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I. History of Human Participant Research Ethics

Prior to the 1970s, there was little oversight as to the ethics of human subject research. The ethical issues were discussed extensively following World War II when the extent of unethical medical research carried out on Concentration Camp inmates was discovered. These discussions led to the Nuremburg Principles but no binding law. Several United States unethical research examples led to the current legislation that regulates human participant research. For example, in 1942, the U.S. military infected four hundred prison inmates with malaria to study the disease and to work on developing a treatment. In another US research project, the Tuskegee Experiments, Mississippi African
Americans with syphilis were monitored over a period of decades to track the onset of symptoms. Even after penicillin was developed during that research period that could have treated the disease, the researchers did not offer treatment to the participants.

These and other research abuses led to the adoption of The Belmont Report in 1978. The report requires beneficence, justice, and autonomy. Under these principles, subjects must not be subjects of convenience, they must be apprised of the risks and benefits of participation and they must have the right to decline to participate.

Ultimately, the National Institute of Health promulgated the Common Rule (45 CFR § 46) that establishes the legal basis regulating human subject research. Western Washington University applies the requirements of the Common Rule to all human participant research.

II. The Human Participant Research Committee

Human Participant Research Committee also known as the Institutional Review Board (IRB) is a committee that reviews human participant research for compliance with federal regulations. The Common Rule requires:

- The IRB must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by WWU. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds to promote respect for its responsibility in safeguarding the rights and welfare of human participants. In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to assess the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
- If the IRB reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB should consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.
- The IRB may not consist entirely of members of one profession or discipline.
- The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- No IRB member can participate in the IRB's initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the IRB.
• An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

III. Activities Requiring IRB Review

IRB review and approval is required for any research involving human participants that:

• Is conducted by University faculty, staff, and students;
• Is performed on the premises of the University or its branches;
• Is performed with or involves the use of facilities or equipment belonging to the University;
• Involves University students, staff, or faculty as participants;
• Satisfies a requirement imposed by the University for an honors or a graduate degree program;

a) When an investigator conducts research with humans, IRB review and approval is required prior to initiation of research activities, including prior to pilot data collection. **Human Participant Research** is research intervening or interacting with live human beings, manipulating the participants' environment, or obtaining identifiable or private information from any source for research purposes. This includes review of previously collected data about living humans.

b) **Research** is a systematic investigation designed to develop or contribute to generalizable knowledge. This includes, but is not limited to, any project that is presented at a conference or to a journal for publication. Research includes pilot studies. 45 CFR §46.102(d). When a researcher is planning to include research data from living humans, s/he needs to consider whether IRB review is required.

c) The key to determining if it is research is whether it is **generalizable knowledge** which is knowledge that could be applied to populations outside of the population served by the covered entity. This definition can vary.

Examples of activities that typically are not generalizable include:

• biographies
• service or course evaluations, unless they can be generalized to other individuals
• services, or concepts where it is not the intention to share the results beyond WWU or any agency supporting the research
• quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the WWU community. For example, if you are surveying incoming freshman to record the demographics, that is not research under the definition of the Common Rule. Likewise, if you are
conducting a survey of how students and faculty use the library, it is not research unless you intend to publish it or present it at a conference.

d) **Student Research** Except as discussed below, any student-initiated and student-conducted human research data collection activities designed to develop or contribute to generalizable knowledge, require IRB review. This includes masters and honors theses, independent study courses as well as research presented as a publication or at a conference. Students may not undertake human research without a faculty sponsor. Faculty are expected to take an active role in educating students in the review process and maintaining study integrity for the entire research experience.

No IRB review is required for classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices. Because student work for a regularly scheduled class is generally done for in class presentation and not intended to be generalized beyond the class, it is not considered human participant research requiring IRB approval. Classroom projects need not be reviewed if all three of the following requirements are satisfied: the project involves minimal risk to participants; and they do not involve vulnerable populations; and results will never be distributed outside the classroom and/or institutional setting. The instructor is responsible to inform the subjects within the class of the elements of informed consent. If a student does not obtain approval prior to data collection they cannot present at a conference even if the research was originally just performed as a classroom assignment.

e) **Internet/Blog Publication** Neither faculty nor students can post human research results on the internet without IRB approval.

f) **Intervention** Includes both the physical procedures by which data are gathered and manipulations of the participant or the participant’s environment that are performed for research purposes. An example of intervention is distributing a pre- and post-test assessment to analyze the effectiveness of a new curriculum. Another example is conducting research on the physical performance of a research participant. 45 CFR §46.102(d)

g) **Interaction** is any communication or interpersonal contact between the investigator(s) and participant(s) whether online, in person, via survey, interview, or behavioral observation during which the researcher manipulates the environment of the participant(s). 45 CFR §46.102(f)(2) Therefore, if the researcher is obtaining information through interaction with human constitutes human participant research and requires IRB review.

h) **Private Information** is information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made
public. Private information must be individually identifiable. 45 CFR 46.102(f)(2). For example, when a researcher is interviewing or surveying a participant and learns information about the person that is private information even if it is conducted in a public location. Likewise, researching a participant's posts on the internet may also be classified as “private” if it is posted at a site that is moderated or that requires a login for access. One example of private information occurs when a researcher looks at a Facebook user’s friends’ comments. Even if the researcher has consent from the Facebook user, they do not have consent from the “friend” so the “friend” would have an expectation of privacy.

