## WWU FAQs:

### Table of Contents

**When does a researcher have to submit a protocol for Human Subjects Review Committee (HSRC) approval?** .......................................................... 2

- What is considered intervention or interaction with live human beings? .................. 2
- What if the survey is administered on-line instead of face-to-face? ......................... 2
- What if the research is limited to reviewing data already collected by another agency such as the government or a doctor’s office? ................................................................. 2

**What is research?** ........................................................................................................ 2

**When can I conduct interviews or surveys without obtaining HSRC approval?** ........ 2

**Do student research projects require HSRC review and approval?** .......................... 3

**What is a quality assurance questionnaire?** ............................................................... 3

**Exempt Research Determination** ............................................................................. 3

**Are the exemptions different for research involving children?** ............................... 4

**Expedited or Full Review** .......................................................................................... 4

**Informed Consent** ....................................................................................................... 5

- What is Informed Consent? .......................................................................................... 6
- What are the basic elements of informed consent? .................................................. 6
- Informed consent from minors .................................................................................. 7
- Is a consent form always required when collecting data from human participants? .. 7
When does a researcher have to submit a protocol for Human Subjects Review Committee (HSRC) approval?

What is considered intervention or interaction with live human beings?

A research protocol must be submitted for review by HSRC when a faculty, staff, or student plans to conduct research involving living people (human subjects – directly, through records, or other data or specimens).

Thus, if a human is being interviewed, surveyed, observed for behavior, a protocol must be submitted. A protocol must also be submitted when blood or body samples are obtained from a human being or when their bodily functions such as brain waves, blood pressure, or heart rate are monitored. It is considered interaction with humans even if the subjects are monitoring their own bodily responses and reporting the results to the researcher.

What if the survey is administered on-line instead of face-to-face?

A protocol must also be submitted when the survey is administered via email or online surveys without and face-to-face interaction with the participants. In these cases the informed consent (discussed below) is accomplished via a click through agreement.

What if the research is limited to reviewing data already collected by another agency such as the government or a doctor’s office?

Even if a researcher has no personal interaction with humans, but is reviewing previously obtained data (e.g., military records or medical records) the researcher still must obtain HSRC approval.

What is research?

A protocol qualifies as “research” if it is a systematic investigation designed to develop or contribute to generalizable knowledge. The most frequent occurrence of research is surveys or interviews performed for analysis and submission as a journal article. Another example of research is the interview of an individual to compile an oral history. A project is considered research when it is used for presentation at a conference whether in a panel presentation, individual presentation, or a poster presentation.

When can I conduct interviews or surveys without obtaining HSRC approval?
Several circumstances permit an individual to interview or survey human subjects without HSRC approval. For example, a faculty member can survey students in a regularly scheduled class, a student can conduct research for a regularly scheduled class assignment, or any researcher or organization within WWU can send out a quality assurance questionnaire without prior approval.

For example, a faculty member can survey their students to ask what the students hope to learn in the class or ask the students what they liked about the course. Also, a student in a research methods class or for any classroom assignment can interview or survey people without obtaining HSRC approval. However, if these research results are to be presented at a conference, then prior HSRC approval must be sought.

Another example of surveys that can be conducted without HSRC approval is “quality assurance” questionnaires.

**Do student research projects require HSRC review and approval?**

Any student research with human participants conducted as part of regularly scheduled class (e.g., a research methods class) is not subject to review, however, any student research project conducted as part of an independent study course, undergraduate honors thesis, undergraduate directed research, or master’s thesis/project must be submitted for HSRC review and approval.

**What is a quality assurance questionnaire?**

A survey qualifies as a quality assurance or quality improvement if it is performed in order to assess and improve customer service?

However, a quality assurance questionnaire administered and data compiled to present at a conference is still subject to review by the HSRC under the exempt category.

**Exempt Research Determination**

A protocol qualifies as exempt where the research subjects will not be exposed to risks greater than those they would encounter in their day-to-day lives (minimal risk). Interview/survey projects are often exempt when questions are not of a sensitive nature and subjects' identities remain confidential. There are six categories of exempt research:

Category #1: research conducted in educational settings on instructional strategies, techniques, etc.

Category #2: research involving survey or interview procedures.

Category #3: (we don’t use category 3 at WWU)
Category #4: research involving the use of existing data (this does not apply to existing data collected by the researcher who did not obtain informed consent to collect the data).

Category #5: research and demonstration projects designed to study, evaluate, or examine programs benefiting the general public.

Category #6: taste and food quality evaluations and consumer acceptance studies.

**Are the exemptions different for research involving children?**

One of the six exemptions of research involving human subjects is narrowed in scope by Subpart D’s additional protections for research involving children. The other five exemptions apply to research involving children as human subjects in the same way that they apply to research involving adults.

