



1 PURPOSE

This guidance is intended to (1) provide a description of how the University of Washington (UW) Human Subjects Division (HSD) applies the **Common Rule definition of research** for all activities except those that are regulated by the Food and Drug Administration (FDA) and (2) promote consistency of determinations within HSD and forward in time. Determinations based on this guidance may be inconsistent with some determinations made in the past.

2 CONTEXT

Activities that do not meet the definition of research do not require (1) IRB review and approval, or (2) a determination of exempt status.

The Common Rule is the informal name given to a set of human subjects regulations initially developed in the 1970s. It was adopted by almost all federal agencies that fund human subjects research – in other words, it is the set of regulations they all have in common. The Common Rule describes responsibilities and requirements for Institutional Review Boards (IRBs), researchers, and the researcher’s institution. Most academic institutions (including the UW) apply the Common Rule regulations to all human subjects research, even if the research is not funded by a federal agency. This guidance includes the clarifying information provided in the revised Common Rule (implementation date: January 21, 2019).

3 AUTHORIZATION TO MAKE DETERMINATIONS

3.1 The UW does not require researchers to obtain a “Research / Not Research” determination from HSD. Instead, each activity must be evaluated by the individual most familiar with the planning and development of the activity. Researchers can self-determine that their study is Not Research using this **GUIDANCE** and the [WORKSHEET: Human Subjects Research Determination](#), or they can ask HSD for a formal determination.

- When an individual makes a self-determination that an activity does not constitute research, HSD recommends that the individual document in writing how the determination was made and retain the document with the activity records. This could be accomplished, for example, by marking the [WORKSHEET: Human Subjects Research Determination](#) and attaching a memo explaining the rationale for the “not research” determination.
- HSD recognizes that some journals and funding agencies may require a formal Not Research determination from someone other than the manuscript author or lead researcher. The process for obtaining a formal determination from HSD is described in the [SOP Human Subjects Research Determination](#).

3.2 Individuals whose activities will involve UW Medicine patients are strongly encouraged to seek a formal determination HSD for all of the following circumstances:

- An investigational procedure, treatment, drug, or device will be used
- The design of the activity dictates (for example, through randomization) which standard care or treatment will be provided to UW Medicine patients

- 3.3 The UW does not acknowledge or accept determinations made by other institutions (except federal funding agencies).
- 3.4 HSD has the authority to over-rule self-determination, or the determination about UW activities made by other institutions or funding agencies.

4 DEFINITIONS AND KEY POINTS

- 4.1 **The Common Rule definition of research** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- 4.2 **Systematic investigation** means a detailed or careful examination that has or involves a prospectively identified approach to the activity based on a system, method, or plan.
- 4.3 **Generalizable knowledge** means 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
- 4.4 The definition states that the activity is **designed** to develop or contribute to generalizable knowledge. This is different from whether or not the activity actually does produce generalizable knowledge.
- 4.6 There is no reference to **size or scale** in the definition. Non-research projects can be very large in size and scale; research projects may be very small in size and scale.
- 4.7 Federal regulatory guidance states that the **intent to publish or present results** is not an appropriate standard for determining whether an activity involves research. Projects that do not meet the definition often publish descriptions of non-research activities for a variety of reasons. For example, the authors may believe that others may be interested in learning about those non-research activities (such as a case report).

5 PRELIMINARY ACTIVITIES (Pilot, feasibility, exploratory, developmental work)

- 5.1 Preliminary activities are small-scale activities intended to assess and refine the study plan or aspects of the study plan (e.g., design, method, instrument) prior to performance of a larger study. These activities are generally considered research because they involve research development, testing and evaluation activities that will affect a larger systematic investigation that is designed to develop or contribute to generalizable knowledge (reference 1).
- 5.2 Occasionally, preliminary activities do not meet the definition of research because they are not part of a systematic investigation. For example:
- Going to a potential site to see if the research is possible
 - Going through a consent process with friends to see if the information is comprehensible
 - Sending your new survey to a few experts in the field for their feedback as to whether or not the questions are appropriate for the topic and/or study population

- Obtaining feedback from colleagues and peers about research design
- Consulting a community advisory board (for example, a tribal group) about what you propose to study and/or how best to conduct your study

6 QUALITY ASSURANCE and QUALITY IMPROVEMENT (QA / QI)

6.1 These refer to projects usually designed to measure, evaluate and/or improve performance or patient care in a clinical area or department that are NOT designed to contribute to generalizable knowledge.

