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WHITWORTH
UNIVERSITY

Policy and Procedures for the Protection of Human Subjects in Research

Based on Revised Common Rule

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I. POLICY

It is the policy of Whitworth University to adhere to the generally accepted ethical and professional standards for the protection of human subjects in research that were formulated in the Belmont Report[1] of the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research and the Nuremberg Code[2]. The three Belmont Principles are as follows:

> ***Respect for Persons*** involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy …Required by the moral principle of respect for persons, informed consent contains three elements: information, comprehension, and voluntariness…Institutional Review Boards should be especially sensitive to these factors when particularly vulnerable subjects are involved.
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> ***Beneficence*** entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks or harm…The Report recommends the Institutional Review Board's insistence upon precise answers to direct questions. The IRB should: (1) determine the 'validity of the presuppositions of the research;' (2) distinguish the 'nature, probability, and magnitude of risk…with as much clarity as possible;' and (3) determine whether the investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.
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> ***Justice*** requires that the benefits and burdens of research be distributed fairly…The principles of justice mandate that the selection of research subjects must be the result of fair selection procedures and must also result in fair selection outcomes. The 'justness' of subject selection relates both to the subject as an individual and to the subject as a member of social, racial, sexual, or ethnic groups.

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[1] *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The National Commission for the protection of Human Subjects of Biomedical and Behavioral Research, DHEW Publication No (OS) 78-0012 (1978).

[2] *Trials of War Criminals Before the Nuremberg Military Tribunals.* Superintendent of Documents. U.S. Government Printing Office, Washington, D.C. (1947).

II. DEFINITIONS

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45CFR46.102(1)]

For the purposes of this policy, the following four types of activities **are not** defined as "research".

1. Certain scholarly (e.g. biographies, oral histories, literary criticism, historical scholarship) and journalistic activities
2. Certain public health surveillance activities
3. Collection and analysis of information, specimens or records, by or for a criminal justice agency for certain criminal justice or investigative purposes
4. Certain authorized operation activities for national security purposes

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and, uses, studies or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

III. INFORMED CONSENT

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

Voluntariness

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 practical. Such persons include minors, persons with impaired decision-making capacity, individuals with limited civil freedom, fetuses, or children.

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-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.

Any payment made to subjects should not be large enough to constitute excessive inducement for participation of the subjects.

Deceit: 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. Deceit, when allowed, must always be debriefed and the subjects offered the opportunity to withdraw their data.
Masking is not the same as deceit and does not require debriefing. With masking, the researcher is collecting more information than what they will actually use, but does not employ deceit by not disclosing the purpose of the research.

Disclosure
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. 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 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.

Comprehension
Comprehension is an important part of 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. Investigators are responsible for ascertaining that the subject has comprehended the information.

Broad Consent
BECAUSE WHITWORTH UNIVERSITY DOES NOT ALLOW RESEARCH UNDER EXEPTIONS 7 and 8 (see page 7) BROAD CONSENT IS NOT UTILIZED IN OUR IRB PROCCESSES
Broad consent is intended to serve as a substitute for traditional informed consent in certain circumstances. Broad consent permits researchers to engage in research use of identifiable biospecimens and identifiable data without the requirement to obtain additional consent for the future storage, maintenance, or research uses, so long as the future activities are within the scope of the broad consent. This form of consent is used with the two new exemption categories (#7, #8) for (i) the storage, maintenance and research use involving identifiable information and biospecimens under which broad consent is a condition for the exception and (ii) a regulatory pathway to obtain broad consent in lieu of traditional informed consent for non-exempt storage, maintenance, and research use involving identifiable information and biospecimens.
The Final Rule also allows for broad consent to be obtained as an alternative to traditional informed consent for the non-exempt storage, maintenance and secondary research use of identifiable private information or identifiable biospecimens (collected for other research studies other than the proposed research or non-research purposes).