Human Research requirements of internet research is rapidly evolving so researchers may wish to contact the Research Compliance Officer prior to writing a protocol for conducting internet research.

i) **Identifiable Information** is information by which the identity of the participant may be ascertained by the investigator or associated with the information (i.e. the identity of the participant is or may be readily ascertained by the investigator or associated with the information). One challenge with maintaining the anonymity of research participants arises when research is done with a very small population such as members of a village resulting to a situation where people could very easily deduce who gave a particular quote or who matches a particular demographic. Likewise, in an online survey, the researcher could identify a participant by specific demographics or an IP address. A researcher must be very careful to protect identity in this type of situation. 45 CFR §46.102(f)(2).

j) **Pilot Projects** must be reviewed by the IRB with the same scrutiny as a full scale research project even though pilot projects may be conducted with a small number of participants to assess the feasibility of a project.

k) Projects that require analysis of **Secondary Use of Data**, that is, data collected for previous research or data collected for non-research purposes (such as medical treatment) must undergo IRB review and approval. Examples of secondary use of data include reviewing academic records, veteran records, or census records if the participants may still be living. 45 CFR §46.101(b)(4).

l) **Ethnographic Research** occurs when the investigator or his/her staff participate, overtly or covertly, in people’s daily lives for an extended period of time. They may be watching what happens, listening to what is said, asking questions and collecting data to create a broader understanding of a particular environment, ethnic group, gender, etc.

Although recruiting cannot begin until the protocol is approved, the researcher may contact the representative of an organization for permission to recruit at their organization or from their membership following approval. For example, a researcher could contact the principal of a school to see if they are willing to give permission to use the students or the
teachers as research participants. Likewise, a researcher could contact the leadership of a Native American tribe to ask permission to conduct research on tribal lands. However, the researcher cannot interview or survey individual participants prior to IRB approval.

IV. Who Must Obtain IRB Review and Approval

a) A researcher is any person who is responsible for the design, conduct, or reporting of human participant research including faculty, staff, students, and collaborators. This includes anyone who has contact with the research participants, collects, or analyzes data, as well as the research advisor of any student conducting the research. The lead researcher is the principle investigator responsible for the research design or overseeing the research team.

b) Faculty Research Utilizing their Classes Students as Participants can raise challenges such as the potential for coercion regarding the student’s ability to exercise free choice because of the possibility that grades or other important factors may be perceived to be affected by the student’s decision to participate.

When requiring research participation for course credit or extra credit students must be given the choice of equitable alternative activities (e.g., write a brief research paper, attend faculty research colloquia). Students should be able to withdraw from the study at any time without losing the credit, impacting their grade, or experiencing any other consequences.

c) Research conducted by non-tenure track faculty is subject to the University’s policy regarding human participant and faculty must submit protocols for IRB review. Any human participant research project that is conducted by or under the direction of any employee or agent of WWU, in connection with his or her institutional responsibilities requires IRB review and approval.

d) Research Projects in which the investigator is a Consultant must be reviewed by the IRB unless the researcher has a strict consulting relationship in which all three of the following must be met:

• The researcher is hired by a non-WWU entity,
• The researcher holds no rights in the work, and
• Neither the researcher nor the WWU retains any data.

e) New Faculty Bringing Ongoing Human Participant Research must provide a copy of their original protocol and approval from their previous institution. The WWU IRB will review and determine whether it will require an independent review of the research requiring a new protocol submission.

f) Collaborations between WWU faculty and other institutions are also subject to WWU IRB review. If the research has been approved by another institution’s IRB, the researcher should provide the other institution’s IRB protocol and approval to
the WWU IRB with a WWU IRB cover sheet identifying the researcher, contact information, etc. The IRB may grant approval based on the previously approved protocol or may require WWU protocol form.

g) Non-affiliated researchers collecting data at WWU must submit a protocol to WWU as discussed in f) above.

V. Levels of Review

There are three levels of IRB protocol review. The first is exempt, the second expedited, and the third is full review. In order for a protocol to be reviewed as either exempt or expedited, there must be minimal risk to the research participants.

a) **Minimal Risk** is defined as “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests”. 45 CFR § 46.102(i). Examples of minimal risk include taking educational or cognitive tests or surveys, being interviewed or talking in a focus group about non-sensitive issues, social media activities, or doing light exercise like walking.

b) **Exempt Review** – Some research is exempt from convened IRB review. Investigators do not have the authority to determine whether research involving human participants is exempt from full review 45 CFR § 46.101(b) and (c). Hence, while research that involves only minimal risk to human participants is sometimes exempt from full IRB committee review, it is still subject to IRB review. Researchers must file an application.

In general, the federal guidelines for research on human participants only allow a project to be exempt from convened IRB review if the research involves minimal risk to the participant and the research falls within the following criteria that establish the category the research falls within:

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 1 applies to research utilizing normal educational processes such as in class tests, assessment of the effectiveness of a particular curriculum, or observation of public behavior. This can include children. It is narrower than the surveys and interviews of category 2 since the intervention must be normal classroom activities. Thus, a survey about cell phone practices or political opinions would not qualify for category 1 because they are not a normal classroom activity. 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.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Category 2 includes research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. Unlike category 1, surveys and interviews can only qualify as exempt if they are conducted with adult participants.