6.2 **The question to consider: Is this QA/QI activity also research?** Individuals often mistakenly believe that the question is to determine whether something is QA/QI or research. This is an incorrect way to frame the issue. Many activities are both research and something else (such as quality improvement).

6.3 Not Research Examples

6.3.1 A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected in the group of affiliated hospitals.

6.3.2 A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

6.3.3 Activities related to (a) delivering healthcare **and** (b) measuring and reporting provider performance data for clinical, practical, or administrative uses (reference 2). Examples of such activities include:

- Helping the public make more informed choices regarding health care providers by gathering and communicating data regarding physician-specific surgical recovery data or infection rates.
- Practical or administrative uses of such data to enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better performance.

6.3.4 Activities that are not related to delivery of patient care, but rather evaluate the delivery or quality of other public benefit or social services. For example, institutions and other entities may provide social services, educational offerings, or other beneficial activities where there is empirical evidence of the value of those efforts, and they may wish to evaluate different ways of enhancing the delivery or quality of those existing services. The evaluation would be considered QA/QI and not research (reference 3).

6.3.5 A randomized study in which half the participating institutions would be assigned to have the staff undergo an educational intervention about the need to use an accepted practice, and the other half would not undergo that intervention, would not be research because it would only be intended to see if the intervention resulted in greater use of the accepted practice in the participating institutions. If the intent were to generalize about this intervention beyond this setting, it would be research.

6.4 Research Examples

- 6.4.1 A project that introduces a clinical intervention for the purpose of improving the quality of care and also collects information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results (reference 2).
- 6.4.2 Quality improvement activities designed to assess the safety and efficacy of the accepted practice (reference 3). Examples of such activities include:
- Assigning patients to different versions of treatments that are within the standard of care in order to evaluate differences between those treatments in terms of effectiveness or risks
 - Assigning students to experimental and control groups to determine the effectiveness of experimental teaching methodologies
- 6.4.3 Studies designed to determine whether a particular weight loss mobile application is or is not more effective than another.

7 PROGRAM EVALUATION

- 7.1 This means data collection and analysis, including the use of biospecimens, for an institution's own internal operational monitoring and program improvement purposes (reference 3).
- 7.2 **The question to consider: Is this QA/QI activity also research?** Individuals often mistakenly believe that the question is to determine whether something is program evaluation or research. This is an incorrect way to frame the issue. Many activities are both research and something else (such as program evaluation).
- 7.3 **Not Research Examples**
- 7.3.1 Activities designed for various administrative purposes related to using information only to improve the quality of services provided by a specific program. For example: A survey of engineering graduate students to evaluate and improve the PhD curriculum at the UW. If designed to be more generally relevant to nationwide PhD programs, the project would be research.
- 7.3.2 Teacher evaluations, customer service surveys or workshop evaluations where results will be used only to facilitate improvements to a particular teacher, customer service group, or workshop.
- 7.3.3. Focus groups, surveys or interviews with faculty or- students intended only to evaluate and improve programs or services provided by the institution or to assess its needs.

7.4 Research Examples

- 7.4.1 Surveys and interviews with medical students at the University of Nairobi, the results of which will be used to inform the development of medical education in East Africa.

