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|  University of Washington Human Subjects DIvision | **WORKSHEET Human Subjects****Research Determination** |

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| **PURPOSE AND APPLICABILITY** |

This worksheet provides assistance for researchers and HSD staff who wish to determine whether an activity is human subjects research by Common Rule and/or FDA definitions. If it is not human subjects research by either, IRB review and approval are not required.

**HSD policy** allows researchers to make this determination themselves ([exception in B1.2](#exception)), using this worksheet as a guide. To ask HSD to make the determination, follow the instructions to “Request a determination” on [Step 1 (Is it Research)](https://www.washington.edu/research/hsd/do-i-need-irb-review/is-your-project-considered-research/) or [Step 2 (Is it Human Subjects Research)](https://www.washington.edu/research/hsd/do-i-need-irb-review/does-your-research-involve-human-subjects/) on the HSD website.

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| **INSTRUCTIONS** |

The Common Rule and FDA regulations each have their own definitions of *research* and *human subject*. HSD applies the FDA definitions only to **activities regulated by the FDA** and the Common Rule definitions to **all other activities**.

To determine whether an activity is human subjects research, assess the activity against each of the definitions in the tables below. **The items should be considered in the order presented** in order to reach the correct conclusion.

Researchers who are using this worksheet to perform a self-determination are advised to check the boxes and then to save or print the completed worksheet for their records and for communication with journal editors and conference organizers.

**Note**,if the activities involve interaction (in-person or remotely) with individuals under the age of 18 you must comply with [UW Administrative Policy 10.13](https://www.washington.edu/youth/policy/protecting-youth-at-uw-aps-10-13/) regardless of whether the activities constitute human subjects research.

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| **C****ONTENTS** |

1. [The Food and Drug Administration](#FDA)
	1. [Activities not Subject to FDA Regulations](#notFDA)
	2. [Definition of Research](#ResearchFDA)
	3. [Definition of Human Subject](#HSRFDA)
2. [The Common Rule](#CommonRule)
	1. [Exclusions from Research](#Exclusions)
	2. [Definition of Research](#Research)
	3. [Definition of Human Subject](#HSR)

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| 1. **T****HE FOOD AND DRUG ADMINISTRATION** (21 CFR 50 AND 56)
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If the activity meets the FDA definitions 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). The FDA has overriding authority on making that determination. In the absence of an FDA opinion about a specific activity, it is **HSD policy** that HSD staff make the final determination about applicability of specific FDA regulations.

If the FDA regulations apply, it does not necessarily mean that an Investigational New Drug (IND) approval or Investigational Device Exemption (IDE) is required from the FDA. To make those determinations, review the [**WORKSHEET FDA Drugs and the IND Requirement**](https://www.washington.edu/research/forms-and-templates/worksheet-fda-drugs-and-the-ind-requirement/)and/or the [**WORKSHEET FDA Devices and the IDE Requirement**](https://www.washington.edu/research/forms-and-templates/worksheet-fda-devices-and-the-ide-requirement/).

1. **A****ctivities Not Subject to FDA Regulations.** HSD believes the activities listed in the table below are not subject to FDA regulations.

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| **CHECK ALL BOXES THAT APPLY.**   | **Met** |
| 1.1 The activity includes review of medical records (prospective or retrospective). | [ ]  |
| 1.2 The activity involves use of a medical device when the purpose is to obtain basic physiological information. | [ ]  |
| 1.3 The activity involves study of surgical techniques that are evaluating only a new technique and not the safety or efficacy of an FDA-regulated item. | [ ]  |
| 1.4 The activity involves use of a custom device, if it is not being used to gather safety or efficacy data that will be submitted to the FDA. | [ ]  |
| 1.5 The FDA-regulated study is being conducted by a non-UW PI and UW employee/agent activities are limited to:* Data analysis (whether or not the data are identifiable)
* Accessing and providing medical records or participants
* Recruiting activities prior to obtaining consent
* Pre-screening of records for eligibility determination
* Procedures that are to be performed as part of clinical practice and which would be performed exactly the same way regardless of whether study entry was contemplated, such as diagnosis or treatment of a disease or medical condition
 | [ ]  |
| **If none of the boxes are checked, proceed to** [**Section A2**](#ResearchFDA)**.****If the project is limited to one or more of the activities listed in this table, it is not subject to FDA regulations - proceed to** [S**ection B**](#CommonRule) **to assess the activity against the Common Rule.** |  |

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1. **D****efinition of Research.** *Note that the FDA uses the following terms synonymously: clinical investigation, clinical study, clinical research, research, study, and experiment.*

**Clinical investigation** means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 529(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

HSD has established the criteria in the table below to decide whether an activity meets the FDA definition of a clinical investigation.

