## Institutional Review Board for Human Subjects Research

### Application for IRB Review

**Return Original + 2 copies for Expedited & 14 copies for Full Reviews to Grants-210 SHW**

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<th>Principal Investigator/Department</th>
<th>Responsible Project Investigator/ (faculty or staff supervisor required if PI is a student)</th>
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<td>Mailing address/phone, email or fax where you can be reached (note: only provide mailing address on original not on copies)</td>
<td>Name:</td>
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**Status:** Undergraduate  Graduate Student  Faculty  Administrator  Staff

For students only: Is this research being done to meet a course, thesis or other academic requirement? (please specify)

If **no**, why is it being done?

Request for:  Expedited review  Full IRB review

**Title of Project**

- Project anticipated starting date
- Anticipated termination date

**Funding:**

- Non-Funded
- Internal Funding
- External Funding

**Funding status:**

- proposal in preparation
- pending agency decision
- funded

**Funding Agency (if applicable):** ________________________  **Grant or Contract Number:** _______________________

**Abstract**

The information provided above is accurate and the project will be conducted in accordance with applicable Federal, State and University regulations.

**Signature, Principal Investigator** ________________________  **Date** ________________________

**Recommendations and Action**

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<th>Responsible Principal Investigator</th>
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<th>Dept IRB representative or Dept Chair</th>
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Subject to the following conditions: ____________________________________________

**Period of Approval**

**Rev 6/08**
I. Research Protocol

Please attach a summary (Attachment A), two pages or less in length, of the proposed research addressing each of the following points (A-E) separately. Do not submit any other document in place of this two page summary.

A. Background or rationale for this activity
B. Objectives of this specific research
C. Describe how subjects will be involved, specify what they will do. Attach (Attachment B) any cover letters, information statements, questionnaires or other formal instruments to be used in the research, describe procedures and/or protocol(s) for unstructured interviews, etc.
D. Explain how data obtained will answer the research problem
E. Identify alternative procedures, if any, that might be advantageous to the subject

II. Human Subjects

A. Number of subjects, including individuals who serve as "controls"

Approximate number (not to be exceeded and ages:

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<th>Age Range</th>
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<td>vulnerable</td>
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B. Source(s) and type(s) of subjects

C. Criteria for selection/exclusion of subjects

D. How subjects will be approached and by whom
E. Location where procedures are to be carried out.

III. Voluntary Participation

A. Describe the method for ensuring that subjects understand that their participation is voluntary and that they do not feel coerced.

B. Will subjects receive an inducement, e.g., payment, services without charge, extra course credit? Specify details. What is the rationale for offering the inducement?

C. If subjects are children and they are capable of assent, describe provisions for soliciting their assent as well as the provisions of soliciting permission of their parent(s) or authorized representative. If there is an assent form or standard briefing statement for children provide a copy as an attachment (Attachment C).
D. Attach a copy of the consent form to be signed by the subject and/or any explanations of the research to be given orally to the subject (Attachment D). If no consent form is to be used, explain the procedures to be used to ensure that participation is voluntary. (See instructions for required contents of consent forms and safeguards for vulnerable populations.)

E. If any deception (withholding of complete information) is required for the validity of this activity, explain why this is necessary, and describe a debriefing plan and/or attach a debriefing statement (Attachment E).

IV. Confidentiality and Anonymity

A. Will participation be anonymous, that is, the investigator will have no way to identify subjects by appearance, name or data? If subjects will be anonymous, describe the procedure for data collection to insure that anonymity is maintained.

B. If data are collected which could be associated with individual subjects, describe the methods to be used to ensure the confidentiality of data obtained. (Confidentiality for data is required unless subjects give express written permission that their data may be identified.)
C. Who specifically will have access to some or all of the data? What provisions are there for control over access to documents and data?

D. How long will data with identifiers (both paper and electronic) be held? How will they be ultimately disposed of? If they will be retained more than five years please explain why this is necessary.

V. Risks/Benefits

A. Will subjects in the proposed research be placed at more than minimal risk, as defined by federal policy.

B. Nature and amount of risk (including side effects), substantial stress, discomfort, or invasion of privacy.
C. What steps are being taken to reduce the level of risk, including any follow-up planned as part of the risk mitigation procedures.