Not all interviews require IRB review. For example, if a historian is interviewing a holocaust survivor about her memories and how it impacted her life it is not research because it is not generalizable knowledge and hence not “human participant research”. However, if the researcher is researching several holocaust survivors regarding their experience and how it impacted their subsequent relationships, it would probably be categorized as generalizable knowledge thus requiring IRB review and approval.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human participants are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) Research involving the collection or study of existing data, documents, records, pathology specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Category 4 is also a common category of research. This category applies when a researcher is analyzing already collected data, documents, records, or biosamples that were not originally collected for research purposes. In order for the data to be analyzed as “existing”, it must have been collected prior to the IRB application. An example of Category 4 is analyzing an existing data set such as census data or previously collected class evaluations or assessments.
Another example is if a professor takes a pre-test and post-test assessment from his or her students or takes data originally recorded for accreditation, and later decides to use it for research. The data can be used for research purposes so long as it is de-identified and the research was not anticipated at the time the data were collected.

5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

To be exempt, the research must not only constitute minimal risk, it also must meet the condition that the data are recorded by the researcher without individual identifiers, and the condition that disclosure of the recorded responses would not place the subjects at risk of criminal or civil liability or be potentially damaging to their financial standing, employability, or reputation. At WWU the three most frequent exempt research categories are category 1, category 2, and category 4.

The Research Compliance Officer (RCO), reviews the proposal, determines whether the protocol includes all the required elements and whether the project qualifies as exempt. The decision as to whether the protocol is confirmed in writing, frequently within one week of submission.

c) **Expedited Review** – Some research qualifies as expedited. 45 CFR § 46.110. To qualify for expedited review, a research procedure must be limited to the activities that are federally approved (63 FR 60364-60367, November 9, 1998) for expedited review and incur no more than minimal risk for participants, or be a minor change in previously approved research that involves no additional risk to the research participant.

The activities approved in the federal regulations for expedited review are:

1) Clinical studies of drugs and medical devices under limited circumstances

2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
3) Prospective collection of biological specimens for research purposes by noninvasive means procedures like hair and nail clippings or saliva.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Category 4 includes minimal risk research where the data are collected through non-invasive ways routinely employed in clinical practice. For example:

- a researcher utilizing physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant’s privacy
- weighing or testing sensory acuity
- magnetic resonance imaging (MRI);
- electrocardiograph (EKG), electroencephalography (EEG), thermography, ultrasound,
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

Category 4 often arises in neuropsychology research with an EEG monitoring brain waves or in Kinesiology research studying exercise, strength testing, and flexibility testing. While the expedited categorization is appropriate for moderate exercise of normal, healthy participants, it would rise to the level of full review if the participant was infirm and subjected to an intense or dangerous exercise.

5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes

6) Collection of data from voice, video, digital, or image recordings made for research purposes

Research involving collecting data from voice, video, digital, or image recordings made for research purposes is usually reviewed in an expedited manner. Because it is virtually impossible to keep the identity of a participant anonymous in a recording, this type of research usually rises to a higher level of review than exempt. Extra precautions must be described as to how the identity of the participant and the confidentiality of the data will be protected.

This category often arises in ethnographic research or in focus group research where the discussions are recorded for later transcription and coding. If the purpose of the recording is to determine the language or manner of speaking such as recording the speech of autistic patients or
studying the linguistics of a population, the research falls within expedited review. However, if the recording is only done to confirm that the notes or transcript are accurate and will be deleted immediately upon confirmation of the written product’s accuracy, the research may be reviewed in the exempt category.

7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research related interventions, and (iii) the research remains active only for the long term follow-up of subjects.

The renewal process will be described in more detail in a subsequent section.

9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The most common categories of expedited research conducted at WWU are categories 4, 6, and 8.

d) **Convened (Full) Review** is research involving humans that does not qualify as exempt or expedited. Thus, any research that constitutes more than minimal risk requires full IRB review. Full review is also required if the research is minimal risk but is not covered in the exempt or expedited categories of review. If a protocol must go to full board for review, the board may request the researcher to come to the meeting to address any questions but they cannot stay for the vote. A project that involves greater than minimal risk requires approval by a convened IRB panel composed of members qualified to review research in that field. Research that requires full committee review includes:

- research that involves greater than minimal risk;
- non-exempt research that involves children or other vulnerable populations;
- research using deception with no informed consent;
- research that involves experimental drugs or devices; and
- research that involves invasive procedures.
- survey research that involves sensitive questions or information about sexual practices or illegal behavior is subject to full review, unless adequate safeguards are in place to protect the anonymity of the participant and the
confidentiality of the data. Similarly, questions about topics that could lead to social stigma, loss of a job or reputation must include safeguards to protect the identity of the participant. This is particularly important in recorded interviews because voices and images can result in loss of anonymity if not properly masked.

A full review must occur at a convened meeting of a quorum of the committee. Protocols must be passed by a majority of those in attendance. Committee members may not send a proxy vote but may attend virtually.