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| **CHECK ALL BOXES THAT APPLY.**   | **Met** |
| 2.1 The *intent* of the activity is to develop information about a test article for submission to, or inspection by, the FDA in connection with any type of *premarket review* by the FDA. | [ ]  |
| **+ Guidance*** **Intent:** likely to; plan to
* **Premarket review (research or marketing permit):** Review of any of the following: investigational new drug (IND) application; investigational device exemption (IDE); humanitarian device exemption (HDE); new drug application (NDA); biologics license application; device premarket notification (510k notification); device reclassification petition; or premarket approval application (PMA)
* **Test article:** Any product that is regulated by the FDA, including:
	+ Foods; dietary supplements; infant formulas; food and color additives; drugs for human use; biological products for human use; certain electronic products used for human health care
	+ Some software and mobile medical devices are regulated by the FDA
 |  |
| 2.2 The activity *involves* the prospective physical use of a *test* article regulated by the FDA in a way this is not completely up to the discretion of a clinical practitioner. | [ ]  |
| **+ Guidance*** **Involves:** The prospective physical use of a test article in a way that is not completely up to the discretion of a clinical practitioner
 |  |
| **If both boxes are checked, the activity is research according to the FDA definition - proceed to section** [**A3**](#HSRFDA)**.****For all other scenarios, the activity is not research according to the FDA definition - proceed to** [S**ection B**](#CommonRule) **to assess the activity against the Common Rule.** |  |

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1. **D****efinition of Human Subject.** Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

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| **CHECK ALL BOXES THAT APPLY.**   | **Met** |
| 3.1 The research involves a living individual who is or becomes a participant in research, either as a recipient of a test drug, device, in vitro diagnostic, or biologic or as a control. | [ ]  |
| 3.2 An individual on whose specimen an investigational device or control is used in the research, even if the specimen is anonymous. | [ ]  |
| **If either box is checked, the activity involves human subjects according to the FDA definition -** [**IRB review is required**](https://www.washington.edu/research/hsd/study-activities/apply-for-review/)**.****If neither box is checked, the activity does not involve human subjects according to the FDA definition – proceed to** [**Section B**](#CommonRule) **to consider the Common Rule.** |  |

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| 1. **THE COMMON RULE** (45 CFR 46 Subpart A)
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1. **E****xclusion from research.** The activities described in the table below are specifically excluded from being considered *research*, per the Common Rule. Two additional, less common exceptions (criminal justice activities and national security activities) are described in the [**GUIDANCE Is it Research**](https://www.washington.edu/research/guidance/research/).

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| **CHECK ALL BOXES THAT APPLY.**  | **Met** |
| * 1. **Scholarly and Journalistic Activities** (e.g., oral history, journalism, biography, literary criticism, legal research, 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 B2](#Research).Note that it is the activity’s focus on specific individuals that removes it from being considered research, not the particular field (e.g., biography, oral history, legal research). | [ ]  |
| **+ Guidance**These types of activities may sometimes be performed in the fields of anthropology or sociology, but not all activities characteristic of these fields are not research. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, and when the findings apply to the studied community or group (not just the individuals from whom the information was obtained) are considered to be research and are subject to the Common Rule.  |  |
| * 1. **Public health surveillance activities (PHSA) that meet the criteria described below.**

