fetuses

 Pregnant women

 Prisoners

 Any other population that requires protection? Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Does your activity involve the ***use of Coded Data*?**

“Coded” means that a living individual’s identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof, and that there is a key exists that links the code to that person’s identifiable information. Coded data are considered “identifiable” under the Common Rule.

Is coding being used as part of this study:
 NO, data are de-identified and no key exists that can link the data/biospecimen to living persons.
 Yes: complete items 1-4 below.

If the research activity involves the use of coded data or biospecimens that are NOT collected specifically for this activity through an interaction or intervention with living individuals, then ONE OF THE FOLLOWING MUST BE TRUE:

1. The provider of the data or biospecimens will remove the code before sending the data/biospecimen to the researcher.
 Yes No

OR
2. The holder of the key and the investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the study subjects are deceased. Provide a copy of this agreement—an informal email exchange is sufficient.
 Yes No

OR
3. The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased. (Provide this documentation.)
 Yes No

OR
4. There are other legal requirements prohibiting the release of the key to the investigator, until the individuals are deceased. (Provide this information.)

 Yes No