VI. Protocol Submission Process

All human participant research protocols must be submitted to the IRB using WWU’s IRB form found at: http://www.wwu.edu/rsp/documents/frmhuman.shtml.

a) The application can be submitted in paper to RSP or electronically by scanning and emailing it to the RCO.

The RCO conducts a preliminary review of the protocol and confirms that the package is complete. A complete package must include the following:

1) The name, department, research title, contact information, and anticipated start date;

2) The researcher and department chair. If the researcher is a student, the protocol must also include the faculty advisor’s signature;

3) The protocol must indicate the category that the researcher thinks that it falls within (for example, category 2 exempt if it involves surveys or interviews or expedited if it includes audio or video recording) See further explanation of categories in section VI;

4) The protocol must describe the hypothesis and research methods and references supporting the proposed research methodology and instruments;

5) Eligibility requirements including all inclusion and exclusion factors;

6) Questionnaires, assessment instruments, or focus group or interview questions. These instruments must be in their final version, no drafts will be accepted. Under certain circumstances such as ethnographic research or focus groups, the researcher may not know all of the specific questions in advance since those tend to evolve in an iterative process. However, the researcher must provide the nature of the research as well as the questions intended to guide the interviews;
7) Recruitment materials, proposed participant instructions, and debriefing materials. Recruitment materials must include the word research and may not list payment in font larger than the rest of the flyer;

8) A protocol and the informed consent must including the risks and benefits to participants. Participants may be paid but the amount and method must be approved by the IRB and the compensation may not be a coercive amount;

9) An informed consent or an explanation requesting a waiver of written consent;

10) The curriculum vitae or resume of the researcher;

11) The NIH or CITI human participant research ethics certificate of all researchers involved with data collection or analysis or an explanation of the plan for alternate training of the research team members (as described below in section IX);

   and

12) A data safety monitoring plan describing how the researcher will protect the privacy and anonymity of the participants and confidentiality of the data. An example of this description is that the informed consents and the data will be stored separately to protect the anonymity of the participants and the data will be stored on a password protected computer or in a locked file cabinet or in a locked office.

   In addition, researcher may be required to submit:
   • Disclosure of Significant Financial Interest; and/or
   • Documentation of approval by another University committee, e.g., Biosafety Committee

b) The RCO will review the protocol for completeness will make an initial determination as to what category of review is warranted. The three levels are exempt, expedited, and full review.

c) If the proposed research constitutes minimal risk and falls within one of the categories of exempt research, the RCO reviews the protocol to determine whether it satisfies the Common Rule criteria. If the protocol is adequate, the RCO may issue an approval memo.

d) If the RCO reviews a protocol and it does not qualify as exempt, the RCO will review the file for completeness then distribute the protocol to the IRB Chair and a designated member of the committee for review. If an initial application qualifies for expedited review, the RCO as the designee by the Chair will select a subcommittee of two members of the IRB to review the application.
e) The reviewer will respond by communicating any additional revisions or supplements required for approval to the RCO. The RCO will send the comments to the researcher and the researcher will re-submit the protocol with the requested changes.

f) The reviewer will then read the revisions and inform the RCO whether the project is approved.

g) If, upon review, any committee member concludes that the protocol does not qualify as exempt or expedited review due to the participant risk, a vulnerable population, or it does not fall within the exempt or expedited categories, the RCO will distribute the protocol to the full membership of the IRB.

h) The committee members will respond by communicating any additional revisions or supplements required for approval to the RCO. The RCO will send the comments to the researcher and the researcher will re-submit the protocol with the requested revisions. The RCO will then schedule an IRB meeting. The committee cannot vote to approve unless there is a quorum at the meeting.

i) At the convened meeting of the IRB must include a majority of the IRB and an approval must be reached by a majority of the quorum.

j) The IRB will then hold a convened meeting to vote on the protocol. The committee will review and discuss the following items, and any additional items deemed necessary, prior to the vote:
   - IRB application with addendums
   - Proposed informed consent document(s) and/or script as appropriate
   - Copies of surveys, questionnaires, or videotapes
   - Copies of letters of assurance or cooperation with research sites
   - Recruitment/advertising intended to be seen or heard by potential participants, including e-mail solicitations and physician letters,
   - Reviewer’s comment sheet and informed consent checklist
   - Translation, if appropriate

k) In order to vote, a majority of the IRB must attend the meeting. The outcome of the vote can include:
   - Approval;
   - Approval dependent on modifications;
   - Deferral on vote until modifications are complete;
   - Fail to approve.

VII. Informed Consent

Informed Consent is a process, not merely a document. The purpose of the process is to ensure that the participants actually understand that they are
voluntarily participating in research, understand the purpose of the research, the risks and benefits of participation, and their legal rights.

a) **Written and Signed Informed Consent** is written document in language understandable to the participants that informs the research participants of their legal rights as well as the risks and benefits of participating in the research. 45 CFR §46.116(a). The consent must be written in language understandable by the research participant. Generally, this requires language at an 8th grade level though the level varies depending on the participant population.

Unless the IRB grants an exception, this document will be signed by the participant. The researcher must provide a copy of this document to the participant and keep the original.

