Human Research

Academics and Research – Research

EWU Policy 302-02	**Authority: Board of Trustees**
Effective: May 10, 2019	**Proponent: Provost and Vice President for Academic Affairs**

Purpose: This policy prescribes standards for the use of human subjects in research activities at Eastern Washington University in accordance with the Revised Common Rule (45 Code of Federal Regulations § 46).

History: This policy updates the previous version dated July 13, 2012. Interim policy changes were approved by the President in response to changes to the Revised Common Rule on January 7, 2019. Final changes were adopted by the Board of Trustees on May 10, 2019.

Scope: This updated policy applies to all future human subject research applications and any current application that has not received initial approval from the institutional review board as of January 1, 2019.

CONTENTS

Chapter 1 – General
Chapter 2 – Policy
Chapter 3 – Review
Chapter 4 – Reviewing Bodies
Chapter 5 – Submission of Proposals
Chapter 6 – Changes in Protocols / Renewals

CHAPTER 1 – GENERAL

1-1. Policy for the Protection of Human Subjects

Eastern Washington University (EWU) adheres to the ethical and professional standards set by the Department of Health and Human Services (DHHS) regulations for the protection of human subjects in research (45 CFR § 46) and the Common Rule (45 CFR § 46, Subpart A). EWU is required to provide assurances to the Office for Human Research Protections, DHHS, that human subjects research complies with the Common Rule and its subparts.

The Common Rule has been shaped by the guidelines and ethical principles set forth in the 1949 Nuremberg Code and the 1976 Belmont Report. Research investigators are encouraged to familiarize themselves with these guidance documents, this policy, and all pertinent federal policies on the OHRP website.

1-2. Definitions

"Human subject" means a living individual about whom an investigator (whether a professional or student) conducting research:

a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or,
b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

"Identifiable biospecimen" is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

"Identifiable private information" is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

"Interaction" includes communication or interpersonal contact between investigator and subject.

"Intervention" includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

"Private information" includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., medical records).

"Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research also includes human subject data/results that will be reported or published (e.g., publication, thesis, classroom presentation, conference presentation) even when they do not contribute to generalizable knowledge. Activities that meet this definition are considered research for the purposes of this policy, regardless of whether they are considered research under other university policies. This may include some demonstration and service programs. However, the following activities are not considered "research" under this policy:

a. In-class data gathering for learning activities within a class with enrolled students practicing research techniques on one another. However, faculty should contact the

HPA to see if additional documentation or training is required;

b. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. Depending on methodology and intent of use of this information, this type of project may or may not be considered research. For example, if oral history activities only document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings these would not be considered research. In any case, researchers must consult with the IRB before beginning such a project;
c. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Additional information about this exception is set forth in 45 CFR § 46.102(l);
d. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes; or,
e. Authorized operational activities in support of intelligence, homeland security, defense, or other national security missions as determined by a federal agency.

1-3. Applicability of Policy

EWU is required to comply with all applicable federal regulations governing federally-funded research. Consistent with such responsibility, all research involving human subjects shall be approved in advance in accordance with this policy by the EWU Institutional Review Board (IRB) and reviewed at the levels appropriate for exempt and non-exempt research as outlined in this policy. This includes any human subject research, whether such research is undertaken on a large or small scale, whether it is preliminarily or fully designed, whether it is student or faculty research, whether it is funded or non-funded, and whether it involves less than minimal risk or more than minimal risk.

The Human Protections Administrator (HPA) or the IRB Chair should be consulted if there are any questions about whether or not a project constitutes research within the scope of this policy. Even if a project does not fall within the definition of human subjects research, investigators are highly encouraged to consult with the appropriate IRB officials before beginning a research project.

1-4. Investigator Responsibilities

Ultimately, individual faculty, staff, and/or students are responsible for maintaining ethical standards and complying with this policy and the Common Rule. Any research involving human subjects must be associated with a responsible project investigator who is a qualified faculty member or a qualified staff member, and who will monitor and be liable for the conduct of the research. Moreover, all student research must be appropriately monitored and/or supervised by a faculty or staff research advisor who is a qualified faculty member or qualified staff member knowledgeable in research ethics and methods. In the case of student research, the faculty or staff research advisor will be identified as the Responsible Project Investigator.