D. Plan for handling adverse effects.

E. Arrangement for financial responsibility for adverse effects.

F. Describe the benefits to the subject and/or society of the proposed research. Why do the benefits outweigh any risks that may be involved?
VI. Checklist to be completed by investigator

A. Will any group, agency, or organization other than EWU be involved?  If yes, please specify and attach letters of permission from other participating groups.

B. Will materials with potential radiation risk be used, e.g., x-rays, radioisotopes?  If yes, please indicate:
   1. Status of annual review by Radiation Safety Officer (RSO). If approved, attach one copy of approval (Attachment F).
   2. Title of application submitted to Radiation Safety Committee (RSC).

C. Will any other hazardous materials come in contact with research subjects?  If yes, indicate nature of hazard and steps taken to mitigate risk to subjects.

D. Will an investigational new drug (IND) be used?  If yes, name, proposed dosage, how administered, status with FDA, and IND number.

Enclose one copy (Attachment G) of: 1. available toxicity data; 2. reports of animal studies; 3. description of human studies done in other countries; 4. a concise review of the literature prepared by the investigator.

E. Will other drugs be used? (including over the counter drugs)  If yes, give names, dosages, how administered, and side effects.

F. Will medical, academic or other records be used?  If yes, please attach HIPPA sir FERPA authorizations as appropriate.

G. Will audio-visual or tape recordings, or photographs be made?

H. Should this activity be covered by adverse effects insurance?  If yes, explain why.
Guidelines for Completing Application for IRB Review

Cover page
Principal Investigator. Principal Investigator is the scientist/scholar with primary responsibility for the design and conduct of a research project. Please include all individuals, but not the faculty sponsor in case of student research unless the faculty member is actively involved as a researcher in the project. The address listed here is the one to which all correspondence will be sent including requests for clarification and notification of approval/non-approval. Please list a telephone number where the PI can be reached, and email and/or fax if desired.

Responsible Project Investigator. All student projects must have a faculty/staff sponsor who is officially liable for their work being conducted in accordance with the requirements of University and federal policy. (This is a federal requirement.) Please include the RPI's campus phone number and address and Mail Stop.

Anticipated starting date. This date should be subsequent to the date of submission of the application for exemption and allow sufficient time for review of the application. Applicants are reminded that they may not begin the research until they have received approval of their IRB application.

Abstract. The abstract ought to present an overview of the protocol, in less than 150 words.

Signatures. Applications without the requisite signatures will not be considered and will be returned to the applicant.

Page 2, Research Protocol
The statement of the proposed research must be limited to two pages. Do not submit thesis proposals, grant applications or any other documents pertaining to the same research in place of this summary. Make sure that each of the five points is addressed separately so they may be easily found by the reviewers and that all requested attachments (B) are included.

Pages 2-3, Human Subjects

IIB. Under Source(s) and type(s) of subjects, it should be indicated whether or not any vulnerable populations will be used. Federally designated vulnerable populations are: children, prisoners, pregnant women, fetuses, mentally disabled persons, or economically or educationally disadvantaged persons. Investigators should be aware that additional regulations may govern the use of these populations for research (consult OGRD for specifics). Standards for the use of pregnant women and of fetuses in research exceed those of other categories of subjects. Pregnant women and fetuses may not be used as research subjects unless studies of animals and non pregnant individuals have been completed, unless the study is to meet the health needs of the woman and fetus, and the risk to each is minimal. A fetus in utero may be used for research only if: (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be
placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

IID. Please state the procedure for obtaining subjects, including who will approach potential subjects. 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. Recruitment procedures need to reflect awareness of risk level to the potential subject and be structured so that no coercion of any kind could be implied.

Pages 3-4, Voluntary Participation

IIIA. 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, as well as that of the subject if practicable.

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-subject relationship, special care must be taken to ensure that the subject feels completely free to decline to participate. 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.

