PRESBYTERIAN

Human Research Determination Form

Complete this form to help determine if your project qualifies as research that involves the use of human participants. You may submit it to the IRB if you would like consultation or assistance in making the determinations.

Important Notice:

1. This form is a guide for researchers. The IRB will make the final determination whether a project qualifies as human subjects research.
2. By PHS policy, any project that may be human subjects research must be submitted to the IRB for determination.

A. **"Human"**

	Yes	No		
1. Does activity involve human subjects? (45 CFR 46.102(f)) *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)) *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)) *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 the answer to question 1 and question 2 or 3 is yes, the activity involves human subjects.*			**Yes** ☐	**No** ☐

4. Does activity involve human subjects as defined in DHHS regulations?				

B. "Research"

	Yes	No		
5. Is the activity systematic? (45 CFR 46.102(f)) *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)) *Investigation: activity that involves development, testing, evaluation, and/or search for information.*	☐	☐		
7. Is the activity designed to generate or contribute to generalizable knowledge? (45 CFR 46.102(f)) *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 the answer to questions 4, 5 and 6 is yes, the 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 the answers to question 4 and 8 is yes, the activity is human research as defined by DHHS and subject to IRB review.

Does the activity meet the definition of human research per DHHS regulations and thus subject to IRB review?

☐ Yes ☐ No

D. **The activity qualifies as human research under FDA regulations if any of the following statements are true:**

1. 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

2. Activity is conducted in the United States and evaluates the safety or effectiveness of a device

in one or more human subjects.

☐ Yes ☐ No

3. 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

4. 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 D. 1-4, the activity is human research per FDA regulations and subject to IRB review*

E. Does the activity meet the definition of human research per FDA regulations and thus subject to IRB review?

☐ Yes ☐ No