All faculty, staff, or students engaging in research under this policy must obtain written approval from the IRB before initiation of subject recruitment or initiation of procedures that involve human subjects. Engaging in research with human subjects without IRB approval puts the researcher at risk and is a violation of university and federal policies. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk.

1-5. Institutional Review Board (IRB)

The IRB is required as an added measure of reassurance and as a local resource for the interpretation of ethical regulations, standards, and guidelines. Standards regarding the composition of the IRB are set forth below in chapter 4.

The IRB has the authority to approve, require modifications necessary to secure their approval, or disapprove all research activities covered by this policy, including any exempt research activities as specified in chapter 3.

Finally, if research is being conducted using human subjects whose protection is the responsibility of an agency/entity other than Eastern Washington University, such research will also be subject to that agency's procedures and approval.

CHAPTER 2 – POLICY

2-1. Informed Consent

Informed consent is a fundamental ethical requirement for human subject research, emphasizing the essential collaborative relationship and understanding between a researcher and participant. In almost all cases, including most exempt research, an investigator must obtain informed consent from the subject or the subject's legally

authorized representative in accordance with 45 C.F.R. § 46.116 before involving a human subject in the research. Informed consent must be in writing and be approved in advance by the IRB, unless the IRB grants an exception in accordance with 45 C.F.R. § 46.117. The original completed form must be maintained by the investigator and a copy provided to the subject.

An investigator should seek informed consent only under circumstances that provide the prospective subject or legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence. Additionally, the prospective subject/legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. Informed consent must begin with a concise and focused presentation of key information that is most likely to assist a prospective subject/legally authorized representative in understanding the reasons why one might or might not want to participate in research and such information must be provided in sufficient detail to allow the person to make an informed choice. Informed consent may not include any exculpatory language, waiver, or release.

Informed consent includes three essential elements: voluntary participation, disclosure, and comprehension.

a. Voluntary Participation. Participation of human subjects in research governed by this policy must be voluntary. The consent of authorized representatives is usually required, in accordance with applicable statutes and regulations, for subjects who have diminished capacity to consent. Such persons include minors, individuals with cognitive or intellectual disabilities, or prisoners.

i. Recruitment. The methods used for approaching subjects and securing their participation should be designed carefully to protect the privacy of the subjects and should be reasonable in terms of their condition or circumstances. No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Where the professional-client or faculty-student relationship is converted into an investigator-research participant relationship, special care must be taken to ensure that the subject feels completely free to decline to participate and is provided with a suitable alternative activity if research participation carries the possibility of incentives such as extra credit, money, etc. Any incentive provided to participants should not be large enough to constitute excessive inducement for participation. Requiring students to participate in out-of-class research projects as part of a course requirement violates the principle of voluntary participation. Where access to subjects is gained through cooperating institutions or individuals, care should be taken not to abridge prior commitments made to the subjects about the confidentiality or other terms of the primary relationship.

ii. Participation. Informed consent procedures should be conducted with participants prior to the onset of the research effort. The research must provide adequate time for potential participants to consider whether or not to participate. Research participants must maintain the right to withdraw from the study or not answer objectionable questions throughout the course of the study without incurring a penalty, such as denial of incentives or adding penalty points to a course grade.

b. Disclosure. Disclosure includes information regarding:

- 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 that 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 that 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 (as defined below), 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 who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of

benefits, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

- If the study involves the collection of identifiable private information or identifiable biospecimens, one of the following statements must be included:
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or,
    - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

In some research, disclosing certain information to the subject would invalidate the research. In such cases, it may be necessary to withhold information (e.g., the hypotheses) from the subject. However, information should not be withheld if withholding it would affect a reasonable person's decision to participate or damage his or her subsequent self-esteem. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

In studies involving the use of deception, appropriate debriefing activities that maintain the dignity of the participant must be conducted immediately after the conclusion of the study.

