The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulated. This worksheet is to be used. It does not need to be completed or retained. The IRB retains final authority for making human subjects determinations.\(^1\)

### 1. Research as Defined by DHHS Regulations

- Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)
- Is the investigation systematic? (Systematic: carried out according to a plan, system, or method)
- Is the systematic investigation designed to develop or contribute to knowledge? (Designed: following devised behaviors, used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: add to. Knowledge: truths, facts, and understanding.)
- Is the knowledge the systematic investigation designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.)

### 2. Human Subject Under DHHS Regulations
- Will the investigator conducting the research gather information or biospecimens about living individuals?

### 3. Human Subject Under DHHS Regulations
- Will the investigator gather that data through either of the following mechanisms (specify which mechanism(s) apply):
  - 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
- Will the investigator gather data that is either? Specify which category(s) apply if yes:
  - The data are 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 a medical record (i.e., "Private information").
  - Can the individuals’ identities be readily ascertained or associated with the information by the investigator (i.e., "Identifiable private information")?
  - Can the individuals’ identities be readily ascertained or associated with the biospecimens (i.e., "Identifiable Biospecimen")?

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 DHHS Regulations
- Has a department or agency head, covered by the Common Rule, retained final judgment (consistent with the ethical principles of the Belmont Report) that the activity is Human Research under DHHS regulations?
  - If checked, the activity is Human Research under DHHS regulations.

### 6. Human Research Under FDA Regulations
- Does the activity involve any of the following? (Check all that apply)

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\(^1\) This document satisfies AAHRPP elements I.1.A, III.1.A

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The term “drug” means: (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

“Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similiar or related article, including any component, part, or accessory, which is: (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, 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.

This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

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