Human research determinations

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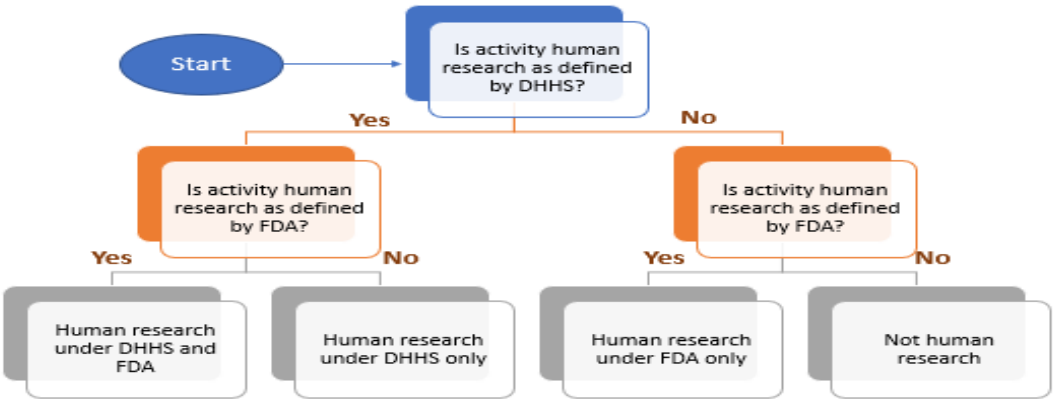

1. Minnesota State Law

- If the box is checked: The activity is human subject research under Minnesota law

☐ 1.1 The research activity includes collection or analysis of newborn dried blood spots or test results from the Minnesota Department of Health (MDH) for public health studies or research not related to newborn screening[i], either identifiable or de-identified.

2. Common Rule (45 CFR 46 Subpart A)

2.1 Activities defined as NOT research by DHHS Regulations (when following 2018 Revised Common Rule requirements)

- If none of the boxes are checked: Continue to 2.2

☐ 2.1.1 **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.
- If the focus includes generalizing to other individuals, then the activity may be research and should be evaluated against the definition of research provided in Section 2.2. *Do not check this box*
- Note that it is not the particular field (e.g., biography, legal research) that removes an activity from being consider research, but rather the particular activity's focus on specific individuals.

☐ 2.1.2 **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).

☐ 2.1.3 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.

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

2.2 Research as defined by DHHS regulations (check the boxes that apply)

- All boxes checked: the activity is research, continue to section 2.3 to consider "human subject"
- All boxes are not checked: the activity is not research under DHHS, go to Section 3 FDA

☐ 2.2.1 Is the activity an investigation (a searching inquiry for facts; detailed or careful examination)?

☐ 2.2.2 Is the investigation systematic (having or involving a system, method, or plan)?

☐ 2.2.3 Is the systematic investigation designed to develop or contribute to knowledge (truths, facts, information)?

☐ 2.2.4 Is the systematic investigation designed to contribute to generalizable (universally or widely applicable) knowledge?

2.3 Human subject as defined by DHHS regulations

- If all boxes are checked: human subjects are involved in the research. IRB review is required (the research may qualify for "exempt" status upon submission to the IRB for a determination).
- If all boxes are not checked: Go to Section 3 FDA

☐ 2.3.1 The activity involves **living individuals.** Individuals who are alive according to applicable local and national regulations and laws. For specimens, data, and other information gathered without direct interaction with the individual, it is assumed that the individuals are alive unless the researcher specifically knows otherwise.

☐ 2.3.2 **About whom:** The data or information relates to the person. Asking what they think about something, how they do something, or similar questions is usually about the individuals. This is in contrast to questions about factual information not related to the person. Biospecimens are always considered to be about the person.

☐ 2.3.3 Select all that apply (only one needs to be checked below to check the box in the left-most column):

☐ Use, study or analyze information or biospecimens obtained through either intervention (physical procedures or manipulation of those individuals or their environment for research purposes) OR interaction (communication or interpersonal contact with the individual) with the individual; **and/or**

☐ Gather data that are either:

(1) about behavior that occurs in a context in which an individual can reasonable expect that no observation is taking place (**private information**) OR

(2) individuals have provided the data for specific purposes and which the individual can reasonably expect will not be made public, such as a medical record (**private information**)

AND

(1) the individuals' identities can be readily ascertained or associated with the information by the investigator (**identifiable private information**) OR

(2) the individuals' identifies can be readily ascertained or associated with the biospecimens (**identifiable biospecimen**)

3 Human Research under FDA Regulations

- If any of the boxes are checked: the activity is human research under the FDA regulations.
- If none of the boxes are checked: the activity is NOT human research under the FDA regulations.

☐ 2.1 The activity involves any of the following (check all that apply):

☐ In the United States: The use of a drug[ii] in one or more persons other than use of an approved drug in the course of medical practice[iii].

☐ In the United States: The use of a device[iv] in one or more persons that evaluates the safety or effectiveness of that device.

☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[v].

☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[vi].

If the activity meets the definition of "research" and "human subject", then the activity must comply with the FDA regulations about informed consent (21 CFR 50) and IRB review (21 CFR 56). This does not necessarily mean that an Investigational New Drug (IND) approval or Investigational Device Exemption (IDE) is required from the FDA.

[i] The Revised Common Rule (2018 Rule) revoked Section 12 of the Newborn Screening Saves Lives Reauthorization Act (NSSLRA) of 2014 which prohibited IRBs from waiving consent, regardless of identifiability. Thus, unless indicated by state law (such as in Minnesota), DHHS considers research involving only non-identified newborn dried blood spots, as not human research. The state of Minnesota has legislation regarding research involving newborn screening dried blood spots and test results obtained by the Minnesota Department of Health that is more restrictive. Although the federal government has altered its position regarding research with newborn screening samples, these activities are still regulated as Human Research under Minnesota statute.

[ii] 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).

[iii] "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.

[iv] The term ''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:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, 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.

[v] 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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