c. Comprehension. Comprehension is the third element in informed consent. The manner and context in which information is conveyed is as important as the information itself. Consideration must be given to the subject's ability to understand the language and terminology used as well as the subject's physical and mental state. Information must be provided in a language understandable to the subject. Investigators are responsible for ascertaining that the subject has comprehended the information.

d. Additional Elements. Unless waived by the IRB, informed consent also must include one or more of the following statements, when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's/legally authorized representative's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study;
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and,
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

2-2. Exceptions to Informed Consent/Broad Consent

When permitted by and in accordance with the Common Rule (45 C.F.R. § 46.116), a researcher may obtain broad consent in lieu of informed consent only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

The IRB may also approve a consent procedure that deviates from the requirements included in 2-1 if it follows the requirements and procedures set forth in 45 C.F.R. § 116(e), (f), (g).

2-3. Confidentiality of Data

In all research involving human subjects, confidentiality of identifiable information is presumed and must be

maintained to the extent permitted by law unless the investigator obtains the express permission of the subject to do otherwise or the information is publically available. In the case of publically available information, if the data are being repurposed or redistributed, the IRB should be consulted regarding any provisions necessary for maintaining confidentiality of the data.

Additional legal requirements apply if the data collected are protected by state or federal law, such as medical records, counseling records, or student education records. Research may also be protected by a Certificate of Confidentiality. A Certificate of Confidentiality is a legal protection that may be issued to researchers by the Department of Health and Human Services to protect identifiable sensitive information collected as part of a study. Information about Certifications of Confidentiality is available at: https://humansubjects.nih.gov/coc/faqs.

The more sensitive the personally identifiable information, the greater the care that must be exercised in obtaining, handling, and storing data. Ordinarily, the following requirements must be met, subject only to their applicability to the particular activity:

a. Questionnaires, inventories, interview schedules, and other data-gathering instruments and procedures should be carefully designed to limit the personal information to be acquired to that which is absolutely essential to the activity. Subjects should not be asked to provide social security numbers or driver's license numbers unless approved in advance by the IRB.

b. Data that include personally identifiable information should be stored in files accessible only to the project investigator and his or her authorized staff or representatives.

c. As early as feasible, the data should be handled in coded form; i.e., the subject's name and information that would reveal their identity should be removed. Plans and a schedule for the ultimate disposition or indefinite retention of the data must be approved by the IRB.

d. The identity of subjects must not be released except with their express written permission unless disclosure is required by law.

e. Use of stored data or information, which were originally obtained for different purposes and which involves identifiable subjects, requires examination of the risk involved, a determination of whether the new use is within the scope of the original consent or whether obtaining additional consent is necessary and feasible, and provision for the preservation of anonymity of the subjects.

For non-exempt research requiring prior review, the material submitted for review must specify the provisions for maintaining the confidentiality of data and/or preserving the anonymity of subjects.

2-4. Classification of Risk and Required Safeguards

A subject is at risk if he or she may be exposed to the possibility of injury, including physical, psychological, or social injury as a consequence of participation as a subject in the research, development, or related activity. These potential injuries must depart from the established and accepted methods necessary to meet the subject's needs or increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. A subject may be at risk when an investigator uses stored data or information obtained for purposes other than the investigator's research.

For the purposes of safeguarding the human subjects and ensuring that these safeguards are continuously provided, two classifications of risks are introduced.

a. Minimal Risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

b. More Than Minimal Risk. The anticipated risks in the proposed research exceed, either in probability or magnitude, those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2-5. Additional Requirements for Research Involving Vulnerable Populations

Standards for the use of vulnerable populations in research exceed those of other categories of subjects. Under federal law, additional protections are required for minors, pregnant women, embryos or fetuses, newborns, prisoners, and persons with intellectual or cognitive disabilities. Any research conducted using one of these vulnerable populations must meet the additional standards applicable to the research imposed by 45 C.F.R. §§ 46.201-207, .301-.306, .401-.409. When these vulnerable populations are being studied, a review by either the expedited process or the full IRB is required except for certain exemptions for educational research involving minors.

Research involving pregnant women and fetuseses must meet the requirements of 45 C.F.R. § 46.204. Research involving neonates must meet the requirements of 45 C.F.R. § 46.205. Research involving a placenta after

delivery, a dead fetus, or fetal material must comply with 45 C.F.R. § 46.206.