8 CLASS PROJECTS

- 8.1 **Class projects** are course-related activities designed specifically for educational or teaching purposes, where data are collected from and about people as part of a class exercise or assignment that is not intended for use outside of the classroom.
- 8.2 **Capstone projects** usually are not research but they should be evaluated against the definition of research (above).
- 8.3 Projects to be presented at the **UW Undergraduate Research Symposium** usually are not research but they should be assessed against the definition of research (above).
- 8.4 Not Research examples
- 8.4.1 Activities in classes whose curriculum consists of teaching research methods such as fieldwork, statistical analysis, or interview techniques
- 8.4.2 Students assigned to conduct interviews, distribute questionnaires, or engage in participant observation as class assignments

9 THESES and DISSERTATIONS

- 9.1 Thesis and dissertation activities involving human beings are considered to be research unless they fit one of the “Not Research” categories described in this document OR the student makes a compelling case otherwise.

10 CRIMINAL JUSTICE ACTIVITIES and NATIONAL SECURITY ACTIVITIES

- 10.1 These activities are considered to be Not Research: 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**.
- 10.2 These activities are considered to be Not Research: Authorized operational activities (as determined by each federal agency) in support of intelligence, homeland security, defense, or other **national security missions**.

11 PUBLIC HEALTH SURVEILLANCE

- 11.1 Public health surveillance activities, including the collection and testing of information or biospecimens, are considered to be Not Research when:
- They are conducted, supported, requested, ordered, required, or authorized by a public health authority, AND
 - The 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 may 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).
- 11.2. **Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or

entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

- The National Institutes of Health (NIH) is not a public health authority.

11.3 The following activities are considered to meet the definition of research:

- Subsequent research using information collected from public health surveillance activities
- Exploratory studies designed to better understand risk factors for chronic diseases (including genetic predisposition)
- Exploratory studies designed to elucidate the relationships between biomarkers of exposure and biomarkers of disease
- Exploratory studies of potential relationships between behavioral factors (e.g., diet) and indicators of environmental exposures

12 CASE STUDIES OR REPORTS

12.1 A case report is generally not research, when it reports about three or fewer patients. A case study is information collected and presented to highlight an interesting experience, observation, treatment, presentation, relationship or outcome. It typically (but not always) results from a retrospective review of an individual's record. It may alternatively involve a prospective intervention or prospective collection of specimens or data that is not part of standard service or care.

12.2 See the [GUIDANCE: Case Studies, HIPAA, and IRB Approval](#) for more information.

13 SCHOLARLY and JOURNALISTIC ACTIVITIES

13.1 Scholarly and journalistic activities, including the collection and use of information, are considered to be Not Research **when they focus directly on the specific individuals** about whom the information is collected. This includes: oral history, journalism, biography, literary criticism, legal research, and historical scholarship.

13.2 These types of activities as performed in anthropology or sociology are likely to be considered research as defined by the human subjects regulations if they focus more broadly than just the specific individuals about whom the information is collected. For example, it is considered to be research when studies use methods such as participant observation and ethnographic studies to gather information from individuals in order to understand their beliefs, customs, and practices, and the findings are applied to the studied community or group and not just the individuals from whom the information was collected.

14 RELATED MATERIALS

[GUIDANCE: Case Reports, HIPAA, and IRB Review](#)
[SOP Human Subjects Research Determination](#)
[WORKSHEET: Human Subjects Research Determination](#)

15 REFERENCES

1. Email communication to the Human Subjects Division from OHRP (September 28, 2015)

2. Office of Human Research Protections, “Quality Improvement Activities FAQs”.
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>
3. Department of Health and Human Services, Notice of Proposed Rulemaking, “Federal Policy for the Protection of Human Subjects”. Federal Register volume 80, number 173; September 8, 2015; pp. 53948-49

Version Number	Revision Date	Summary of Changes
2.1	01/31/2020	Updated OHRP QI link
2.0	09/28/2018	Incorporates information from the revised Common Rule; removes some information and examples from the section on Quality Improvement/Quality Assurance that has proved to be confusing.