According to Federal Regulations the Consent must include:

- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the subject's participation;
- A description of the procedures to be followed;
- Identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant 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;
- Research, Rights or Injury is an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled.

b) WWU and Federal Law require that the consent must include language indication that confidentiality must be waived if the research indicates that the participant has been the victim of sexual abuse.

c) **Written but not Signed Consent** is available under limited circumstances. Sometimes, the IRB will approve a process where an informed consent is written
and approved but does not require the participant’s signature. In this scenario, the consent is read to the participant and the participant must acknowledge that they understand the terms of the consent. Preferably, there will be a signed form from the individual who reads the consent.

An example of when signed consent can be waived is when the participants live in a culture where it is socially unacceptable to sign documents such as mistreatment inflicted on the society in the past. For example, in some communities, the members were requested to sign forms that had the result of transferring property ownership of the land rather than providing consent to participate in research. Another example of when the signature could be waived is if there could be increased political or societal risk to the participant by documenting their identity in relation to the research. For example, informed consent might be waived when the participant is in a politically dangerous situation where the participants’ statements might have consequences for their safety if someone learned that they had participated in the research.

d) **Waiver of Consent.** Under limited circumstances consent can be waived. The criteria for waiving consent include:

a) The research involves no more than minimal risk to the participants;

b) The waiver or alteration will not adversely affect the rights and welfare of the participants;

c) The research could not practicably be carried out without the waiver or alteration; and

d) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

45 CFR 46 §116(d).

An example of when consent may be waived is if a researcher is reviewing medical records regarding the occurrence and treatment of melanoma. Because the records were originally collected for treatment as opposed to research, the project can be conducted as exempt category #4. Because it would be impractical or impossible to obtain consent from the individuals whose records are being reviewed and it is minimal risk because the records are de-identified, consent can be waived.

**VIII. Ongoing Review Issues**

After review by the IRB panel, the application will be:

- approved as submitted;
- approved with minor suggestions for changes;
- approved with stipulations (conditions that must be met before final approval is granted) - *most common*;
- deferred, pending receipt of additional information or major revisions; or
not approved.

a) **Approval** of an exempt protocol at WWU is valid for five years. During that time there is no need for further review by the IRB unless the investigator revises the protocol. If there is a modification, such as a change in recruitment procedure or location, a revision of the survey instrument, or change in the consent, or an addition to the research team, the investigator must submit a protocol modification request to the IRB.

b) Expedited and Full review protocol approvals are valid for up to one year. The investigator must contact the Research Compliance Officer prior to expiration of the protocol and request a continuation. Recruitment of new participants is forbidden if the protocol approval period has lapsed. Recruitment outside the approval period may constitute research misconduct.

c) **Continuing Review** Once approved by the IRB, non-exempt research must be reviewed at least annually. The IRB can review more frequently where there are specific concerns. Once the request for renewal is submitted to the RCO, the research compliance officer will review and determine whether to renew the protocol for another term or whether it must be referred to the IRB for review. The compliance officer will notify the investigator with an approval notice stating the term of the approval.

**Modifications** – If, subsequent to IRB approval the researcher modifies the approved protocol, they must submit a modification form. The modification form must describe the change and must be submitted to the RCO. The Modification form must be approved by the IRB before the modification is implemented.

Minor modifications can be reviewed like an expedited review. Examples of minor modification include the researcher changing research personnel, procedure changes that constitute same or lower risk level to the participants, changing the study title, changing the number of the participants, and changes to improve the language of the consent form.

Major modifications require expedited or full IRB review depending on the category of the original review. A modification is major when the change is substantive and may alter the risk and/or benefit to subjects who participate in the research. A major modification occurs when the researcher becomes aware that a new risk may affect the risk/benefit ratio, there is an increase in the length of time a subject is exposed to the experimental aspect of the study, changing the target population to a more at risk population

**Post-Approval Monitoring** The purpose of continuing to review and monitor ongoing studies is to ensure that the research remains justified and the rights
and welfare of the participants continue to be protected. The IRB retains the right to inspect investigators’ records to confirm compliance with the assertions in the approved protocol. For example, the committee can review the signed informed consents to ensure that the consent approved by the committee has been used, have been signed by the same number of participants as enrolled in the research, and are stored in a secure manner as approved in the protocol.

IX. Ethics Training

WWU requires ethics training of all members of the research team to complete ethics training and documentation of the training be submitted with the protocol. There are two methods of obtaining the training certificate:

The first is completing the course offered on the Office of Human Research Protection website. Upon completion, the investigator can print out a certificate issued by the National Institutes of Health (NIH) course entitled “Protecting Human Research Participants”. Another training option is the Collaborative Institutional Training Initiative (CITI) Social and Behavioral Research course. This is an online training module that provides more in depth human research examples. For example, it includes modules on cultural competence and internet research that are not included in the NIH training.

Federal Regulations, OHRP guidelines and other applicable guidance, state and local laws, and institutional policies for the protection of human subjects require ethics training. The University provides an on-line training program to IRB members and staff before they begin reviewing human participant research and research investigators must complete educational training before conducting human participant research.