The narrowed exemption is the exemption at 45 CFR 46.101(b)(2), which generally applies to research involving educational tests, interviews or survey procedures or observation of public behavior, if the data are recorded without individual identifiers, or if disclosure of the recorded responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Where children will be involved as research subjects, however, the use of survey or interview procedures is eliminated from this exemption, and so is research involving the observation of public behavior if the investigators participate in the activity being observed.

In other words, the only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. To be exempt, these activities must also meet the condition that the data are recorded without individual identifiers, or the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. Otherwise, all the requirements of the human subject regulations apply.

**Expedited or Full Review**

If a research protocol involves human subjects and does not fall within the exceptions listed above under exempt review, it is subject to an expedited or full review. A full review is evaluated and must be approved by a majority of the entire human subjects committee.
A full review must be conducted if the research involves more than minimal risk or distress to the participants in the study. The research is also subject to full review when the study involves members of vulnerable populations of research participants. Vulnerable class includes: minors, prisoners, mentally ill or disabled populations, pregnant women, and vulnerable senior citizens. Under limited circumstances, research with children can be exempt from a full or expedited review.

Research that does not qualify as exempt, but has minimal risk of harm or distress to the participants may be reviewed under an expedited review. An expedited review is conducted by the HSRC chair and one additional member of the review committee. The seven categories of research that qualify for expedited review in accordance with the requirements set forth in 45 CFR 46.110 include the following:

Research on drugs or devices for which an investigational new drug exemption or an investigational device is not required

Blood samples by venipuncture (with limitations) from subjects 18 years or older who are in good health, not pregnant and weigh at least 110 pounds.

Collection of biological specimens for research purposes by noninvasive means.

Collection of data through noninvasive procedures (no general anesthesia or sedation) excluding procedures involving x-rays or microwaves. Examples include:

Physical sensors applied either to the surface of the body or at a distance that do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy

Weighing or testing sensory acuity;

MRI

ECG, EEG, ultrasound, etc.

Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Study of existing data, documents, records, pathological specimens, or diagnostic specimens.

Voice, video, digital, or image recordings made for research purposes.

Research on individual or group characteristics or behavior (such as studies of perception, cognition, game theory, or test development).

**Informed Consent**
What is Informed Consent?

Researchers are required to obtain the informed consent of all participants in human subject research prior to enrolling those individuals in a study. The individual's consent must be voluntary and based upon adequate knowledge of the purpose, risks, and potential benefits of a research study. All potential participants should also be informed of their right to abstain from participation or to withdraw consent to participate at any time without an adverse consequence. After ensuring that a person has understood the information, the researcher should then obtain the person's consent, preferably in writing. If consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

In cases where individuals are unable to provide consent, either because they are minors or because they are physically or mentally incapable of making informed decisions, researchers are required to obtain "assent" or agreement to participate in a study from the individual. No individual should be enrolled in a study if they do not want to participate, even in cases where their legal guardian consents to their participation. When possible, an assent form should be used to document an individual’s assent.

The IRB may waive the requirement to obtain a subject's consent for a limited class of research.

What are the basic elements of informed consent?

The regulations require that the following information must be applied to each research project:

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

- a description of any reasonably foreseeable risks or discomforts to the subject;

- a description of any benefits to the subject or to others which may reasonably be expected from the research;

- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

- for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
an explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject; and

a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

a statement that the participant is over the age of 18.

**Informed consent from minors**

Investigators planning research with children should also consider developmentally appropriate procedures for gaining the assent of these study participants in addition to acquiring the informed consent of their parent or legal guardian. Assent is defined as an acquiescence by the child to participate in the research. Sample consent, assent, and parental permission forms are available on the forms page of the RSP website.

**Is a consent form always required when collecting data from human participants?**

Federal regulations governing human subjects research allow for circumstances in which the requirements for written documentation of informed consent may be waived by the HSRC. You may find it helpful to consult with Research Compliance Officer (ext. 3082) prior to submitting your research protocol for HSRC review.

In order to minimize the risk to the subjects involved in research, the data collected should be anonymous or confidential. *Anonymity* and *confidentiality* are not the same.

**Anonymous**

When data are anonymous, they are not linked to the identity of individual subjects in any way that would make it possible to connect the information to the individual from whom it came. Anonymous data do NOT have direct identifiers like names, addresses, clinic or hospital number, Social Security Number, or insurance agency numbers.

Data that are linked to subjects via a CODE are NOT anonymous. When participation is anonymous, it is impossible to know whether or not an individual participated in a study.

**Confidential**
When data are confidential, there is a link between data and the individuals who provide it, but the link is obscured by coding or other procedures so that even someone who has access to the raw data cannot identify a subject without also having access to the link between the subject code and the subject's identity. When participation is confidential, the study participation of a specific individual is recorded, but cannot be known by anyone except the researcher and authorized research staff who have legitimate access to participation records.