Avera

Institutional Review Board
Checklist: Human Subject Research Determination

NUMBER	HRP-310

The purpose of this checklist is to provide support for individuals in determining whether an activity is Human Research or how it is regulated**. This worksheet must be used, and returned to the IRB**

IRB Number:	
Protocol Name:	
Investigator:	
Reviewer Name:	

1 Research as Defined by DHHS Regulations (Check if "Yes")		
☐	Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)	
☐	Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.)	
☐	Is the systematic investigation designed to develop or contribute to generalizable knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Generalizable Knowledge: Information where the intended use of the research findings can be applied to populations or situations beyond that studied.	
☐	Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.)	
2 Human Subject Under DHHS Regulations (Check if "Yes")		
☐	Is the investigator conducting the Research gathering information or biospecimens about *living* individuals?	
3 Human Subject Under DHHS Regulations (Check if "Yes")		
☐	Will the investigator gather that data through either of the following mechanisms? Specify which mechanism(s) apply, if yes:	
	☐	Physical procedures or manipulations of those individuals or their environment for research purposes ("intervention").
	☐	Communication or interpersonal contact with the individuals ("interaction").
4 Human Subject Under DHHS Regulations (Check if "Yes")		
☐	Will the investigator gather data that is either? Specify which category(s) apply if yes:	
	☐	The data is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private Information").
	☐	Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will **NOT** be made public, such as medical record (i.e. "Private Information").
☐	Can the individuals' identities be readily ascertained or associated with the information by the investigator (i.e. "Identifiable information")?	
If all items are checked under 1, 2, and 3 OR 1, 2, and 4, the activity is Human Research under DHHS regulations.		
5 Human Research Under FDA Regulations (Check if "Yes")		
☐	Does the activity involve any of the following? ☐ In the U.S.: The use of a drug in one or more persons other than use of an approved drug in the course of medical practice. ☐ In the U.S.: The use of a device in one or more persons that evaluates the safety or effectiveness of that device. ☐ Data regarding subjects or control subjects submitted to or help for inspection by FDA. ☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or help for inspection by FDA.	
If anything in Section 5 is Checked, then the activity is Human Research under FDA Regulations.		
If the activity is Human Research under DHHS or FDA regulations, it is Human Research under Avera policy, and needs to be reviewed by the IRB.		

Chart 1: Is an Activity Research Involving Human Subjects?

https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1 (Additional charts here)