There are unique challenges when a WWU researcher is collaborating with a data collector or colleague in other countries. Because of cultural differences, it is vital for all members of the research training team to understand ethical principles such as anonymity and confidentiality. Training co-researchers from other countries and cultures is particularly challenging because the researcher may not speak English or may not have access to the Internet for the on-line course. Johns Hopkins provides a model for an effective human researcher training course for foreign data collectors: http://www.jhsphs.edu/offices-and-services/institutional-review-board/training/field-training-guides-for-data-collectors/. This ethics training manual is available in several languages. In order to utilize foreign data collectors or foreign co-researchers, the faculty member must provide them with a copy of the guide and the research colleagues need to sign and acknowledge in writing that they have read it.

Under certain circumstances, the research may be conducted in a foreign country or a location with no internet service or speaks a language for which the Johns Hopkins training course has not translated. In that situation, the investigator should write up a training plan that may serve as an acceptable substitute for IRB approval. The investigator must sign a document that the data collectors or foreign colleagues have completed the approved training.
X. Internet Research

The development of Internet research has opened up many opportunities, especially social behavioral research. However, with the advantages and opportunities, it creates a new set of ethics challenges not previously faced by IRBs. Some of the challenges such as privacy, confidentiality, and informed consent are discussed below.

Some of the various types of web-based research include chat rooms, listserves, surveys, social media, mTurk, participant recruitment, and Skype. The Office of Human Research Protection (OHRP) has indicated that data collection from the internet OHRPs human participant research and should be reviewed by the IRB.

In order to constitute human participant research, the researcher must interact or intervene with humans. This creates a unique dilemma for online research because of the lack of face-to-face interaction. While it is easy to determine there is interaction with the participant if the researcher sends out an online survey or participates in a chat room while collecting data, it is more difficult to determine if the research constitutes intervention or interaction when the researcher is observing posts that are posted on the internet. The topic of online research ethics continues to evolve so when planning to conduct internet research, it is best to contact the RCO prior to writing the protocol to discuss the research logistics.

Online chat rooms and support groups are a rich source of research content. However, there are several challenges including privacy and consent. If the chat room is a moderated room and requires a login, then the researcher must obtain permission from the gatekeeper/site administrator in addition to the individual participants. A challenging ethical issue arises in online support groups that require no login is that the participants may be sharing assuming that they are talking with people who have a similar problem when, in fact, their discussions are being read by a researcher. Simply announcing that you are a researcher when entering the chat room may not be sufficient because of individuals entering and leaving the chatroom at random intervals. The specific method for obtaining consent must be resolved with the IRB prior to conducting research.

Another privacy issue arises when conducting social media research. Even if the researcher may have obtained consent from a participant, the researcher doesn’t have consent from the people who comment on the participant’s posts. It is an ethical dilemma as to whether a researcher can use not only the data of consenting participant but also the “friends” of that participant who unknowingly volunteer information that could be used for research.

The opportunity to distribute surveys on the internet is beneficial because it decreases the cost of printing and mailing the survey, and also increases participation rates. Also, electronic surveys can speed scoring time. However, online surveys raise unique challenges that have not been resolved by OHRP. For example, it is impossible to get signed consent in an online survey. Also, how can a researcher determine or verify identity or whether the participant is an adult?
For web-based surveys, the informed consent should be placed on the first page of the survey. The researcher should add a click through button that prohibits the participants from continuing with the survey unless they click accept. Online informed consent requires all of the elements of written consent. At the end of the consent for online surveys include the language: By clicking on “accept” and completing the survey you are agreeing that you read the consent and agree to participate in the research.

Online consent must also include language that there is a limit to the guarantee of confidentiality due the technology itself. Specifically, although the risk is small, no guarantees can be made regarding the interception of data sent via the Internet by any third parties. In order to meet the requirement of autonomy, the researcher should design the online survey so that any question can be skipped. The only button that must be clicked is the agreement to the terms of the informed consent.

A program that is increasingly popular for online research is Amazon’s mTurk. A researcher can post a survey and provide a small monetary incentive. An advantage of this is that the researcher can draw upon a much larger and more diverse participant pool than utilizing students or community members. The consent issues should be addressed as discussed above for online surveys.

Skype is useful for conducting interviews without the cost of travel. In Skype interviews a researcher may be able to get verbal consent from the participant. If the researcher is recording the interview, they must obtain permission to record in addition to consent to participate in research. Another possibility that might be approved under certain circumstances is the researcher sends an email with the consent language and the participant replies giving consent to participate in the research.

Unless the protocol provides compelling reasons, no participants’ IP addresses can be collected. These addresses can be used to track the participants down to a particular location and thereby jeopardize anonymity. Some online survey programs have the capability to turn off the IP address collection function.

Another challenge inherent in online research is storing the data in a secure manner. Some survey programs are very secure such as Qualtrics, however, some programs like Survey Monkey and Google docs are not secure and the data can be compromised. In some cases, the privacy statement of the survey program provider explicitly states that the data collected can be viewed and used by the company. Any protocol proposing an online survey must provide details as to how the data will be protected. This is particularly important when the research topic involves sexual or criminal activities where disclosure of the data could lead to social or economic consequences to the participant. Because privacy policies for on-line survey programs are frequently revised, the research should contact the RCO for acceptably secure programs prior to acquisition.
Participant recruitment using the internet whether solicitation by emails, social media, or internet ads must adhere to the same rules as print recruitment. The language must be submitted to and approved by the IRB. If a researcher plans on recruiting participants through campus email, access to the email list must be approved by a University official such as the Registrar.