IIIB. Any payment made to subjects should not be large enough to constitute excessive inducement for participation in the research. If partial payment or other benefits are to be given to subjects who withdraw or otherwise cease to participate in the research, the terms under which such payments will or won’t be given should be stated.

IIIC. In research involving children and some disabled subjects it is often necessary to obtain their assent if possible. There is information available from OGRD that offers suggestions for obtaining such assent for children of various ages and other vulnerable subjects.

IIID. Disclosure generally includes: the research procedures; their general purposes, risks, and anticipated benefits; alternative procedures where therapy is involved; and a statement offering the subject the opportunity to ask questions and to withdraw without negative consequences at any time from the research. The extent and nature of information should be such that persons, knowing that the procedures are neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, subjects should understand clearly the range of risk and the voluntary nature of participation. For research involving more than minimal risk, it is necessary to provide an explanation as to whether any compensation and/or any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
Consent must be given positively, it cannot be given negatively, i.e., failure to return a form by the subject or retention of a consent form by the subject does not give legitimate consent. The subject must consent actively by returning a signed consent form or voluntarily returning a questionnaire or other such positive act.

An example of a consent form is appended to these instructions. A consent form must be on letterhead stationery and is required to include: identification of project, purpose, procedures, risks and/or discomforts, benefits, opportunity to ask questions, freedom to withdraw, name, address and phone number of investigator(s), dated signatures of research subject and of principal investigator(s). Additional elements may be necessary in a consent form when using vulnerable populations, in projects involving more than minimal risk, and in grants from some agencies, e.g., FDA. Researchers must provide a signed, dated copy of the consent form to each subject as well as having one for their own records.

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. Investigators are responsible for ascertaining that the subject has comprehended the information.

III E. In some research, fully informing the subject would invalidate the research. In such cases, it may be necessary to withhold information 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.

Pages 4-5, Confidentiality and Anonymity

Anonymity means that the researcher cannot identify specific data as coming from a specific subject. Confidentiality means that the researcher can identify a subject with some or all of their data but has undertaken safeguards so that the association of subject and data is not known by anyone outside of those researchers who need to know. An entire project cannot be both confidential and anonymous although different segments of a protocol may be one or the other.

In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise.

The University recognizes the rights of the subjects to be protected against injury or illegal invasions of their privacy and their interests as members of a free society in preserving their dignity. The more sensitive the material, 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.
(b). Data that include information which would reveal a subject’s identity 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 his or her identity should be removed. Plans and a schedule for the ultimate disposition or indefinite retention of the data must be approved by the IRB. The usual maximum time of retention of raw data is five years after publication; retention for periods longer than that or indefinitely must be justified. The usual methods of destruction are burning or shredding; for electronic data the method is erasure and/or destruction of tapes, videos, etc.

(d). The identity of subjects must not be released except with their express written permission.

(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.

Data that are part of the public domain are not covered by the foregoing restrictions.

Pages 5-6, Risk/Benefit

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: The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, 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.

Definitions of risk may vary when dealing with vulnerable populations. Consult OGRD for further information

Page 7, Checklist
If any entity other than Eastern Washington University is to be involved in the research, a letter of support and permission for the researcher to undertake the project in cooperation with them should accompany the application.
Consent Format
[On Eastern Washington University departmental letterhead]

Consent Form
(Title of Activity)

[Principal Investigator's and co-investigator's name(s), position(s), department(s) and telephone number(s); also Responsible Project Investigator if PI is a student]

[investigator's statement]

Purpose and Benefits

[Include statements concerning what the activity is about, why it is being conducted, and who might benefit.]

Procedures

[Outline procedures, including the commitment of time for each, the total amount of time involved, and for what period. If a questionnaire or interview is involved, include examples of the most personal and sensitive questions. Indicate that individuals are free not to answer any questions which they find objectionable. If audio or video recording of subjects is to be done, or part or all of conversations is to be quoted verbatim, state: "Washington State law provides that private conversations may not be recorded, intercepted, or divulged without permission of the individual(s) involved."]

Risk, Stress or Discomfort

[Avoid stating that there are no risks. Include information on reasonable risks and any possible invasion of privacy. List side effects and, if appropriate, how they will be handled.]