If broad consent is obtained, any subsequent storage, maintenance, and secondary research uses of the individual's identifiable biospecimens and data consistent with the broad consent would not require additional consent, so long as additional conditions are met, including limited review by an IRB. Researchers are bound by the limitation that if a subject "refuses to consent" a waiver of informed consent cannot be obtained. Refusal to consent is only a person's express declination to give broad consent, as demonstrated by an individual's unambiguous written or oral communication to that effect. A non-response to broad consent cannot be construed as a refusal. Therefore, the form must state that failure to respond (i) will not be treated as a refusal to consent, (ii) will not prevent researchers from seeking a waiver of consent or pursing an exemption, and (iii) will not act as affirmative broad consent. For persons who were offered broad consent and did not respond, researchers may consider a second attempt to obtain broad consent before using the above approach. Refusal to provide broad consent does not preclude another researcher at another institution from seeking it for a new project. If broad consent is refused, the data can still be used if it is stripped of its identifiers. If a subject withdraws their broad consent at a later date, that data should no longer be used. However, once disseminated beyond the institution is may be difficult to retrieve and subjects should be made aware of that in the broad consent form.

Waiver of Informed Consent

When identifiable biospecimens or private information are involved, the IRB must determine that the research could not practicably be conducted without the use of the identifiable information. If the research could be done using non-identifiable information, then that is what should be done. If the written consent is the only way to identify the subject and if identified, the subject would be at risk of arrest, loss of financial status, loss of social status, etc., then written consent can be waived. The IRB may also waive written consent when the subjects are members of a distinct cultural group or community in which signing forms is not the norm, and the research involves no more than minimal risk and there is an alternative method for documenting that consent was obtained. If there is no response the IRB can waive consent for the future research uses of that person's identifiable data or biospecimens.

Either the IRB chair or administrator shall be responsible for limited review. The review of broad consent will consist of reviewing the broad consent document and having the researcher certify that all identifiable biospecimens and identifiable private information to be used for the secondary research purpose have documented and legally effective broad consents from the human sources.

Confidentiality of Data

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 right 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 that would reveal a subject's identity should be stored in files accessible only to the project investigator and his or her authorized staff or representative.
(c) As early as is feasible, the data must 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.
(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.

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, social or cultural as a consequence of participating as a subject in the research 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; **however, Whitworth does not allow this use.**

Templates for Informed Consent
The IRB has developed templates to be used by researchers for adult and parental consent and for child assent as well as scripts if consent is to be verbal or on a survey cover.
Those templates can be found here:
https://www.whitworth.edu/Administration/AcademicAffairs/SponsoredPrograms/IRB/Index.htm

Each informed consent (regardless of the format) must:

1. Give prospective subjects the information that a reasonable person would want to have in order to make an informed decision.
2. Present the information in a way that facilitates an understanding of why one might or might not want to participate.
3. The consent form should not simply list isolated facts, but instead should help people process complicated information.
4. Key information such as the study's purpose, risks, benefits, and alternative, must be provided at the beginning of the consent form.
5. Required for all: A statement about whether participants' information or biospecimens might (or will not) be stripped of identifiers and used for future research.
6. Information about commercial profit
7. Information about whether clinically relevant research results will be returned to the subjects
8. Information about whether research activities will or might include whole genome sequencing

IV. REVIEW LEVELS

There are three levels of review:

1. Exempt
2. Expedited
3. Full Board

Exempt Review

Exempt Review requires a short application if the project falls under one of the categories listed below. If the proposal does not require limited review (see below), it will only be reviewed by the IRB Chair or administrator to confirm that neither limited review (see below) nor expedited/full review are required. No modifications will be requested if the project does not need limited review.

Exemption 1 (Educational Practices): research in established or commonly accepted educational settings (e.g. a teacher's classroom) that involves certain normal educational practices, such as research on instructional techniques already in use or classroom management. The research also must not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.

Exemption 2 (Educational tests, surveys, interviews, observation of public behavior): This exemption **only** includes: (i) interactions involving educational tests, surveys, interviews, and observation of public behavior. Exemption 2 is not applicable to research involving interventions. (ii) The disclosure of the subjects' responses outside the research would not reasonably be damaging to the subjects' "educational advancement." (iii) Allows for the use of the limited IRB review where identifiable information (even if sensitive) is recorded. Exemption 2 **does not** include interventions. May require Limited Review if the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained whether directly or through identifiers.