A defining characteristic of these activities is a *direct link to decision making and action by a public health authority*. Activities whose purpose is not to directly inform public health decision making or action generally are not public health surveillance, even if they might be considered surveillance for other purposes. Some activities may be a combination of public health surveillance components and research components. The PHSA exclusion depends on the project purpose, the context in which it is conducted, and the role of the public health authority. It is not necessary to consider the standard Common Rule definition of research (i.e., whether the activity is a systematic investigation designed to develop or contribute to generalizable knowledge).**R****esearchers are not allowed to self-determine whether this exclusion applies to their activities.** * For NIH-funded research, the researcher must request the determination from NIH. This policy process is described in NIH notice [NOT-OD-22-001](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-001.html).
* For all other research, HSD must make the determination. Researchers should follow the instructions under “Request a determination” on the HSD webpage, [**Does Your Research Involve Human Subjects?**](https://www.washington.edu/research/hsd/do-i-need-irb-review/does-your-research-involve-human-subjects/)
 | [ ]  |
| **+ Guidance****Rationale.** Public health surveillance activities are deemed not to be research because federal agencies do not want to impede a public health authority’s ability to accomplish its mandated mission to protect and maintain the health and welfare of the population(s) for which it is responsible. Other laws, regulations, policies, or standards may be applicable to the conduct of these activities, such as HIPAA.**Other public health activities.** Public health activities that do not meet the definition of *surveillance* activities should be evaluated against the definition of research provided below in [Section B2](#Research). Note that there are many types of public health activities that may be neither research nor surveillance. Examples: Providing public service health messages; conducting vaccination campaigns.**Examples of public health surveillance activities that are not considered to be research.*** Safety and injury surveillance activities designed to enable a public health authority to identify, monitor, assess, and investigate potential safety signals for a specific product or class of products (e.g., the surveillance activities of FDA’s Adverse Event Reporting System, the Vaccine Adverse Event Reporting System).
* Surveillance activities designed to enable a public health authority to identify unexpected changes in the incidence or prevalence of a disease in a defined geographic region where specific public health concerns have been raised (e.g., the U.S. influenza surveillance system).
* Surveillance activities designed to enable a public health authority to identify the prevalence or incidence of known risk factors associated with a health problem in the context of a domestic or international public health emergency.
* Surveillance activities designed to enable a public health authority to locate the range and source of a disease outbreak or to identify cases of a disease outbreak.
* Surveillance activities designed to enable a public health authority to identify the prevalence or incidence of a condition of public health importance, known risk factors associated with the condition, or behaviors or medical practices related to prevalence of the condition (e.g., surveillance of the prevalence of tobacco use, exposure to secondhand smoke, lung cancer, or use of smoking cessation treatments).
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| **If either box is checked, the activity is an exclusion and does not need IRB review - you are done with this worksheet.****If neither box is checked – proceed to** [**Section B2**](#Research)**.** |  |

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1. **D****efinition of Research.** Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Use the table below to determine whether your project meets the Common Rule definition of research.

Review the [**GUIDANCE Is it Research?**](https://www.washington.edu/research/guidance/research/)for a discussion of certain activities that may or may not be research such as classroom activities, quality improvement, and program evaluation.

Review the [**GUIDANCE Case Reports, HIPAA, and IRB Review**](https://www.washington.edu/research/policies/guidance-case-reports-irb-review-hipaa/) for information about how to identify which case reports do, or do not, meet the definition of *research*.

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| **CHECK ALL BOXES THAT APPLY.**   | **Met** |
| * 1. **The activity is a systematic investigation.** A detailed or careful examination that has or involves a prospectively identified approach to the activity based on a system, method, or plan.
 | [ ]  |
| * 1. **The activity is designed to produce generalizable knowledge.** The information is expected to expand the knowledge base of a scientific discipline or other scholarly field or study and yield one or both of the following:
		+ - results that are applicable to a larger population beyond the site of data collection or the specific subjects studied.
			- results that are intended to be used to develop, test, or support theories, principles, and statements of relationships or to inform policy beyond the study.
 | [ ]  |
| **If both boxes are checked, the activity is research according to the Common Rule - proceed to section** [**B3**](#HSR)**.****For all other scenarios, the project is not research according to the Common Rule and does not need IRB review - you are done with this worksheet.** |  |

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1. **D****efinition of Human Subject.** Human subject means a *living individual* *about whom* an investigator (whether professional or student) conducting research: **(a)** obtains information or biospecimens through *intervention* or *interaction* with the individual, and uses, studies, or analyzes the information or biospecimens; **or (b)** obtains, uses, studies, analyzes, or generates *identifiable private information or identifiable biospecimens*.