XI. Vulnerable Populations

Vulnerable Populations are populations in which some or all of the participants are likely to be vulnerable to coercion or undue influence. The regulations specifically list children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. 45 CFR § 46.111(a)(3) and 21 CFR § 56. The Belmont Report adds three additional categories: racial minorities, the very sick, and the institutionalized. In reviewing a protocol, the IRB must consider whether the participants fall within a protected category and if they do, the IRB must give extra scrutiny to assure that the participants are protected. Categorizing some populations as “vulnerable” can create a stigma implying that the population cannot be autonomous and decide for themselves as to whether to participate in a research project. However, to label a group as vulnerable merely means that the group may have been subject to discrimination in the past, or are in a position that including them in a research population may be coercive either because they lack the capacity to give informed consent or they are in a position where it is difficult to say no. Research with vulnerable populations triggers a high level of scrutiny by the IRB.

These protections arose, in part, as a result of research such as the Tuskegee Syphilis study where southern black men were induced to participate in order with promises of free medical care. The researchers tracked their health symptoms and deterioration for decades and didn’t inform the participants when penicillin became available that would have treated their condition. There has also been mistreatment of socially and educationally vulnerable populations. Another recent example is that there have been instances of pharmaceutical researchers providing free housing to undocumented immigrants, addicts, and homeless people in exchange for participation in medical drug trials. This is a potentially very coercive inducement and hence warrants a high level of scrutiny by the IRB in the analysis of risk versus benefit.

While a higher level of review is required for vulnerable populations, it is still required that research benefits and burdens should be distributed fairly. An individual should not be denied access to research that might benefit them merely because they are in a category requiring higher protections. This relates back to the concept of Justice in the Belmont Report. Research participation should be based on the relevant population, not a population of convenience. Therefore, a participant should not be excluded simply because they are pregnant women, a prisoners, or some other vulnerable population. NIH regulations require a scientific justification if some populations are excluded from participation.
a) **Children** are categorized as vulnerable participants in Section D of the Common Rule. They are subject to coercion and warrant extra protection during the IRB review process. As discussed above, the only situation in which research with children can be exempt is research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional practices, such as (1) research on regular and special education instructional strategies or (2) research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods qualifies as category 1 exempt is if it is conducted regarding normal educational activity.

Unlike adult research, surveys and interviews with children cannot be reviewed as exempt. Similarly, it cannot be reviewed as exempt if the researcher interacts with the children while observing their behavior.

Thus, if a researcher is analyzing pre- and post-assessments of the children testing out a new curriculum that is probably exempt category 1 because it is a normal educational practice. However, if they are surveying children’s attitudes toward smoking or drugs, that would probably not fall within the exempt category unless it is a health class that normally performs that type of activity.

Because they are minors, children, in most cases, are deemed incapable of giving consent. Thus, normally the researcher must obtain parental consent and child assent. **Child Assent** indicates a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (45 CFR 46.402(b)). Assent should be signed by the participant except for children under the age of six. When judging whether children are capable of assent, the IRB takes into account the age, maturity, and psychological state of the children involved. The IRB has the discretion to judge children’s capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.

When signed parental consent can be waived:
- Minimal risk to the participants
- The documentation of consent is the only record linking the child to the research, and the principal risk would be potential harm resulting from a breach of confidentiality.
- The research involves procedures for which consent is not normally required outside the research environment.
- Under certain limited circumstances, parental consent can be waived if the research involves investigation of child abuse.

b) **Prisoners** are also categorized as a vulnerable population warranting a higher level of scrutiny and protection by the IRB. In the 1970s, more than 85% of pharmaceuticals were tested on prisoners prior to FDA approval. Prisoners are especially subject to coercion since they are literally a captive audience and any
inducement they are offered can lead to an improved quality of life. Therefore, the Common Rule places special protection in reviewing research involving prisoners. In order to conduct a protocol involving prisoners, the IRB must have a committee member to represent the prisoners’ perspective and interests. Examples of people who might satisfy this requirement is a former prisoner, a prison chaplain, a defense attorney, or a member of ACLU. Prisoner research must be reviewed and approved by a full IRB review.

c) Pregnant Women and Fetuses are also listed as vulnerable populations under the Common Rule. In situations of pregnant women, extra protection must be provided to protect the interests of the fetus who is not only incapable of giving consent, but also highly vulnerable. However, the protection primarily applies to medical research not social behavioral. When a researcher is conducting social behavioral research, there is rarely a scientific basis to exclude pregnant women from participation.

XII. Cross-cultural and International Research

Cultural Competence refers to understanding the importance of social and cultural influence on the beliefs and behaviors of the research participants. Cultural competence is required in all contexts whether local, national, or international. Cultural competence requires more than just awareness of cultural differences, it requires efforts to improve skills and values in order to conduct research effectively in multi-cultural settings. It is necessary both to exhibit respect for persons, but also to establish a trusting relationship between the participants and the research.

While human participants in foreign countries merit the same level of protection as participants in the United States, acceptable practices vary from place to place. Different mores, traditions, and institutions may require different research practices, particularly relating to informed consent, recruitment practices, interview questions and documentation. Special attention should be given to local customs and to local cultural and religious norms in drafting consent documents.