Exemption 3 (Benign Behavioral Interventions): research involving benign behavioral interventions with adults 1) limited to verbal or written responses, including data entry or audiovisual recordings and, (2)the information recorded cannot be readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the subject or; (3) any disclosure of this information would not place the subjects at risk of certain harms, the information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study. Additionally, this intervention must be brief in duration (although data collection may take longer. The intervention must be harmless, painless, and not physically invasive. Further, the intervention must not be likely to have a significant adverse lasting impact on subjects. The investigator must have no reason to believe that the intervention will be offensive or embarrassing to subjects, and should take into consideration the subjects' population, the context of the research, the topic, and other characteristics of the study. Limited review is required only if the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers

Exemption 4 (Research on existing data): secondary research use of identifiable private information or identifiable biospecimens. The private information and biospecimens no longer have to be in existence prior to the start of the research but must meet one of the applicability provisions. If an investigator records information about individuals in a non-identifiable manner, the investigator must not attempt to re-identify or contact the research subjects.

Exemption 5 (Public benefit service): expanded to include research that is also supported by a federal department or agency (for example, through a grant of funding). There is also a requirement for the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins.

Exemption 6 (Taste and Food Evaluations): research involving taste and food quality evaluation and consumer acceptance studies.

WHITWORTH UNIVERSITY HAS CHOSEN NOT TO USE THE FOLLOWING TWO EXEMPTIONS (7 & 8)

Exemption 7 (Storage and maintenance for secondary research collected under broad consent): covers the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. Secondary research refers to research with materials originally obtained for non-research purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

Exemption 8 (Secondary research for which broad consent is required): covers the secondary research use of identifiable private information or identifiable biospecimens originally obtained for non-research purposes or for research other than the current proposal. There are four requirements that must be satisfied:

- Broad consent must be obtained from the subjects for the secondary research use of their identifiable materials,
- Documentation or waiver of documentation of informed consent must be obtained, AND
- An IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and investigators cannot include the return of individual research results to subjects in the study plan. Note that this requirement does not limit an investigator's ability to abide by any other legal requirement to return individual research results.

Exceptions to granting exempt status:

- If any of the subjects are children as defined by state law AND the research is not a regular classroom activity. Ex: the child fills out a survey, the child is interviewed, the investigator will manipulate the environment or interact with the child as part of the data gathering.
- If any of the subjects are confined in a correctional or detention facility
- If subjects are individuals with impaired decision-making capacity
- If funding is federal
- If the subjects are all veterans
- If the subjects are all members of a protected minority class

- If fetuses *in utero* are the subjects
- If the subjects are employees or one's own students
- If data is directly identifiable (not coded)
- If data could damage a subjects' financial standing, employability or reputation
- If alcohol, prescription drugs, or OTC drugs will be ingested
- **If blood or bodily fluids will be collected (beyond a finger stick)**

Limited Review Required for Exemptions 2, 3, 7 & 8

Exemption 2 requires limited review if the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained whether directly or through identifiers. Limited review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

Exemption 3 requires limited review only if the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. Review service to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

WHITWORTH UNVIERSITY WILL NOT USE EXEMPTIONS 7 & 8 AND THEREFORE WILL NOT USE LIMITED REVIEW FOR CASES THAT MEET THE CRITERIA FOR THESE EXEMPTIONS

Exemptions 7 & 8 under the Final Rule §45.104(d)(7), storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use shall be exempt, if, among other things, an IRB conducts a limited review. Specifically, the IRB must determine that:

i. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the applicable informed consent and broad consent requirements;
ii. Broad consent is appropriately documented or waiver of documentation is appropriate; and
iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
iv. That the proposed use would not be fundamentally shocking to or fundamentally inconsistent with prevailing community attitudes among those who have given their broad consent.

Expedited Review

Projects that qualify for expedited review (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories. Expedited review may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB. Categories in this list apply regardless of the age of subjects, except as noted.

Examples of Commonly Expedited Research
Studies involving collection of hair or saliva samples
Studies of blood samples from healthy volunteers
Studies involved the analysis of voice recordings
Studies involving the collection of identifiable information in surveys, interviews, or focus groups
Studies of existing pathological specimens or data with patient identifies.

