



Human Research Determination Worksheet

This worksheet is intended to provide support for individuals in determining whether an activity is *human research* and/or how the activity should be regulated. This worksheet is not meant to be completed or retained on record. Decisions on whether IRB review is required for activities can only be made by the SLU IRB. For an official determination, please submit the [SLU IRB Human Subjects Research Determination Form](#).

Is it human research under DHHS Regulations?

A. “Human”

1. Does activity involve human subjects? (45 CFR 46.102(f)) Yes No

Human subject: a *living* individual about whom an investigator conducting research collects data ([OHRP](#))

2. Does activity involve the prospective collection of data or information through **intervention** or **interaction** with the individual? (45 CFR 46.102(f)) Yes No

Intervention: physical procedure by which data are gathered **or** manipulations of the subject or the subject’s environment that are performed for research purposes ([OHRP](#))

Interaction: communication or interpersonal contact with the individuals (including electronic interaction) ([OHRP](#))

3. Does activity involve the collection or use of **individually identifiable** and **private** information? (45 CFR 46.102(f)) Yes No

Individually identifiable: information contains one or more elements that identify the individual **or** can be combined with other available information to ascertain the identity of the individual ([OHRP](#))

Private information: information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical or psychological information) **or** information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place ([OHRP](#))

If answered “Yes” to question 1 **and** question 2 **or** 3, activity involves human subjects.

4. Does activity involve human subjects as defined in DHHS regulations? Yes No

B. “Research”

5. Is the activity **systematic**? (45 CFR 46.102(f)) Yes No

Systematic: activity that involves data collection, either quantitative or qualitative, and data analysis to answer a question

6. Is the activity an **investigation**? (45 CFR 46.102(f)) Yes No

Investigation: activity that involves development, testing, evaluation, and/or search for information



Human Research Determination Worksheet

This worksheet is intended to provide support for individuals in determining whether an activity is *human research* and/or how the activity should be regulated. This worksheet is not meant to be completed or retained on record. Decisions on whether IRB review is required for activities can only be made by the SLU IRB. For an official determination, please submit the [SLU IRB Human Subjects Research Determination Form](#).

7. Is the activity designed to **generate or contribute to generalizable knowledge**? (45 CFR 46.102(f)) Yes No

Generalizable knowledge: activity that draws general conclusions (knowledge gained may be applied to other populations outside of study), informs policy, or is universally or widely applicable; contributing to generalizable knowledge normally involves public dissemination of that knowledge

If answered “Yes” to questions 5, 6, **and** 7, activity meets the definition of research.

8. Does the activity meet the definition of research defined in DHHS regulation? Yes No

C. “Human Research”

If answered “Yes” to questions 4 **and** 8, activity is human research as defined by DHHS and subject to IRB review.

9. Does the activity meet the definition of human research per DHHS regulations and thus subject to IRB review? Yes No

Is it human research under FDA Regulations?

10. Are any of the following statements true?

- a. Activity is conducted in the United States and involves use of a drug in one or more human subjects (as recipients of a test article or as controls, patient or healthy, [21 CFR 50.3](#)), but is **not** the use of an approved drug in the course of medical practice. Yes No
- b. Activity is conducted in the United States and evaluates the safety or effectiveness of a device in one or more human subjects. Yes No
- c. Data regarding subjects (including controls) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit. Yes No
- d. Data regarding the use of a device (IVD) on human specimens (including de-identified/anonymous specimens) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit. Yes No

If answered “Yes” to **any** of the items 10a-10d, the activity is human research per FDA regulations and subject to IRB review.

11. Does the activity meet the definition of human research per FDA regulations and thus subject to IRB review? Yes No

(Note: If activity is determined to be human research, subject to FDA regulation, this does not necessarily mean it is also subject to DHHS regulation, and vice versa. Separate determinations should be made.)