**Screening activities.** Individuals who screen out of a study are still considered to be human subjects if the information/biospecimens that researchers obtained about them meet the definition cited above.

**Third party subjects.** When a researcher obtains private identifiable information about an individual through an interaction with another individual, that third-party individual is considered to be a human subject.

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| **CHECK ALL BOXES THAT APPLY**   | **Met** |
| * 1. **The project includes living individuals.** 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.
 | [ ]  |
| * 1. **The data or information is about 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.
 | [ ]  |
| **+ Examples*** **Not about the person.** A survey of elementary school teachers that asks them factual questions about class size, classroom features, and availability of classroom materials.
* **About the person.** The same scenario above but the researcher also asks the teachers how long they’ve been teaching and/or asks their opinions about the standard curriculum.
* **About the person.** A researcher is developing a new user interface for a computer program. Their research uses the “think aloud” method, asking college students to verbally express their thought processes as they use the interface. Though the object of the researcher’s interest is the interface, not the students, they are collecting data *about* the students.
* **Not about the person.** A researcher asks individuals, “How does your hospital respond to confidentiality breaches?” because they are interested in seeking information about hospital procedures.
* **About the person.** A researcher asks individuals, “How does your hospital respond to confidentiality breaches?” because they are interested in finding out how often hospital employees know the correct answer.
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| * 1. **One or both of the following are true:**
 | [ ]  |
| * + 1. **The researcher will obtain information/biospecimens through intervention or interaction with the individual and use, study, or analyze the information/biospecimens.**
 |  |
| **+ Guidance*** **Obtain:** Record in any way (writing, video, email, voice recording, photography, etc.) for research purposes and retained for any length of time.
* **Intervention:** Physical procedures or manipulations of the individual or individual’s environment that are performed for research purposes. *Manipulations* may be physical, social, psychological, or emotional. *Environment* includes an individual’s social and virtual environments as well as physical environment.
* **Interaction:** Communication or interpersonal contact between a member of the research team and the individual. Surveys, whether in person, by mail, email, phone or social media are an example of interaction between researchers and individuals.
 |  |
| * + 1. **The researcher will obtain and use, study, analyze or generate identifiable private information and/or identifiable biospecimens.**
 |  |
| **+ Guidance*** **Obtain:** Record in any way (writing, video, email, voice recording, photography, etc.) for research purposes and retained for any length of time, from any source. This includes any private identifiable information/biospecimens already in the possession of the research team.
* **Private**
	+ Publicly available data are not considered private. For example, there are many large data sets that are widely available. These are not considered to involve *human subjects* as defined by the Common Rule. Review [**GUIDANCE Data Sets Not Requiring HSD or IRB Review**](https://www.washington.edu/research/policies/guidance-data-sets-not-requiring-hsd-or-irb-review-2/)for a list of data sets that HSD has already determined to not involve human subjects.
	+ Information/biospecimens that are collected specifically for the proposed research through an interaction or intervention are always considered to be private.
	+ If permission is required to obtain information, then the information is almost always considered to be private.
	+ There are many gray areas distinguishing *private* from *non-private*. Some situations are best considered *semi-private*, such as some behaviors, communications, and interactions that occur in electronic or social media. Some types of information may be considered private for one group of individuals but not for others.
* **Identifiable:** The identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimen.
	+ **HIPAA.** Note that information that is considered to be an *identifier* by HIPAA regulations may not be *identifiable* according to the Common Rule, depending on the context. If the data are not identifiable per the Common Rule but they are identifiable per HIPAA, you may be required to obtain HIPAA authorization or a waiver.
	+ **Coded information or specimens.** Some specific circumstances in which information/biospecimens would not be considered identifiable:
		- The identifiers or key to the identifier code have been destroyed.
		- The research team has entered into an agreement with the holder of the identifiers or code key that prohibits the release of the identifiers or code key to the team members.
		- When the data come from a repository, data center, or similar source: there are IRB approved written policies and procedures for the source that prohibit release of the key to the team members.
		- There are other legal requirements prohibiting the release of the identifiers or code key to the team.
* **Secondary use of de-identified UW Medicine Data involving AI**
	+ To mitigate risks that may result from re-identification, it is **UW Policy** that data are considered to be identifiable for the purposes of this worksheet and HSD/IRB review if **all** of the following apply:
	+ The research is led by a **School of Medicine PI**;
	+ The research involves [**use of Artificial Intelligence**](https://depts.washington.edu/comply/docs/308_G1.pdf)**;**
	+ The research involves use of de-identified [**UW Medicine Data**](https://depts.washington.edu/comply/docs/308_G1.pdf) (including medical images such as head scans); **and,**
	+ **Re-identification of the data would cause it to fall into risk levels 3 or 4** of HSD’s [Guidance on Data Security Requirements](https://www.washington.edu/research/hsd/guidance/data-security/) (e.g., personal health information, financial account information, HR records, information about illegal behavior).
	+ **This policy does not apply if either of the following conditions are met:**
	+ The data have been determined by a [UW Medicine certified honest broker](https://uwnetid.sharepoint.com/sites/uw_medicine_honest_broker/SitePages/Home.aspx) to have low risk of re-identification.
	+ The data remain within a secure [UW Medicine environment](https://depts.washington.edu/comply/docs/308_G1.pdf).
 |  |
| **If all three boxes are checked, the research involves human subjects according to the Common Rule definition - continue from** [**Step 3 on the HSD webpage “Do I Need IRB Review”**](https://www.washington.edu/research/hsd/do-i-need-irb-review/is-your-human-subjects-research-exempt-from-regulations/) **to determine whether your research is exempt or if it requires IRB review.** **For all other scenarios, the project does not involve human subjects research according to the Common Rule definition and you don’t need IRB review - you are done with this worksheet.** |  |

