

WSU IRB

Policies and Procedures



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Office of Research Assurances (ORA) and
Institutional Review Board (IRB)
Washington State University

Introduction

The Washington State University (WSU), Institutional Review Board (IRB) Policies and Procedures Manual is your reference document detailing the policies and regulations governing research involving human participants and the requirements for submitting research proposals for review by the WSU Institutional Review Board (IRB).

Sections of the manual describe and explain the various aspects of the review process and regulatory requirements. Investigators and IRB committee members should familiarize themselves with the contents of the manual. In addition, investigators should carefully review the sections of the manual that address their specific research activities before submitting applications to the IRB.

This manual presents the most current information for reference by investigators, staff, and students. ***Since the field of human participant protection is constantly evolving, sections of the manual may be subject to change.***

The review of research performed by faculty, students, or employees of WSU is conducted by the IRB. The IRB is comprised of faculty representatives from various academic disciplines and regional campuses at WSU; physicians, researchers, and non-scientific members; and community representatives who are not affiliated with the University. The IRB operates within the federal guidelines with respect to the review and approval of research applications involving human participants. The welfare and dignity of individuals who participate in research is a central concern of everyone involved with the protection of human research participants. Our primary goal is to develop a fair and transparent process in which participants voluntarily decide to take part in a study based on an intelligent and knowledgeable assessment of the risks and benefits of the research.

The University, investigators and their research staff, and the IRB, share the collective responsibility for the ethical conduct of research. This collaboration must exist in a culture of trust, complete openness, and honesty by upholding the highest ethical principles in the conduct of research. By upholding the highest standards, we build public support for the pursuit of greater knowledge in a safe research environment.

The IRB is charged with a twofold mission: 1) to determine and certify that all research reviewed by the IRB conform to the regulations and policies set forth by the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Washington State regulations and University policies regarding the health, welfare, safety, rights, and privileges of human participants; and 2) assist investigators in conducting ethical research which complies with the DHHS, FDA, Washington State regulations and University policies in a way that permits accomplishment of the research activity.

Ethics and ethical review are a potentially dynamic and humanizing element in the search for knowledge. In preparing an application, the investigator is creating an ethical strategy that should reflect the norms and standards of the scientific community and the society served by the research.

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100 AUTHORITY AND PURPOSE

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1. PURPOSE

The purpose of this policy is to:

- State the institutional authority under which the Human Research Protection Program and specifically how the IRBs are established and empowered.
- Define the purpose of the IRBs.
- State the ethical principles governing the investigators, staff and IRBs to ensure that the rights and welfare of human participants are protected.
- State the authority and jurisdiction of the IRB.
- Define the independence of the IRBs.
- Define the relationship of the IRBs to other University committees, University officials and other institutions.

2. POLICY

2.1 Mission

The IRB is charged with a twofold mission: 1) to determine and certify that all research reviewed by the IRB conform to the regulations and policies set forth by DHHS, the FDA, Washington State regulations and University policies regarding the health, welfare, safety, rights, and privileges of human participants; and 2) assist investigators in conducting ethical research which complies with the DHHS, FDA, Washington State regulations and University policies in a way that permits accomplishment of the research activity.

2.2 Statement of Institutional Authority

The Washington State University Institutional Review Board (WSU IRB) is a Presidential Committee. The Institutional Official (IO) for the IRB is the Vice President for Research. The IO signs the WSU Federal Wide Assurance (FWA) with the U.S. DHHS which among other requirements assures that all human participant research will comply with 21 CFR (FDA Good Clinical Practice) and 45 CFR Part 46 (DHHS Protection of Human Participants). WSU IRB is registered with the Office of Human Research Protections and the Food and Drug Administration.

2.3 Purpose of the IRB

The WSU IRB is an administrative body established to protect the rights and welfare of human participants recruited to participate in research activities conducted under the auspices of WSU. The WSU IRB also assists researchers in conducting safe and ethically sound research involving human participants.