Other Information

[Include information on alternative procedures available. State whether the identity of subjects will remain confidential or is anonymous, as applicable. Include that subjects are free to withdraw at any time without penalty, or, for patient subjects, "without penalty or jeopardizing future care." Include specific information when subjects will receive an inducement, e.g., money, free services, extra course credit (alternatives must be spelled out in this case) for participation in the study; also indicate what they will receive if they withdraw.]

Signature of Principal Investigator

Date

[subject's statement]

[I understand that by signing this form I am not waiving my legal rights. I understand that I will receive a signed copy of this form.]

Signature of Subject

Date

[as appropriate]

Signature of Parent/Legal Guardian

Date
Institutional Review Board
for Human Subjects Research

Summary of Policy

The Institutional Review Board (IRB)
The IRB has been established, in accordance with Federal regulations (45CFR46) and University policy, to ensure that research involving human subjects carried out under the auspices of Eastern Washington University conforms to established ethical standards. The Board is committed to carrying out this charge in a manner that will support and assist researchers rather than obstruct research progress. The information in this packet is intended to provide the necessary guidance for researchers to complete the IRB review process from initial request to final approval.

IRB Responsibility and Jurisdiction
The University's Institutional Review Board policy and procedures apply to any research activity which involves human subjects, whether such research is undertaken on a large or small scale, whether it is preliminary or fully designed, whether it is student or faculty research, whether it is funded or non-funded, and whether it involves minimal risk or more than minimal risk.

The main considerations and responsibilities of the IRB are

  a. to determine that potential risks to research subjects are adequately addressed and their anonymity assured when appropriate;
  b. to determine that adequate explanation of the potential risks and safeguards, as well as benefits, are given to the subjects and their consent to participate is validated;
  c. to determine that the risk:benefit ratio to the subjects is clearly articulated.

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.

“The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and

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1 A copy of "Eastern Washington University Policy for the Protection of Human Subjects in Research" may be obtained from the Office of Grants and Research Development.
approved by [the] IRB may be subject to review and disapproval by officials of the [University]. However, those officials may not approve research if it has been disapproved by the IRB." (Federal Policy 45CFR46.112)

In addition to compliance with federal and University procedures, projects involving human subjects whose protection is the responsibility of an agency other than Eastern Washington University, will also be subject to that agency's procedures.

**Responsibility for Ethical Treatment of Human Subjects**

Ultimately, the responsibility for maintaining ethical standards and protecting human rights rests with the individual researcher (and in the case of University students their faculty research advisor). The IRB and, when available, Departmental Research Committees are an added measure of reassurance and each serves as a resource for the interpretation of ethical guidelines. Any research involving human subjects must have associated with it a Responsible Project Investigator who is a qualified faculty member or a qualified staff member, and who will monitor and be responsible for the conduct of the research.

**Approval to Proceed with Research**

Written approval from the IRB must be received before initiation of subject recruitment or initiation of procedures that involve human subjects, regardless of whether that research has been declared exempt or not.

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**Procedures for Submitting Requests for Approval of Research Using Human Subjects**

**I. Necessity for Review**

It must first be determined as to whether or not the activity to be undertaken involves research and involves human subjects. In a university setting there is frequently a pedagogical as well as research function to activities, especially in group student projects, which may make it difficult to determine whether actual research is involved as opposed to teaching the methodology of research.

Research is defined by federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." [Federal Policy 45CFR45.102(d)] Resulting generalizable knowledge is the key element in the definition. If results of a study are to be published, presented in a paper or otherwise implied to have applicability beyond the test population, this is considered evidence of the intent of obtaining generalizable knowledge.

Human subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [Federal Regulation 45CFR45.102(f)]. Additionally, there are guidelines that distinguish therapeutic activities from research in the health fields. If the Responsible Project Investigator is unsure as to whether an activity should be classified
as research, the Administrative Director of Academic Grants and Contracts or the Chair of the IRB should be consulted.

II. Determining Review Status

Research involving human subjects or data derived from human subjects falls into one of three review categories: Exempt, Expedited and Full IRB Review.

