Driscoll Children's Hospital (DCH)
Institutional Review Board (IRB)

Determining Whether an Activity is Human Research

According to federal regulations from the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), all human research must be reviewed and approved by the IRB. This worksheet is designed to determine whether an activity is considered human research under either regulation. Answer the questions in the order they appear on the worksheet. The IRB Office can provide assistance with making this determination.

Step 1. Determining Whether the Activity is Human Research According to DHHS Regulations

Criterion 1 – Is this activity research? *Answer the following questions in the order indicated. [Follow the instructions on the form]*	**YES**	**NO**
Question 1.1. Is this activity part of a systematic investigation (including research development, testing and evaluation)?	☐	☐
Question 1.2. Is this activity designed to contribute to generalizable knowledge?	☐	☐
	If you answered yes to both, then the activity is research, **Go to criterion 2 to determine if the research involves human subjects**	If you answered no to both, then the activity is not considered human research by HHS. Go to FDA questions in **Step 2**

Criterion 2 – Determining whether the research involves human participants. . *Answer the following questions in order indicated.*		**YES**	**NO**
Question 2.1. Will the investigator obtain data about living individuals?		☐ **Go to question 2.2**	☐ STOP Not HHS human research, Go to FDA **Step 2**
Question 2.2. Are either or both of the following statements true? Note: place a check next to each true statement below ↓ -- if neither are true, check no in the column to the right →		☐ **The activity is Human Research according to HHS regulations** Continue to FDA **Step 2**	☐ STOP Not HHS human research, Go to FDA
True	**Statement 1** - The investigator will obtain data through intervention or interaction with the individuals mentioned in		

☐	question 2.1. Note: 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 includes communication or interpersonal contact between investigator and subject.			Step 2
True ☐	**Statement 2** - The information obtained by the investigator is both private and identifiable. Note: place a check next to each true statement below ↓ -- (both statements must be checked for this statement to be true)			
	True ☐	The information is **private** because it 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).		
	True ☐	The information is **individually identifiable** because the identity of the participant is or may be ascertained by the investigator or associated with the information.		

Step 2. Determining Whether the Activity is Human Research According to FDA Regulations

Criterion 1 – Determining whether the activity involves an FDA regulated test article. *Answer the following questions in order indicated.*	**Yes**	**No**
Does the activity involve the use of a drug, other than the use of a marketed drug in the course of medical practice?	☐	☐
Does the activity involves the use of a device to evaluate safety or effectiveness of that device?	☐	☐
Will data from the activity will be submitted to, or held for inspection by the FDA in support of a marketing or research application for an FDA-regulated product?	☐	☐
	If you answered yes to ANY, then the activity involves an FDA regulated test article, **Go to criterion 2**	If you answered no to ALL, then the activity is not Human Research according to FDA regulations  Go to Step 3

Criterion 2 – Determining whether the activity involves human participants. *Answer the following questions in order indicated*	**Yes**	**No**
Will the test article be used on one or more humans?	☐	☐
Will data obtained from controls be submitted to, or held for inspection by the FDA in support of a marketing or research application for an FDA-regulated product?	☐	☐
Will data obtained from use of a device on tissue specimens be submitted to, or held for inspection by, the FDA in support of a marketing application or research application for an FDA regulated product?	☐	☐
	If you answered yes to any of the questions, **the activity is Human Research according to FDA regulations**	If you answered no to ALL, then the activity is not Human Research according to FDA regulations

Step 3 - Summary of HHS & FDA

Final Determination: *Use the determinations in Step 1 & 2 to complete this section.*	**Yes**	**No**
Is this activity Human Research according to **HHS** regulations? ("yes" to Step 1, question 2.2 above)	☐	☐
Is this activity Human Research according to **FDA** regulations? (Step 2, answered yes to the bottom of criterion 2)	☐	☐
	If you answered yes to either, then the activity is human research. This human research must be approved by IRB. 	If you answered no to both, continue to Step 4

Step 4. HHS Funded Research Projects

	Yes	**No**
Will the DCH or an affiliated institution receive a direct federal (e.g., DHHS) award to conduct human subjects research, even where all activities involving human subjects are carried out by a non-DCH entity (e.g., subcontractor or collaborator)? Research Funding from the Department of Health and Human Services (DHHS) includes: Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); National Institutes of Health (NIH)	☐ This human research must be approved by IRB.	☐ This activity is not human research.

Non-Research/Non-Human Research

An investigator may request a determination that an activity is “Non-research" or "Non-Human Subjects Research,” but the final determination will be made by the IRB.