2.4 Governing Principles and Ethical Obligations

The organization, IRB members, IRB staff, investigators, and research staff are expected to understand, adhere and apply their obligation to protect the rights and welfare of research participants. All individuals involved are guided by the ethical principles regarding all research involving humans as participants as set forth in the report of the National Commission for the Protections of Human Participants of Biomedical and Behavioral Research, entitled: *Ethical*

Principles and Guidelines for the Protections of Human Participants of Research (the Belmont Report). These principles are defined in the Belmont Report as follows:

- Beneficence -- The sum of the benefits to the participant and the importance of the knowledge to be gained to outweigh the risks to the participants as to warrant a decision to allow the participant to accept these risks.
- Autonomy -- Legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.
- Justice -- The selection of participants is equitable and is representative of the group that will benefit from the research.

The IRB's duty is to inform and assist the investigators and advisors on ethical and procedural issues related to the use of human participants in research, to facilitate compliance with university policies and procedures, federal regulations and state law.

The Principal Investigator's duty is to carry out all human participant protections, as required by good clinical practice, WSU policy, and by state and federal regulations. When the protocol is designed and carried out by a student, his or her faculty advisor must submit the IRB application as the Principal Investigator, and the responsibility of ensuring human subject protections ultimately rests on the PI. The Faculty Advisor-PI has an obligation to consider carefully whether an individual (student or staff) is qualified to adequately safeguard the rights and welfare of participants.

2.5 IRB Authority and Jurisdiction

Scope of authority defined:

The WSU IRB has the authority to certify exempt projects, approve and review all non-exempt (expedited and full board) human participant research (prior to and after approval), require amendments in, suspend, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations, state regulations and Institutional policy.

- 2.5.1 The IRB has the authority to ensure that research conducted under its jurisdiction is designed and conducted in such a manner that protects the rights and welfare and privacy of research participants. Specifically:
- The IRB may disapprove, modify, or approve studies based upon consideration of human participant protection aspects.
 - The IRB reviews, and has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.
 - The IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare and privacy of research participants, including requiring progress reports from investigators and review of the conduct of the study.
 - The IRB may suspend or terminate approval of a study not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants.

- The WSU IRB has the authority to conduct post approval reviews on any applications for any reason. Review may consist of a review of documents and/or review of the activities to determine whether the research is being conducted in accordance with the IRB's requirements and the approved application.
- The IRB has the authority to observe or have a third party observe the informed consent process and/or audit the progress of any study in its jurisdiction as it deems necessary to protect the rights and welfare of human participants.

2.6 Independence of the IRBs

The IRB is independent and does not answer to individuals, departments, or units that rely on the IRB for the review of their research. The IRB is the final authority for all decisions regarding the protection and welfare of humans participating as participants in research activities. Institutional officials may not approve the research if it has not been approved by the IRB.

Inappropriate attempts to influence the IRB process, individual IRB members, or IRB ORA staff will be reported to the IO. The IO will respond to and stop any attempt at inappropriate influence and has the authority to limit or remove an investigator's privilege to conduct research.

3. SPECIFIC POLICY

3.1 Externally Funded Research

If the study is part of an application to a sponsoring agency, the human protocol must be reviewed by the IRB before, or when the grant or contract application is processed, and/or prior to release of grant funds.

Contracts or other funding agreements: If an IRB application indicates that a study has a contract or other funding agreement, the contract is reviewed.

3.2 Relationship of the IRBs to University Officials and Other Committees

3.2.1 Review of research by officials and other committees.

Even though the IRB application may be approved, the PI must also apply to any other committees that require approval: such as the Institutional Biosafety Committee (IBC), the Institutional Animal Care and Use Committee (IACUC), and the Radiation Safety Committee.

Biosafety: Research involving the direct and deliberate transfer of biologically derived products listed below into human participants must receive approval from the IBC. The IRB may grant final approval of study, but the approval letter will state that the research cannot commence until approval of the IBC. The investigator is responsible for providing the IRB with the IBC approval before the start of the study. The final approval will be listed on the next month's agenda. The following is a list of biologically derived products. It is not all-inclusive:

- Human gene therapy even if the recombinant DNA is produced elsewhere.

- Modification of the germ line genes of animals (transgenic).
- Recombinant DNA.
- Experimentation using carcinogenic (known or suspected) or highly toxic compounds.
- Experimentation using BL2 or BL3 infectious microorganisms.

Radiation Safety Committee: Research involving exposing human participants to radiation through x-rays or radionuclide for which the participants would otherwise not have been exposed except for the research must receive approval from the Radiation Safety Committee or approval from the Radiation Safety Officer (RSO).

3.2.2 **IRB relationship to University officials and other committees:** The IRB functions independently of, but in coordination with, University officials and other internal or external committees.

