



Title:	Human Subject Research Determination		
SOP Number:	501	Effective Date:	April 6, 2018
Previous Version Dates:	June 2, 2017		

1 Purpose

All non-exempt human subjects research must be reviewed by the IRB. The first step in determining whether research must be reviewed is to determine whether it meets the regulatory definition of human subjects research.

2 Procedure

2.1 Initial Determination by Investigator

The responsibility for initial determination whether an activity constitutes human subject research rests with the investigator. The investigator should make this determination based on the definitions of “human subject” and “research” in SOP 101.3. Because they will be held responsible if the determination is not correct, investigators are urged to request a confirmation that an activity does not constitute human subject research from the OHRE. The request must be made through IRBIS using the online form that guides them through the determination as to whether their project is human subjects research or not. If not, they can get a “Not Human Subjects Research” letter from the IRB. If so, they go on to complete the application. All requests must include sufficient description of the activity and the rationale for the investigator’s initial determination.

2.2 Determinations by the OHRE

Determinations whether an activity constitutes human subject research will be made according to the definitions in SOP 101.3. Determinations regarding activities that are either clearly human subject research or clearly not human subject research, may be made by the IRB Analysts. Determinations regarding less clear-cut activities will be referred to the IRB Chair, who may make the determination or refer the matter to the full IRB.

Documentation of all determinations made through the OHRE will be recorded and maintained in IRBIS.