Categories of Expedited Review

1. Clinical studies of drugs and medical devices
    a. Whitworth does not do this type of research unless it is OTC, all research with OTC drugs is reviewed at either the expedited or full board level.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy individuals weighing at least 110 pounds. The amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week
    a. From other adults and children consider the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
    a. Hair and nail clippings
    b. Deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction
    c. Excreta and external secretions (including sweat).
    d. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solutions to the tongue
    e. Placenta removed at delivery
    f. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
    g. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive that routine scaling of the teeth
    h. Mucosal and skill cells collected by buccal scraping or swab, skin swab, or mouth washings
    i. Sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-ray or microwaves. Examples:
    a. Physical sensors that are applied wither to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
    b. Weighing or testing sensory acuity
    c. MRI
    d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography

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

5. Research involving materials (date, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Some research in this category may be exempt.

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

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

Full board review
Projects that require full board review are categorized as more than minimal risk. Any project not meeting an exempt or expedited category will be reviewed by the full board.

Subparts B, C, & D to the Common Rule
The Subparts to the Common Rule require additional protections for vulnerable or potentially vulnerable populations so that adequate procedures are in place to minimize the risks related to physical, harm, psychological harm and breach of privacy and confidentiality. The research must be relevant to the vulnerable population and not otherwise capable of being carried out with a non-vulnerable population.

Subpart B –Pregnant Women, Human Fetuses and Neonates involved in research: Proposed studies involving pregnant women may qualify for exempt or expedited review when no more than minimal risk is involved.

Subpart C – Prisoners: At least one member of the IRB must be a prisoner representative. This subpart applies if there is only one prisoner or if all the subjects are prisoners.

Subpart D – Children: Children are persons who have not attained the legal age for consent to treatments or procedures involved in research. Proposed studies involving children may qualify for exempt or expedited review if the study falls into one of the federally-approved categories. Exemption categories 1-5 do not apply to FDA regulated studies. Also, the Exemption 2 involving survey or interview procedures or observations of public behavior does not apply to research involving children unless the research involves the observation of public behavior and the investigator(s) do not participate in the activities being observed. Exemption 1 applies in the case of a regular classroom procedure that the student would be doing anyway.

Other populations where a full board review might be required, if all the subjects are members of the population: individuals with impaired decision-making ability; minorities; students, employees or patients.

Continuing Review and Extended Approval Process

The following do not require continuing review unless the IRB determines otherwise:

- Exempt projects
- Projects under expedited categories
- Projects requiring limited review
- Full board project that have progressed to the data analysis stage.

Full board projects that are still in the data collection stage require and annual review.

Events and information that require prompt reporting to the IRB

Unanticipated Problems Involving Risks to Participants or Others (UPs) Events (internal or external, deaths, life-threatening experiences, injuries, or other) occurring during the research study, which in the opinion of the Investigator and/or IRB meet all of the following criteria:

1. Unexpected in terms of nature, severity, or frequency, given (a) the research procedures described in the protocol-related documents, and (b) the characteristics of the subject population being studied; AND
2. Related to participation in the research or there is a reasonable possibility or likelihood that the incident, experience, or outcome may have been caused by the procedures involved in the research; AND
3. Harmful the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

A project meeting all of the above criteria generally will warrant consideration of substantive changes in the research protocol or informed consent process/document, or other corrective actions, in order to protect the safety, welfare, or rights of subjects or others.

New Information that indicates a change to the risks or potential benefits of the research in terms of severity or frequency or impacts the subject's willingness to participate.

Noncompliance: an action or activity in human subject research at variance with the approved IRB protocol, other requirements and determinations of the IRB or other applicable policies. When the event is:

- Possibly serious: noncompliance that affects the rights or welfare of human subject research participants.
- Possibly continuing: A pattern of non-compliance that continues to occur after a report of noncompliance and a corrective action plan has been reviewed and approved by the IRB, after an investigator has been warned to correct errors or noncompliance, or a circumstance in which an investigator fails to cooperate with investigating or correcting non-compliance.

Complaint unresolved by the research team.

Other events or information: Examples include: a deviation intended to eliminate an immediate hazard to a participant, suicide or suicide attempt of a participant, other Audit or Monitoring Visit reports and Corrective Action Preventative Action (CAPA) plans. Report only after consulting with the IRB Administrator.