Research involving minors (anyone under the age of 18) requires assent from the minor participant when the minor, in the opinion of the IRB, is capable of providing assent and consent of a parent/guardian. "Assent" means the minor has affirmatively agreed to participate in the research. Mere failure to object, absent affirmative agreement, is not assent. IRB approval is required for research on minors and the IRB is responsible for ensuring the proposed research complies with all of the requirements of 45 C.F.R. §§ 46.401-.409 and 21 C.F.R. part 50, subpart D before approving the research. The IRB can waive the consent requirements if the research meets all of the requirements of the federal regulation. Research involving minors in an educational setting is typically also subject to the requirements of the Family Educational Rights and Privacy Act.

For research involving prisoners, additional safeguards are required as specified in 45 C.F.R. §§ 46.301-.306. All research involving prisoners must be approved by the IRB. Any study that recruits prisoners that does not qualify for expedited review must be reviewed at a fully-convened IRB meeting with a prisoner representative present for the discussion and vote of that study protocol. The research must comply with any applicable requirements/restrictions from the Federal Bureau of Prisons and/or state prison systems. The Principal Investigator must obtain approval from the applicable penal institution to conduct prison-based research.

Finally, individuals in a wide-variety of situations may have an impaired capacity to make decisions. However, individuals with neurologic, psychiatric, or substance abuse problems should not be presumed to lack capacity to make decisions. Federal regulations do not specifically address research involving persons with intellectual disabilities or who are otherwise cognitively-impaired. However, additional scrutiny is warranted for research involving persons with transient or permanent cognitive impairments to make sure there is participant consent. IRB applications for the proposed involvement of cognitively-impaired participants should propose a plan to screen for participants who may not have the capacity to consent. Surrogate informed consent may be appropriate in some situations.

2-6. Posting of Clinical Trial Consent Form

The university will follow the posting requirements of the Common Rule, 45 C.F.R. § 46.1116(h), for any clinical trials conducted or supported by a federal department/agency.

CHAPTER 3 – REVIEW

In classifying research involving human subjects, the investigator and those who review the proposed use of subjects should follow the principles and procedures of this document in arriving at a carefully reasoned decision.

Research using human subjects can be divided into three review categories: Exempt, Expedited Review, and Full IRB Review.

3-1. Exempt Research

Based on university policy and procedures, exempt research requires IRB approval. The IRB exercises the right to require review of specific research activities or classes of research activities even though they may qualify for exemption under the federal regulations so that the IRB can evaluate whether or not the proposed research actually qualifies as exempt research and to meet any requirements of a sponsoring agency.

Categories of exempt research are established by federal regulations and cannot be amended. Research may be exempt from further review by the IRB if it meets one of the eight federal categories of exemption:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

> (i) information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
>
> (ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or,
>
> (iii) the information obtained is recorded by the investigator in such a manner that the identity of the

human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR § 164.501 or for "public health activities and purposes" as described under 45 CFR §164.512(b); or,

(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects that are conducted or supported by a federal department or agency that are designed to study, evaluate, improve, or otherwise examine public benefit or service 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 of 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.

7. Storage or maintenance for secondary research for which broad consent is required: storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use.

8. Secondary research for which broad consent is required if it complies with the requirements of 45 C.F.R. § 46.104(d)(8).

3-2. Ineligibility for Exempt Status

Based on both federal policy and/or university policy, exempt status may not be granted for research that exceeds minimal risk as defined above. In addition, if any of the following conditions apply to the research, it may not be considered exempt:

- The subjects involve any vulnerable populations, unless the research involves children and falls within section 3-1(1).
- The subjects involve anyone who is likely to not have adequate decision-making capacity sufficient to provide informed consent.

- Personal records (medical, academic, etc.) with personally identifiable information are used without written consent.
- Data from subjects (responses, information, specimens, etc.) are directly or indirectly identifiable.
- Data may be damaging to subjects' financial standing, employability, educational advancement, or reputation.
- The intervention or the methods used to collect data introduce risks of harm, physical or emotional discomfort, offense, or embarrassment.
- Material obtained from an autopsy is to be used in the research.