In some cases, research projects must be approved by local experts or community leaders prior to IRB submission. This is often referred to as gatekeeper consent. Leadership approval must be obtained prior to contact with the participants. The IRB requires documentation of this "local approval" before it approves. Depending on the community, it may be the leadership of a Native American tribe, a village chief in an international setting, or the president of an organization. In their protocol, researchers should describe what if any, knowledge or experience they possess regarding the language and culture of the country in question.

The proposed research must comply with the ethical rules of the country or community in which the research is conducted. The Office for Human Research Protection (OHRP) can determine whether procedures described by a foreign institution afford protections that are at least equivalent to U.S. regulations (45 CFR 46 101 [h]). Under this provision, the
IRB researches the foreign country’s guidelines for human participants research, and if the foreign guidelines are found to be equivalent to U.S. regulations, the investigator is permitted to substitute those foreign procedures.

Researchers proposing international research should allow additional time for this review process.

**Community Participatory Action Based Research (CBPR)** is research with a topic specific to a particular community with the goal of knowledge and action to improve community health or some other topic of community social importance. Community engagement is a core element. The community participants become part of the research team to guide the development of the research topic, to provide knowledge, and help develop an action that will address the needs of the community. Likewise, the academic member becomes part of the community as well as part of the research team. Cultural competence is vital to effective CBPR because the research must be respectful of cultural values. An understanding of Cultural Competence in Research is thus not only required for successful and culturally respectful CBPR and community engagement, but also for effective research design, implementation, and recruitment of research participants for traditional modes of scientific research.

Community Partners involved with recruiting participants, obtaining informed consent, or collecting data must obtain research ethics training. The extent of the training depends on the nature of the research project and the sensitivity of the data collected. See the discussion in the previous section regarding consent.

**XIII. Appeal of IRB Determination**
If a researcher is not satisfied with an IRB determination, he or she can submit an appeal to the Vice Provost for Research within 30 days of the determination. The appeal document must provide a regulatory basis for reversing the IRB’s determination. The Vice Provost for Research will review the protocol file, the meeting minutes, the appeal documents, and determines whether to decision is upheld or overturned.

**XIV. Non-Compliance and Reporting Adverse Events**

All members of the research team are required to conduct the research in compliance with the procedures established in the approved research protocol. **Non-compliance** is failure to comply with applicable federal regulations, WWU IRB policies and procedures, or the determinations of the WWU IRB. When the researcher is in non-compliance, they may be committing research misconduct. Non-compliance will be investigated as discussed below.

**Serious Non-compliance** is an action or omission taken by an investigator, study personnel, or individual that any other reasonable individual would have seen as compromising the rights and/or welfare of the participants.

Examples of serious non-compliance:
1) Failure to adhere to the federal regulations governing the use of humans in research;
2) Failure to obtain IRB approval prior to recruiting participants or initiating research procedures;
3) Failure to notify the IRB of changes in approved procedures or changes in the scope/intent of the study;
4) Failure to obtain or document informed consent (unless approved by the IRB);
5) Breaching participant confidentiality;
6) Enrolling participants after the protocol has expired;
7) Failing to report adverse events;
8) Applying coercion or undue influence to recruit or keep participants in a study.

Investigations of noncompliance will be conducted by a sub-committee of the IRB as appointed by the Research Integrity Officer. The subcommittee will:

1) Contact the researcher with the allegations. The researcher will have 14 days to respond in writing.
2) The committee will review the protocol, the researcher's response, and any other documents related to the non-compliance allegation. The committee may also interview people with knowledge about the allegation.
3) The investigation committee will write a report with their findings and present it to the institutional official.
4) The committee will give the report to the researcher who will have 14 days to respond in writing.
5) The institutional official will review all relevant documents and determine the actions to be taken as a result of the finding.

Actions that may be taken during or after the investigation of non-compliance include:

- No action
- Suspension of enrollment of the study
- Termination of the research
- Modification of the research protocol
- Require participants to re-consent
- Refer to other organizational entities including a research misconduct committee
- Notify the funding agency

An adverse event is an unanticipated problem involving risks to participants or others. This can include both physical and psychological harms. The investigator must report any adverse event promptly. Examples of an adverse event include a breach of a participant's anonymity, loss of a computer containing transcripts or interview recordings, death of a participant, or legal consequences of a participant based on their involvement or research responses. For example, a participant being arrested or losing his job after admitting to drug use in a research interview following an anonymity or confidentiality breach.
IX. Records and Data Retention

Researchers must maintain a file of all documents concerning their use of human participants in research. These documents must be maintained for six years following completion of the research. These records may be maintained electronically or in print. For example, a researcher may scan all of the informed consents and store them electronically.

The documents that researchers should keep on file include:

- A copy of the original application submitted to the IRB, including the consent form and the research protocol;
- The IRB’s response;
- Notice of the final approval;
- Copies of all other correspondence with the IRB;
- Copies of completed “continuing review” forms and attachments;
- The notice of renewal of approval and certification where applicable;
- Copies of any inspection or audit reports; and
- Copies of all signed informed consents.

IRB records are subject to inspection by federal authorities as well as the WWU IRB. Sanctions for incomplete or nonexistent records include suspension of funding, fines, exclusion from future funding, and suspension of laboratory access and investigation for non-compliance and research misconduct.