ID:	
Notes:	

Is an activity Research Involving Human Subjects?

Common Rule:[1]

☐ Check here to apply the <Original Rule>

Which category describes this activity?

- ○ 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 (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- ○ 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.
- ◉ None of the above

Is the activity a **Systematic Investigation Designed to Develop or Contribute to Generalizable Knowledge**?

◉ Yes ○ No ○ Uncertain

Is the activity an **Investigation** (a searching inquiry for ascertaining facts; detailed or careful examination)?

○ Yes ○ No

Is the investigation **Systematic** (carried out according to a plan)?

○ Yes ○ No

Is the systematic investigation **Designed** (following a behavior devised) to Develop (form the basis of in the future) or **Contribute** (add to) Knowledge (facts and understanding)?

○ Yes ○ No

Is the knowledge the systematic investigation is designed to develop or contribute **Generalizable** (widely and universally applicable)?

○ Yes ○ No

The activity is NOT <Research as Defined by HHS>

The activity is <Research as Defined by HHS>

Will the investigator conducting the research obtain information or biospecimens about living individuals?
◉ Yes ○ No

Will the investigator obtain the information through communication or interpersonal contact between investigator and individual? ("interaction")
○ Yes ◉ No

Will the investigator use, study, or analyze the information or biospecimens obtained through interaction?
○ Yes ○ No

Will the investigator obtain the information or biospecimens through physical procedures or manipulations of the individual or the individual's environment that are performed for research purposes? ("intervention")
○ Yes ◉ No

Will the investigator use, study, or analyze the information or biospecimens obtained through intervention?
○ Yes ○ No

Will the investigator obtain information that is either or both: ("private information")
- About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place?
- Provided for specific purposes by the individual where the individual can reasonably expect the information will not be made public?

◉ Yes ○ No

Can the identity of the individual be readily ascertained by the investigator or associated with the information? ("Identifiable Information")
○ Yes ◉ No

Can the identity of the individual be readily ascertained by the investigator or associated with the biospecimens? ("Identifiable Biospecimen")
○ Yes ◉ No

Will the investigator conducting the research obtain information about living individuals?
○ Yes ○ No

Will the investigator obtain the information through communication or interpersonal contact between investigator and individual? ("interaction")
○ Yes ○ No

Will the investigator obtain the information through physical procedures or manipulations of the individual or the individual's environment that are performed for research purposes? ("intervention")
○ Yes ○ No

Will the investigator obtain information that is either or both: ("private information")
- About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place?
- Provided for specific purposes by the individual where the individual can reasonably expect the information will not be made public?

○ Yes ○ No

Can the identity of the individual be readily ascertained by the investigator or associated with the information? ("Identifiable")
○ Yes ○ No

The <Research as Defined by HHS> does not involve <Human Subjects as Defined by HHS>

The activity is <Human Research as Defined by HHS>

FDA[2]

Will data be submitted to or held for inspection by FDA in support of a research application or marketing permit?

◯ Yes ◯ No

Will the protocol be conducted in the United States?

◯ Yes ◯ No

Drugs

Does the protocol involve an article that is: ("drug")
(1) Recognized by the FDA as an approved drug;
(2) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or
(3) Not a food or dietary supplement but is intended to affect the structure or any function of the body.

◯ Yes ◯ No

Does the protocol specify the use of that drug in one or more humans in a way that is not completely up to the discretion of a practitioner?

◯ Yes ◯ No

Does the protocol gather data from controls to compare to data from another protocol that specifies or specified the use of that drug in one or more humans in a way that is not completely up to the discretion of a practitioner?

◯ Yes ◯ No

Will a physician be treating a patient with an unapproved drug?

◯ Yes ◯ No

Devices

Does the protocol involve an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: ("device")
(1) Recognized by the FDA as an approved device;
(2) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or
(3) Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

◯ Yes ◯ No

Does the protocol evaluate the safety or effectiveness of the device through its use in one or more humans?

◯ Yes ◯ No

Does the protocol gather data from controls to compare to data from another protocol that evaluates or evaluated the safety or effectiveness of the device through its use in one or more humans?

◯ Yes ◯ No

Does the protocol evaluate the safety or effectiveness of the device through its use one or more human specimens from living individuals?

◯ Yes ◯ No

The activity is <Human Research as Defined by FDA> involving a drug

The activity is <Human Research as Defined by FDA> involving a device

The activity is NOT <Human Research as Defined by FDA>

Footnotes

1. 45 CFR §46.102
1. 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2, 21 CFR §812.3, FDC Act §201(g), FDC Act §201(h)