- Alcohol or any other drugs will be ingested.
- Blood or body fluids will be drawn.

3-3. Non-exempt Research

Non-exempt research is subject to one of two levels of review, either Expedited Review or Full IRB Review.

a. Expedited Review

The following list of research activities (carried out through standard methods) may be reviewed through expedited review procedures as long as the research poses no more than a minimal risk to the subjects, as assessed by the reviewer, does not use subjects who are not component to give consent, and consists of research for which each of the procedures falls within one of the categories outlined below. This list is based on federal regulations so that additions to and extrapolation from the list by the IRB are not appropriate. In the case of expedited review, the investigator will not begin the research until informed that the IRB will not conduct a full review of the project.

Expedited review is available for research:

- If it falls within one of the categories identified by the Secretary of Health & Human Services as having a minimal risk and, thus, available for expedited review, unless the reviewer determines the study involves more than a minimal risk;
- Minor changes in previously approved research during the period for which approval is authorized; or,
- Research for which limited IRB review is a condition of exemption, as detailed above.

b. Restrictions on Expedited Review

Expedited review procedures may not be used where:

- Identification of the subjects and/or their responses would easily place them at risk of criminal or civil liability or be damaging to the subjects' reputation, financial standing, employability, educational advancement, etc., unless reasonable and sufficient protections will be implemented so that risks related to invasion of privacy and/or breach of confidentiality are no greater than minimal.
- Classified research involving human subjects.

c. Full IRB Review

All research not exempted or eligible for expedited review shall be reviewed by the full IRB; this includes all research that involves more than minimal risk to the subjects, addresses sensitive issues, uses subjects who are not competent to give consent, and/or is required by a funding source to undergo full IRB review.

CHAPTER 4 – REVIEWING BODIES

There are three administrative units that may participate in the several levels of the review process: The Office of Grant and Research Development (OGRD), the Institutional Review Board (IRB), and the Departmental Review Committee (if one exists in the sponsoring academic department).

4-1. The Office of Grant and Research Development

The OGRD is the administrative unit responsible for coordinating all reviews of research conducted with human subjects because of its Human Protections Administration and compliance role. It is also the office that maintains the records of all applications, IRB meeting proceedings and results. The Human Protections Administrator shall be a member of the IRB and shall be the authorized institutional official whose responsibility is to ensure that the university will effectively fulfill its research-oversight function.

The OGRD must prepare and maintain adequate documentation of IRB activities. Such documentation must include copies of all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects.

The OGRD is also responsible for filling the IRB roster, maintaining training records for the IRB members, and completing any assurances required by OHRP or a federal granting department/agency.

4-2. The Institutional Review Board

The IRB will consist of a minimum of five members with varying backgrounds to promote complete and adequate review of the university's research activities. The IRB must be sufficiently qualified through the experience and

expertise of its members, and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Each department in the university that regularly conducts research that involves human subjects shall provide a member. In addition, departments that occasionally conduct or have the potential to conduct research that involves human subjects may be invited to provide a member as appropriate to their current interest. The chair will be chosen from the IRB members. In addition, the HPA shall be a voting member of the IRB.

In accordance with federal regulations, the IRB must include one or more individuals who are knowledgeable about and experienced in working with subjects from vulnerable populations; at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas; and must include at least one member who is not otherwise affiliated with the university and who is not part of the immediate family of a person who is affiliated with the university. The IRB may invite individuals with special expertise not available on the IRB to assist in the review of specific issues; these individuals may not vote. No IRB member may participate in the review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. A list of current IRB members must be submitted to OPRR and also kept with the IRB's records. Any changes in IRB membership must be reported to the Office for Protection from Research Risks (OPRR).