How to report an Adverse Event

The Investigator is responsible for reporting to the IRB Administrator within 5-10 working days from when the Investigator learns of the event or new information. A form for reporting is available here: https://www.whitworth.edu/Administration/AcademicAffairs/SponsoredPrograms/IRB/Index.htm

V. ADDITIONAL IRB POLICIES

Policy on applications from other institutions to use our students, faculty or staff as subjects

The university has agreements with Eastern Washington University and Gonzaga University to accept their application in place of Whitworth's for their faculty or students who wish to conduct part of their research using Whitworth subjects. They will also accept our application and generally require a letter of approval (see compliance folder/human subjects/correspondence). We would consider accepting SCC's application as well.

Whitworth has a policy for requests from other outside organizations. Whitworth will accept requests to conduct research on our campus under the following circumstances and will accept the IRB application and approval from that institution for review by Whitworth's IRB (generally reviewed by the IRB administrator):

1. The investigator is working in collaboration with a Whitworth faculty.
2. The investigator is a Whitworth alum conducting research at another institution either as a student or faculty and who has contacted a faculty member for facilitation.
3. National surveys such as NSSE where a Whitworth faculty/staff apply to the IRB.
4. In special circumstances a waiver of this policy may be appealed to the IRB in writing. That appeal is reviewed and voted on by all IRB members.

Policy on the use of alcohol/controlled substances/OTC drugs in student research

The IRB will not approve student research projects using any controlled substance including alcohol and prescription drugs. Projects using over-the-counter (OTC) drugs and supplements must include a complete, literature-based risk assessment plan that details all potential side-effects and health risks of the drug, and includes a protocol for minimizing and mitigating said risks should they occur in a study participant. The risk assessment plan must be a minimum of one single-spaced page based on at least five references from the primary scientific literature. The IRB reserves the right to reject any proposal using OTC drugs that does not have a sufficient risk assessment plan.

Policy on IRB Review of Class Projects

The primary goal of class projects and independent studies is to provide students with experiential learning in research methods and the practice of inquiry; there is no intent to contribute to generalizable knowledge. However, some projects, particularly capstone and research methods courses, have as an additional goal, the intent of contributing to generalizable knowledge, for example when students present a project from a class assignment or independent study at a regional interdisciplinary student research conference or a disciplinary conference. The University considers such projects as constituting research with human subjects and course instructors and/or students must submit a protocol to the IRB before any data are collected or experiments run. If a class project or independent study has not received IRB approval, the results of the assignment cannot be shared beyond members of the University. For class projects that fall under Exemption 1, the instructor may apply as a single project rather than having each student apply.

Policy on Student-Conducted Surveys

Only student-survey-email requests that have been approved by the IRB will be granted and these will be granted only when the request is for less that the entire student population. Students who wish to send out surveys to the entire student population will need to make that request to the provost's office. Process: when a request is made, the Institutional Research director who then approves then release of the emails by Network Systems manager checks the SharePoint system. Emails can be provided in three ways: random, class level, and student type. If students need to limit their samples by other demographic information, (e.g. all female students) they must contact the registrar's office.

VI. PROCEDURES

PERSONNEL

IRB Administrator and Authorized Institutional Official

The Provost and Executive Vice President shall be the Authorized Institutional Official whose responsibility is to ensure that the university will effectively fulfill its research oversight function. The director of Sponsored Programs or a faculty member who is a member of IRB and is trained on appropriate regulations serves as the IRB Administrator. The IRB Administrator is a voting member of the board fulfilling the "someone familiar with the regulations" category. The administrator signs all final IRB approvals based on committee/member review.

Support Staff

The IRB is supported by the Academic Affairs Program Coordinator. The program coordinator keeps all records, assigns reviewers in the online system notifies members regarding the status of the scheduled full board meetings, sends the applications for full board review out to members and provides other support as needed.

Members

By regulations the committee must have at least the following 5 members[2] Members serve a term of three years, but may renew. Membership consists of:

1. At least one member whose primary concerns are in scientific areas
2. A least one member whose primary concerns are not in scientific areas
3. At least one member whose is knowledgeable about and experience in working with vulnerable categories of subjects
4. At least one member who is familiar with the regulations
5. A community member with no ties to the university who will speak for the community

Members may fulfill more than one category. The board may not convene if the nonscientist is absent. The community member does not have to be present for the board to vote.

