Guidelines for Completing an Application for Non-Exempt Research
EWU Institutional Review Board for Human Subjects Research

Cover page & Signatures

Request. Select the type of request, "Full Review" or "Expedited." If unsure, use the Determining Need for Review: Research Category, Changes, and Renewals, to determine the kind of request to apply for.

Principal Investigator (PI). 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.

Phone number and E-mail. Please list a telephone number where the PI can be reached, and e-mail.

Responsible Project Investigator (RPI). All student projects must have a faculty/staff sponsor who is accountable 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 address, mail stop, campus phone number, and e-mail.

Project anticipated starting date. This date should be subsequent to the date of submission of the application 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 should 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.

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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.

Human Subjects, Part B. 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 the Office of Grant and Research Development (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.

Human Subjects, Part D. 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.

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Voluntary Participation, Part A. 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.

Voluntary Participation, Part B. 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.

Voluntary Participation, Part C. In research involving children and some disabled subjects it is necessary to obtain their assent. There is information available from OGRD that offers suggestions for obtaining such assent for children of various ages and other vulnerable subjects.

Voluntary Participation, Part D. 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.

A Consent Form Template is available at https://access.ewu.edu/grants/human- subjects/forms. A consent form must be on university 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.

Voluntary Participation, Part 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.

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Confidentiality and Anonymity. 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. Anonymity means that the researcher cannot identify specific data as coming from a specific subject. 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. However, data obtained from social media that are re-purposed or re-disclosed for research should conform to section (e) above.

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Risks/Benefits. 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

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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.

Submission and IRB Review Procedures

Applications for Non-Exempt Research 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 or designated IRB departmental representative.

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 non-exempt research that is then submitted for IRB approval. Such departmental committees/ IRB representative may also make the initial determination of exempt/non-exempt status for research, to be then submitted for IRB/OGRD approval. If a department has a Departmental Review Committee/IRB representative, that body/person is to 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/IRB representative review.

Submission for departmental/IRB representative review should be done well in advance of the intended start of research. The Departmental Review Committee/IRB representative must use IRB-approved guidelines consistent with the IRB policies and procedures contained in this document and have completed CITI certification. Disapproval of research by the Departmental Review Committee/IRB representative may be appealed to the university IRB. In the case of Departmental Review Committee/IRB representative approval of research, that recommendation is conveyed by approval of the application prior to moving it forward to OGRD. The approval of research by the IRB Chair is synonymous with the IRB. All non-exempt applications will be reviewed and approval or disapproval by the university IRB and/or officials of the university is a possibility.

(a) Regardless of whether the non-exempt application is considered expedited or full board,

all relevant materials should be submitted as email attachments to OGRD (ogrd@ewu.edu).

- Expedited applications will be reviewed by one member of the IRB (usually the applicant's departmental IRB representative) plus the IRB chair. Final approval of expedited reviews is given by the IRB chair providing any conditions for change have been met.

- Full Board applications will be reviewed and approved by majority vote of all members of the Board. Applicants are encouraged to attend the Full Board meeting at which their application is reviewed. Final approval of full board reviews is given by the IRB chair providing any conditions for change have been met.

Human subjects approvals granted by the IRB for expedited and full board review level research 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 may take longer and are dependent on the meeting schedule of the IRB.