Determination of "Research"
(ver 2.0; 12 Dec 2024)

Principal Investigator	Name (First Last)	
Funding Opportunity/ Grant Number		
Grant Title		
Sponsor	Select One; if Other, please specify	If other, please specify
Due Date	Day, Month, Year	
Brief Abstract/ Summary of Project	d	

Principal Investigator

For ORSP

Research as defined by the Department of Health and Human Services means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)). Research is considered synonymous with Clinical Investigation as defined by the FDA. The following activities are considered not research by DHHS:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

The proposed activity:

- is **systematic investigation** (*an activity that is planned in advance and that uses data collection and analysis to answer a question.*) Select one

- will result in **generalizable knowledge** (*information that expands the knowledge base of a scientific discipline or other scholarly field of study*.) Select One

- is a **Clinical Investigation** *(as defined by the FDA, is synonymous with "research" as defined by DHHS and means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA, or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.)* Select One

If the answer to any of the above is "yes", then the study is classified as "research" and all compliance needs must be met according to the timelines of the sponsor

Does this study need IRB approval (*i.e., is it considered research with human subjects)?*

- are **living individuals** about whom an investigator conducting the research:
    - Obtains information or bio-specimens through intervention or interaction with the individual — Select One
    - Uses, studies, or analyzes the information or bio-speciments — Select One

      OR
    - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens. — Select One

If the answer to the first question and ***either*** of the second two questions is "yes", then it is considered "human research" and IRB approval is necessary and must be in place according to the timelines of fthe sponsor and before the collection of any data and/or the access to any funds.