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| **RELATED MATERIALS** |

[GUIDANCE Case Reports, HIPAA, and IRB Review](https://www.washington.edu/research/policies/guidance-case-reports-irb-review-hipaa/)

[GUIDANCE Data Sets Not Requiring HSD or IRB Review](https://www.washington.edu/research/policies/guidance-data-sets-not-requiring-hsd-or-irb-review-2/)

[GUIDANCE Is it Research?](https://www.washington.edu/research/guidance/research/)

[WEBPAGE Apply for Review](https://www.washington.edu/research/hsd/study-activities/apply-for-review/)

[WEBPAGE Do I Need IRB Review?](https://www.washington.edu/research/hsd/do-i-need-irb-review/)

[WORKSHEET FDA Devices and the IDE Requirement](https://www.washington.edu/research/forms-and-templates/worksheet-fda-devices-and-the-ide-requirement/)

[WORKSHEET FDA Drugs and the IND Requirement](https://www.washington.edu/research/forms-and-templates/worksheet-fda-drugs-and-the-ind-requirement/)

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| **Version Number** | **Posted Date** | **Implementation Date** | **Summary of Changes** |
| 3.2 | 08.29.2025 | 08.29.2025 | Updated with our expanded definition of “identifiable” and the new requirements for School of Medicine Research involving AI |
| 3.1 | 10.31.2024 | 10.31.2024 | Clarify requirements when the data are identifiable per HIPAA but not identifiable per the Common Rule |
| 3.0 | 01.26.2023 | 01.26.2023 | Move content from PDF to Word; moderate reorganization and wordsmithing throughout |
| 2.5 | 11.23.2021 | 11.23.2021 | Clarify requirements for PHSA exception; remove section 1 on WA state law; remove guidance distinguishing OCR and RCR |
| 2.4 | 06.24.2021 | 06.24.2021 | Updated information about decedents and WA state law RCW 70.02 |
| 2.3 | 11.02.2020 | 11.02.2020 | Add reminder about UW Administrative Policy 10.13 |
| Previous versions |  |  | For older versions: HSD Staff - see the SharePoint Document Library; Others - contact hsdinfo@uw.edu. |

**Keywords:** Human subject; Pre-review; Research