This worksheet is used when individuals need assistance in determining whether an activity is <Human Research> and whether it is FDA-regulated.

### HHS

1.1 and 2.2 must be Yes to be human research under HHS. (see Footnotes 1 and 2)

#### 1.1

**Research:** Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? 45 CFR §46.102(d)

- **Y** Yes
- **N** No

1.1.1 Is the activity an **Investigation** (a searching inquiry for ascertaining facts; detailed or careful examination)?
- **Y** Yes
- **N** No

1.1.2 Is the investigation **Systematic** (carried out according to a plan)?
- **Y** Yes
- **N** No

1.1.3 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)?
- **Y** Yes
- **N** No

1.1.4 Is the knowledge the systematic investigation is designed to develop or contribute **Generalizable** (widely and universally applicable)?
- **Y** Yes
- **N** No

#### 1.2

**Human Subject:** Are there any living individuals about whom an investigator conducting research obtains: 45 CFR §46.102(f)

- **(1)** data through intervention or interaction with the individual, or
- **(2)** identifiable private information?

Or is the research funded by the Public Health Service Act and carried out on newborn dried blood spots collected after 3/15/2015?

- **Y** Yes
- **N** No

1.2.1 Will the investigator conducting the research gather data about living individuals?
- **Y** Yes
- **N** No

1.2.2 Will the investigator obtain that data through physical procedures or manipulations of the individual or the individual’s environment that are performed for research purposes? ("intervention")
- **Y** Yes
- **N** No

1.2.3 Will the investigator obtain that data through communication or interpersonal contact between investigator and individual? ("interaction")
- **Y** Yes
- **N** No

1.2.4 Will that data include information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public? ("private information")
- **Y** Yes
- **N** No

1.2.5 Can the identity of the individual be readily ascertained by the investigator or readily associated with the information by the investigator? ("individualy identifiable information") (see Footnote 3 for coded data guidance)
- **Y** Yes
- **N** No

1.2.6 Is the research funded by the Public Health Service Act and carried out on newborn dried blood spots collected after 3/15/2015?
- **Y** Yes
- **N** No

### FDA (see Footnotes 5, 6, and 7) 21 §50, §56.102, §312.3, §812.3

2.1 Will data be submitted to or held for inspection by FDA in support of a research application or marketing permit?
- **Y** Yes
- **N** No

2.2 Will the protocol be conducted in the United States?
- **Y** Yes
- **N** No

2.3 Does the protocol specify the use of a drug in one or more humans in a way that is not completely up to the discretion of a practitioner?
- **Y** Yes
- **N** No

2.4 Does the protocol gather data from controls to compare to data from another protocol that specifies or specified the use of a drug in one or more humans in a way that is not completely up to the discretion of a practitioner?
- **Y** Yes
- **N** No

2.5 Will a physician be treating a patient with an unapproved drug?
- **Y** Yes
- **N** No

2.6 Does the protocol evaluate the safety or effectiveness of a device through its use in one or more humans?
- **Y** Yes
- **N** No

2.7 Does the protocol gather data from controls to compare to data from another protocol that evaluates or evaluated the safety or effectiveness of a device through its use in one or more humans?
- **Y** Yes
- **N** No

2.8 Does the protocol evaluate the safety or effectiveness of a device through its use one or more human specimens from living individuals?
- **Y** Yes
- **N** No

### 3. Notes

### 4. Footnotes

4.1 The Department of Justice does not consider implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects to be research.

4.2 The Department of Energy defines “research involving human subjects” to also includes studies of the intentional modification of the human environment, generalizable includes the study of tracer chemical, particles or other materials to characterize airflow. Generalizable also includes studies in occupied homes or offices that:
- • Manipulate the environment to achieve research aims.
- • Test new materials.
- • Involve collecting information on occupants’ views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
  Generalizable should be viewed in terms of the contribution to knowledge within the specific field of study.
4.3 OHRP considers the answer to this question to be “No: when information or specimens cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. In the following three situations OHRP automatically considers that answer to this question to be “No”:

- The investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement).
- There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased.
- There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

The above situations are examples. There may be other where OHRP would consider information to be not identifiable. (OHRP - Guidance on Research Involving Coded Private Information or Biological Specimens)

4.4 See section 12 of Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240). OHRP advises that stakeholders initially consult the relevant funding agencies for advice regarding implementation of this law. OHRP may be contacted with further questions.

4.5 Drug means an article that is: FDC Sec. 201(g)

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.

4.6 Device means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: FDC Sec. 201(g)

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.

4.7 FDA does NOT consider some mobile medical applications to meet the definition of medical device. See "Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications" for examples and additional information. [http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf](http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf)