1 PURPOSE

This guidance is intended to (1) provide an explicit description of how the University of Washington Human Subjects Division (HSD) applies the 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 RELEVANCE

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

3 DEFINITIONS

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (Reference 13.1)

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.

Generalizable knowledge: The information is expected to expand the knowledge base of a scientific discipline or other scholarly field of 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.

Additional information

3.1 The definition of research explicitly 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.

3.2 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.

3.3 Federal regulatory guidance states that the intent to publish or present results is not an appropriate criterion for determining whether an activity involves research. Projects that do not meet the federal 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.

4 AUTHORIZATION TO MAKE DETERMINATIONS

4.1 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**, or submit to HSD for a formal determination.

4.1.1 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 by marking the **WORKSHEET: Human Subjects Research**and attaching a short note or memo explaining the rationale for the "not research" decision.

4.1.2 HSD recognizes that some journals and funding agencies may require a formal Not Research Determination from someone other than the manuscript author. The process for obtaining a formal determination from HSD is described in the **SOP Human Subjects Research**.

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

- An investigational procedure or treatment 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

4.3 HSD has the authority to over-rule self-determination, or the determination about UW activities made by other institutions or funding agencies.

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 13.2)

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 instrument to a few experts in the field for their feedback as to whether or not the questions are appropriate for the topic and/or cohort of the research
- Obtaining feedback from colleagues and peers about research design
- Consulting a community advisory board (e.g. tribe) about what you propose to study and/or

how best to conduct your study

6 QUALITY ASSURANCE and QUALITY IMPROVEMENT (QA/QI

6.1 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). The appropriate question to ask is: Is this QA/QI activity also research?

6.2 Definition of QA/QI: Activities involving the implementation of an accepted practice to improve the delivery or quality of care or services if the purposes are limited to altering the utilization of the accepted practice and collecting data or biospecimens to evaluate the effects on the utilization of the practice. (Reference 13.3)

6.3 To not be considered research, the QA/QI activity must be related to the delivery of (i.e., implementing) an accepted form of care or services, and not an attempt to evaluate the efficacy or risks of the care or services. The evaluation of an accepted practice itself, or evaluations of different accepted practices, is considered research. (Reference 13.3)

NOT RESEARCH EXAMPLES

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.

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.

3. Activities related to (a) delivering healthcare, **and** (b) measuring and reporting provider performance data for clinical, practical, or administrative uses (Reference 13.4). Examples of such activities include:
    i. 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.
    ii. 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.

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 13.3)

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 since 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.

RESEARCH EXAMPLES

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 13.4)

2. Quality improvement activities designed to assess the safety and efficacy of the accepted practice. (Reference 13.3) Examples of such activities include:

    a. Assigning patients to different versions of treatments that are within the standard of care in order to evaluate the differences between those treatments in terms of effectiveness or risks
    b. Assigning students to experimental and control groups to determine the effectiveness of experimental teaching methodologies

3. A study designed to determine how well an accepted practice, when it is used, reduces infections. This study would be research because it would be studying the effectiveness of the practice itself, in contrast to studying an effort to increase use of the practice.

4. Studies designed to determine whether a particular weight loss mobile application is or is not more effective than another.

7 PROGRAM EVALUTION

7.1 The question to consider: **Is this program evaluation 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). The appropriate question to ask is: Is this program evaluation also research?

7.2 Definition of Program Evaluation: Data collection and analysis, including the use of biospecimens, for an institution's own internal operational monitoring and program improvement purposes. (Reference 13.5)

NOT RESEARCH EXAMPLES

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.

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.

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.

RESEARCH EXAMPLE

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 CLASSROOM and COURSE-RELATED PROJECTS

8.1 Class projects are course-related activities designed specifically for educational or teaching purposes, where data is collected from and about people as part of a class exercise or assignment that is not intended for use outside of the classroom.

- Capstone projects should be evaluated against the definition of research provided in Section 3 (above).
- Projects to be presented at the Undergraduate Research Symposium may or may not be research, and should be assessed against the definition of research.

EXAMPLES:

1. Activities in classes whose curriculum consists of teaching research methods such as fieldwork, statistical analysis, or interview techniques.
2. Students assigned to conduct interviews, distribute questionnaires, or engage in participant observation as class assignments.

These are generally not considered research unless they meet the definition of research described in Section 3.

9 THESES and DISSERTATIONS

9.1 It is UW IRB policy to consider thesis and dissertation activities involving human beings to be research unless they fit one of the not research categories described in this document OR the students make a compelling case otherwise.

10 PUBLIC HEALTH SURVEILLANCE

10.1 Public health surveillance activities are not considered research when they consist solely of:

1) the collection of information and/or the collection and testing of biospecimens that is conducted, supported, requested, ordered, required, or authorized by a public health authority

and

2) that is limited to those collection activities necessary to allow the public health authority to identify, monitor, assess, or investigate potential public health signals or the onset of a disease outbreak

Examples include surveillance activities that examine trends, or signals, and patterns in diseases, or a sudden increase in injuries from using a consumer product, or conditions of public health importance, from data, and including 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 (Reference 13.6)

11 CASE STUDIES OR REPORTS

11.1 A case report is generally not research. 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. See HSD's **GUIDANCE: Case Reports, IRB Review and HIPAA** for more details.

12 ORAL HISTORY, JOURNALISM, BIOGRAPHY, AND HISTORICAL SCHOLARSHIP ACTIVITIES

12.1 Projects that focus directly on the specific individuals about whom the information is collected – rather than individuals as exemplars of a general population-are not research.

This includes collecting and publishing personal or professional stories, not designed to draw conclusions or generalize findings. These activities are also examples in which consideration of all aspects of the definition of research (e.g., "systematic," "investigation") may be illuminating when determining whether the project meets the federal definition of research.

13 REFERENCES

13.1 45 CFR 46.102(d)

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

13.3 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.

13.4 Office of Human Research Protections, "Quality Improvement Activities FAQs".

13.5 http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/index.html

13.6 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. 53947-48.

13.7 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. 53949.

13.8 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.