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| 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 | |
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| 1. Activities Defined as Not Research by DHHS Regulations[[1]](#endnote-1) (Check if one of the following is true.  Not applicable to FDA regulated research.) | |
|  | The following are deemed not to be Research (when following 2018 revised Common Rule requirements)  (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.  (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).  (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.  (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. |
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| 1. Research as Defined by DHHS Regulations[[2]](#endnote-2) (Check if “Yes”. Not applicable to FDA regulated research.) | |
|  | Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.) |
|  | Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.) |
|  | Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.) |
|  | Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.) |
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| 1. Human Subject Under DHHS Regulations (Check if “Yes”. Not applicable to FDA regulated research.) | |
|  | Is the investigator conducting the Research gathering information or biospecimens about *living* individuals? |
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| 1. Human Subject Under DHHS Regulations (Check if “Yes”. Not applicable to FDA regulated research.) | |
|  | Human Subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. Will the investigator use, study, or analyze information or biospecimens obtained through any of the following mechanisms? If yes, 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”).  For research involving coded private information or specimens, not regulated by the FDA:  Research involving coded private information or specimens does not involve human subjects under DHHS Regulations if both conditions below are met:  (1) The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and  (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example, there are agreements, IRB-approved policies and procedures, or legal requirements in place that prohibit the release of the key to the code to the investigators under any circumstances until the individuals are deceased.[[3]](#endnote-3) |
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| 1. Human Subject Under DHHS Regulations (Check if “Yes”. Not applicable to FDA regulated research.) | |
|  | 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 information”)? |
|  | Can the individuals’ identities be readily ascertained or associated with the biospecimens (i.e., “identifiable biospecimen”)? |
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| 1. Research Involving Newborn Dried Blood Spots (Check if “Yes”) | |
|  | Does the activity include:  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[[4]](#endnote-4), either identifiable or de-identified. |
| **If all items are checked under 2, 3, and 4 or 2, 3, and 5, the activity is Human Research under DHHS regulations. If Section 6 is checked, then the activity is Human Research under Minnesota law. Continue to section 7 and 8 to determine whether the activity is Human Research by determination of a department or agency head or Human Research under FDA Regulations.** | |
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| 1. Human Research Under DHHS Regulations (Check if “Yes”) | |
|  | 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. | |
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| 1. Human Research[[5]](#endnote-5) Under FDA Regulations (Check if “Yes”) | |
|  | Does the activity involve any of the following? **(Check all that apply)**  In the United States: The use of a drug[[6]](#endnote-6) in one or more persons other than use of an approved drug in the course of medical practice[[7]](#endnote-7).  In the United States: The use of a device[[8]](#endnote-8) 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[[9]](#endnote-9).  Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[[10]](#endnote-10). |
| If **“Yes”,** the activity is Human Research under FDA regulations. | |
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| **If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under university policy. For Human Research under DHHS regulations, determine whether the university is engaged. The question of engagement does not apply to FDA regulated Human Research.** | |
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| 1. Engagement (Complete if the activity is Human Research that is conducted or supported by DHHS. (Check if “Yes”) | |
|  | The university is engaged in Human Research. Use WORKSHEET: Engagement (HRP-311). |
| Comments: | |

1. 45 CFR 102(l). Note that the activity may still be research as defined by FDA or DOJ. [↑](#endnote-ref-1)
2. The following activities conducted or supported by the Department of Defense (DOD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01. [↑](#endnote-ref-2)
3. As described in OHRP’s 2008 Guidance, “[Coded Private Information or Specimens Use in Research](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html)” [↑](#endnote-ref-3)
4. iii  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. See “POLICY: Minnesota State Laws Affecting Human Research (HRP-112).” 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. [↑](#endnote-ref-4)
5. Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used. [↑](#endnote-ref-5)
6. The term ‘‘drug’’ means:

   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

   articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

   articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

   articles intended for use as a component of any article specified in clause (A), (B), or (C). [↑](#endnote-ref-6)
7. “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. [↑](#endnote-ref-7)
8. 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:

   recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

   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

   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. [↑](#endnote-ref-8)
9. 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. [↑](#endnote-ref-9)
10. 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. [↑](#endnote-ref-10)