Exempt Research

Categories of exempt research are established by federal regulations and cannot be amended. In general, research that does not disrupt or manipulate subjects' normal life experiences, or incorporate any form of intrusive procedures, may be exempt as long as it does not include one of 12 exceptions to the provisions for exemption. These exceptions focus on more than minimal risk and on the protection of vulnerable subjects.

In the Application for Exemption, the criteria for exemption established by federal regulation 45CFR46.101(b)(1-6) are listed in the Decision Aid. If the proposed research conforms to one of these categories and does not include one of the 12 exceptions to the exemptions, then the investigator may apply for an exemption from further IRB review. When there is no more than minimal risk, some research involving vulnerable populations, particularly children, may be exempt in some instances. All six grounds for exemption may be applied to children except in some cases exemption #2. The legislation regarding the differences in exemptions for children is as follows:

"The exemption at 45CFR46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at 45CFR46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed." (45CFR 46.401(b)).

Based on applicable federal regulations and/or provisions of the University's Policy and Procedures, investigators whose research involves human subjects will not make final determination of exemption. Exemption requires the approval of the IRB.

The IRB reserves the right to require review of specific research activities or classes of research activities even though they qualify for exemption. Exercise of such oversight will rarely be necessary. Requirements of sponsoring agencies, unexpected problems, and the need to evaluate experiences with exemption categories might trigger such review.

Submission procedure: The investigator should complete the Application for Exemption and submit three copies to the appropriate review body, either the IRB (through the Office of Grants and Research Development) or the Departmental Review Committee. If a department has a Departmental Review Committee, that body should review the application in the case of all student research; in the case of faculty or staff applications for exemption these may be submitted directly to the IRB unless department policy requires department
review. This should be done in a timely manner prior to the start of research. If
the research is approved as exempt by a Department Review Committee, the
Application will be signed by the Chair of the review committee and forwarded
from the department to the OGRD for concurrence, recorded by the OGRD, and
returned to the investigator. This must be done before initiation of subject
recruitment or initiation of any procedures that involve human subjects.
Approval of exempt protocols is valid for five years from the date of approval.

Guidelines for Completing Application for Exemption from Review

Principal Investigator. Please include all individuals, but not the faculty sponsor
in case of student research unless the faculty member is actively involved as a
researcher in the project. The address listed here is the one to which all
correspondence will be sent including requests for clarification and notification
of approval/non-approval. Please list a telephone number where the PI can be
reached, and email and/or fax if desired.

Responsible Project Investigator. All student projects must have a faculty/staff
sponsor who is officially liable for their work being conducted in accordance with
the requirements of University and federal policy. (This is a federal
requirement.) Please include the RPI’s campus phone number and address.

Anticipated starting date. This date should be subsequent to the date of
submission of the application for exemption and allow sufficient time for review
of the application. Applicants are reminded that they may not begin the
research until they have received approval of their IRB application.

Rationale for exemption. Please state exactly why you feel the research meets
the specific grounds listed in the exemption checked. If the applicant checks
"yes" under any of the twelve conditions in the decision aid list that contravene
an exemption then they should explain why an exemption should still be
considered.

Purpose and methodology of the research. Please state concisely what the
purpose of the research is and, as appropriate, the hypothesis to be tested, the
dependent and independent variables, and the research methodology. Be
specific and provide sufficient information so that the IRB can make an informed
decision as to what the research will entail. Failure to provide sufficient
information in this and the following question is the basic cause of slowing the
approval process.

Procedure for the subjects. Please state explicitly what the subjects will be
required to do for the research. To be exempt the subjects will usually be
anonymous and will be involved in procedures that involve no more than
minimal risk. If there is to be a survey or questionnaire administered please
attach a copy of the questionnaire to the application as well as any written cover
material or the script for an oral explanation to the subjects as to what they will
have to do. State the procedure for ensuring the subjects’ anonymity will be
maintained. If the researcher also has the role of teacher in relation to the
subject, the pedagogical procedures should not be included, state only the
procedures used in the research. Admittedly it will sometimes be difficult to
distinguish between these two roles, but in the case of children the teacher can
interact with the student, but when they are behaving as researcher they may
not interact with the child in some instances (see above).