The responsibilities of the IRB shall be to review all research involving human subjects that is not exempt, as defined above, either by a full Board review or as an expedited review.

a. In the case of exempt research, the IRB will be regularly notified of the approval of such exemptions by the OGRD.

b. In the case of expedited review, the chair of the IRB or the HPA will review all applications along with one or more members as necessary from the IRB. The expedited review procedure may result only in one of three decisions: approval, approval contingent upon minor changes, or referral to the full IRB for further consideration.

c. In the case of full board review, the IRB will hold an open meeting at least once per quarter, and more frequently as needed, to review all research neither exempt nor expedited. At such meetings a majority of the members of the IRB must be present, including at least one member whose primary concerns are in nonscientific areas and one member who is unaffiliated with the university. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. The IRB may approve, disapprove, or ask for further modification/clarification of all research proposals. Acceptance by the IRB does not guarantee institutional or administrative approval of the project.

4-3. Departmental Review Committee

Departments that have a large volume of research involving human subjects, which is neither externally funded nor involves research above minimal risk, may have a prior review process for nonexempt research that is then submitted for IRB approval. Such departmental committees may also make the initial determination of exempt status for research, to be then submitted for IRB approval. If a department has a departmental review committee, that body should provide the initial review of all student research. In the case of faculty or staff members, applications for review may be submitted directly to the IRB unless department policy requires preliminary department review. The departmental review committee must use IRB-approved guidelines consistent with the IRB policies and procedures contained in this document.

Disapproval of research by the departmental review committee may be appealed to the university IRB.

In the case of departmental review committee approval of research, that recommendation shall be conveyed to the HPA. The HPA or the chair of the IRB will notify the department if the IRB concurs with the approval of the research. Research that has been approved by a departmental review process must be subject to appropriate review and approval or disapproval by the IRB. If approved by the IRB, the research proposal may also be subject to review and approval or disapproval by officials of the university, in accordance with the policies and processes for university review of research proposals for reasons other than protection of human subjects.

CHAPTER 5 – SUBMISSION AND CHANGES IN PROTOCOLS / RENEWALS

5-1. Submission of Protocols

Applications for exempt and non-exempt research must be submitted to the relevant department and/or university offices according to the procedures outline on the OGRD website.

5-2. Changes to Protocols

If, subsequent to initial approval, a research protocol requires minor changes, the OGRD should be notified of those changes prior to their implementation. Any major departures from the original proposal must be approved by the appropriate review process before the protocol may be altered. An application for change of protocol must be submitted to the IRB for any substantial change in the protocol.

5-3. Annual Renewals

If research is to continue, with no substantial changes, beyond the term for which it has been approved, an application for renewal of approval must be obtained prior to continuation of the project. Annual renewals are not necessary if all data has been collected and there is no further contact with research subjects.

CHAPTER 6 – TRAINING

Student training is offered online through the Collaborative Institutional Training Initiative (CITI) (http://www.citiprogram.org). Students, serving as Principal Investigators, must successfully complete *Human Subjects in Research Training for Student Investigators* and provide the CITI training certificate (showing at least a 80% pass rate) as part of their application to conduct research. Additional CITI training may be required at the discretion of Responsible Project Investigators, faculty, and departments involved in human subjects research.

CHAPTER 7 – NONCOMPLIANCE

Any concerns about human subjects research or information regarding potential violations of this policy and/or federal regulations should be directed to:

Human Protections Administrator

Office of Grants and Research Development

210 Showalter Hall

Cheney, WA 99004

ogrd@ewu.edu

(509) 359-6567

Violations of this policy may result in one of more of the following university actions:

a. IRB suspension or termination of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension/termination of research shall include a statement to the investigators of the reasons for the IRB's actions and shall be reported promptly to the investigator, appropriate institution officials, and the department or agency head (see also (b) below). Research may not resume until a corrective action plan is approved by the IRB and put in place.

b. When the research is funded by a federal agency, any serious noncompliance or violations of the federal regulations or this policy must be reported to the Office for Human Research Protections immediately. An incident report must be submitted by EWU to OHRP's Division of Compliance Oversight. OHRP will evaluate the university's response to the noncompliance. OHRP will respond in writing and will either state that the report was adequate or request additional information.

c. Violations of this policy or the corresponding federal regulations may result, for employees, in discipline up to and including termination. Violations of this policy or the corresponding federal regulations may result, for students, in discipline, up to and including suspension or expulsion.