Board members are recruited by the Associate Provost and/or Sponsored Programs director and appointed by the Provost. Members serve a three-year term that is renewable. As per the Faculty Handbook, each academic department that submits at least eight expedited or full board proposals per academic year shall provide a committee member.[1] 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.

[1] Faculty Handbook 2.2.5.8

The Chair is chosen from amongst the IRB members by a simple majority vote of IRB members (the IRB administrator cannot be the chair). The IRB may invite individuals with special expertise not available on the IRB to assist in the review of specific issues; these individuals serve in an ex-officio capacity and 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.

The final approval signatory is the IRB Administrator once any stipulations have been met.

Application Review

Full Board Meetings – A simple majority quorum is required for the board to meet. Voting is by a simple majority. IRB meetings are open. Investigators are encouraged to attend when their project is being reviewed. Meeting times are posted on the IRB website for Fall semester. The Board does not meet in Jan term, spring meetings are scheduled as needed and meeting in the summer is done via email whenever possible.

Exempt applications – are approved by the IRB Administrator. Protocol changes are not required at this level. The Administrator determines if the application qualifies for exempt and if limited review is required.

Expedited applications require two members for review and the final approval rests with the IRB administrator once all stipulations are met.

Full Board review takes place at a meeting of the board. Two members are assigned as the primary reviews and present their findings to the full board. A quorum of members is required to vote.

Applying to the IRB

The IRB application is in Sharepoint and can be found here: https://www.whitworth.edu/Administration/AcademicAffairs/SponsoredPrograms/IRB/IRBFormInstructionsTipsForSuccessAndLinks.html

Submission timing

Applications that require a full board review must be submitted by Monday for the IRB to meet that Friday to review. Expedited reviewers are encouraged to review the application within three working days of submission. Exempt review turn around should also be within the three day window, whenever possible

Application Instructions

1. **NO SUBJECTS MAY BE RECRUITED UNTIL THE RESEARCHER HAS APPROVAL FROM THE IRB VIA A NOTICE IN THE ONLINE SYSTEM.**
2. Open a blank application from the site above
3. Fill out the application and attach requested forms *such* as consent, surveys, letters, etc.
4. Submit the application
5. Save the first email received from “Whitworth Student Processes.” It is the only way back to the application. Forward the email to other investigators on the project because they will need to sign the application.
6. Once every Investigator has signed, submit the application.
7. If the researcher is faculty, the application will go to the IRB and be assigned a reviewer, if the application needs review by the full board, a meeting time will be scheduled.

8. If the researcher is a student, the application goes to the course professor for review first and then comes to the IRB.
9. If the application is submitted in full by Monday, a full board review can usually be scheduled for the following Friday.
10. If the research falls into the expedited review category, two faculty will review and a response should be received within three days.
11. If a Protocol Change is requested, make the changes and attach new documents and any needed clarifications on the Protocol Change page.
12. The final review is conducted by the IRB Administrator and the project is then approved.
13. If the project is not approved, the board may offer some suggestions of how it might be redesigned so that it can be approved.

Records Repository
IRB records are housed in the Sponsored Programs Office in Academic Affairs.

Clinical Trials
The university does not undertake clinical trials and therefore does not incorporate those regulations in this policy.

Independence of the IRB
The IRB is independent of the university. If the IRB approves a protocol, the Authorized Institutional Official may deny it. However, if the IRB denies a protocol, the institution cannot approve it.

Records Retention
IRB records are retained for three years. The applications are housed in the university's Sharepoint system.
Minutes and other records are kept in the Sponsored Programs Office.

Training
- The IRB Administrator can provide in-class training on the history, the regulations, and the process at Whitworth University. Contact the Sponsored Programs director to schedule a meeting. X3701.
- The Power Point slides used in training can be upload to a class blackboard site.
- The university has a tutorial for the protection of human subjects in a blackboard course. Any student or faculty receiving federal funding for a research project must take assigned tutorials in the Blackboard course **prior** to beginning research.