Vulnerable subjects. Depending on the specifics of the research, some
vulnerable populations of subjects may not be granted exemptions that would
apply to normal or non-vulnerable subjects.

Signatures. Applications without the requisite signatures will not be considered
and will be returned to the applicant.
Expedited review. Investigators may apply for expedited review if their research is included in the list of research activities below, as long as the research is carried out through standard methods, contains no more than minimal risk to the subjects, does not address sensitive issues, and does not use subjects who are not competent to give consent. This list is based on federal regulations (Federal Register 46: 8392; January 26, 1981) so that additions to and extrapolation from the list by the IRB are not appropriate. If there is external funding, projects shall comply with the review requirements of the funding agency as well as complying with the minimum requirements set forth in this document. 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.

1. Collection of hair and nail clippings, in a non disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects 18 years of age or older using non invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects’ behavior and the research will not involve stress to subjects.

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

If research involving both Eastern Washington University and another institution or agency has already been approved through that institution's federally-approved IRB procedure, a copy of the approval and one copy of the proposal as submitted to that institution should be filed with the OGRD in lieu of Eastern Washington University Full IRB Review. The University IRB reserves the right additionally to review the proposal.

**Submission and IRB Review Procedures:** Expedited and Full IRB Review applications should be submitted to the Office of Grants and Research Development (OGRD) unless the investigator is in a department that has a 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/OGRD 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. Submission for departmental review should be done in a timely manner prior to the start of research. 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 OGRD. The Administrative Director of Academic Grants and Contracts or the Chair of the IRB will usually notify the Department of IRB concurrence with the approval of the research. However, research that has been approved by an IRB-approved departmental review process may be subject to further appropriate review and approval or disapproval by the University IRB and/or officials of the University.

(a) In the case of full IRB review, fourteen copies of Application for IRB Review with relevant attachments should be submitted at least one week prior to the next scheduled open meeting of the University IRB, unless other arrangements are made with the OGRD. Principal investigators are encouraged to attend the IRB meeting to respond to questions raised by the board members. The IRB may approve, conditionally approve, disapprove, or ask for further modification/clarification of all research proposals. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the University, but University officials may not approve the research if it has been disapproved by the IRB.

(b) In the case of IRB expedited review, three copies of Application for IRB Review with relevant attachments should be submitted sufficiently in
advance of the desired date to begin research that the IRB reviewers have a reasonable length of time to respond to the proposal and, if deemed necessary, submit it to full IRB review. The expedited review procedure may result only in one of three decisions: approval, conditional approval contingent upon minor changes, or referral to the full IRB for further consideration. Expedited procedure reviewers may not disapprove research.

(c) If the research is to be reviewed by a Departmental Review Committee, the investigator should check with his/her department to determine the number of copies to be submitted and how long approval is likely to take. Subsequent to departmental approval, three copies of this complete form with relevant attachments should be submitted sufficiently in advance of the desired date to begin research that the OGRD/IRB has a reasonable length of time to respond to the proposal.

Human subjects approvals granted by the IRB are good for one year from the date of approval.

Reviewers and reviewing bodies will endeavor in good faith to submit and respond to proposals in a reasonably timely manner so that research, that would otherwise be approved, shall not be jeopardized by the administrative constraints of the process. Full IRB reviews will take longer and are dependent on the meeting schedule of the IRB.

Changes in Protocols: If, subsequent to initial approval, a research protocol requires minor changes, the OGRD should be notified of those changes. Any major departures from the original proposal must be approved by the appropriate review process before the protocol may be altered. A Change of Protocol application must be submitted to the IRB for any substantial change in the protocol. The Administrative Director of Academic Grants and Contracts or the Chair of the IRB will determine whether or not the research must then be resubmitted for approval. An approved protocol may not be altered without consent of the IRB.

Annual Renewals: If research is to continue, with no substantial changes, beyond the term for which it has been approved, a renewal of IRB approval must be obtained prior to continuation of the project. The procedure for renewal involves submission to the OGRD of a Renewal of Approval application accompanied by one copy of the previously approved IRB review application.