3.3 Cooperative Research

In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human participants and for complying with any applicable regulations. Federal regulations [45 CFR 46.114 & 21 CFR 56.114] allow for cooperative research projects which involve more than one institution. To avoid duplication of review efforts by IRB's, WSU can choose to conduct joint reviews, accept the review of another qualified IRB, or make other arrangements to establish oversight responsibilities.

The WSU IRB will make a determination about whether or not a cooperating institution is engaged in human participant research and how the review of the research will be conducted. This determination is made by the ORA Director, in consultation with Chair, based on the outside institution's role and whether that the role meets any of the criteria for "engaged in research" as defined in [OHRP Guidance of October 2008](#).

3.4 Use of Policies and Procedures

The ORA staff and IRB must maintain and follow all written policies and procedures consistent with federal regulations, good clinical practices, and biomedical ethics when reviewing proposed research.

3.5 Serving as IRB of Record for Other Institutions

The WSU IRB will enter Inter-Institutional agreements with other IRBs.

3.6 Multiple IRB Approvals Needed [To Conduct Research at another Site(s)]

Many times a researcher conducting research at another site may need approval from that site's IRB.

If the site/hospital does not have an agreement with the WSU IRB, the WSU researcher must secure approval from both the WSU IRB, and the site/hospital IRB. The researcher must notify the IRB that he/she has submitted to another IRB. This information must be included on the IRB Submission Form.

3.7 Accepting Review of another IRB

WSU's IRB does not accept the review of another IRB unless that IRB has an FWA and a written Cooperative or Inter-Institutional Agreement is in effect between WSU and the external IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.113
 45 CFR 46.108, 45 CFR 160 &164
 Belmont Report

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IO, ORA Director, Chairpersons of IRB's, IRB members, IRB Coordinator</i>	Ensure compliance with federal regulations, policy and procedures to guarantee the protection of human participants participating in research. Report to the VP for Research any inappropriate attempts to influence the IRB process.
<i>IO, ORA Director</i>	Investigate and act on reports of inappropriate attempts to influence the IRB process.
<i>ORA Director</i>	Evaluate on an on-going basis the IRB program for adherence and compliance with federal, state, and local policy and regulations. Evaluate (at least yearly) the IRB workload in regard to timely and thorough review. Is a designated signatory for the IRB.
<i>IRB Coordinator</i>	Ensure communications between IRB and any additional IRBs where approval is sought. All copies of correspondence with investigator will be sent to additional IRBs. Copies of correspondence between additional IRB and investigator will be requested.

101 ACTIVITIES REQUIRING IRB REVIEW

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1. PURPOSE

The purpose of this policy is to describe specific activities that require IRB review and the applicable regulations and definitions.

2. POLICY

Investigators engaged in research involving human participants (as defined below) and all other activities which, even in part, involve such research, regardless of sponsorship, must be reviewed and approved by WSU IRB.

An institution becomes engaged in human research when its employees or agents:

- (1) Intervene or interact with living individuals for research purposes, or
- (2) Obtain individually identifiable private information for research purposes.

No intervention or interaction with human participants in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol.

Specific determinations as to the definition of research or human participant, and their implications for the jurisdiction of the IRB under WSU policy are determined by the IRB. See the [Guidance for Determination of Human Subject Research](#).

3. SPECIFIC POLICY

3.1 Applicable Regulations and Definitions

The WSU IRB reviews and approves research in accordance with:

- FDA regulations,
- DHHS regulations or other Common Rule Regulations,
- Any other applicable federal, state or local regulations.

3.1.1 Definitions:

Human Participant Research Under FDA Regulation

Activities are human research under FDA regulations when they meet the FDA definition of “research” (21 CFR §50.3(c), 21 CFR §56.103(c), 21 CFR §312.3(b), or 21 CFR §812.3(h)) and involve a “participant” as defined in FDA regulations (21 CFR §50.3(g), 21 CFR §56.103(e), 21 CFR §56.312(b) 21 CFR §812.3(p)).

An activity is FDA-regulated research when:

- It involves any use of a drug other than the use of an approved drug in the course of medical practice (21 CFR 312.3(b)). This is the meaning of “experiments that must

meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act” in the definition of “clinical investigation.”

- It evaluates the safety or effectiveness of a medical device (21 CFR 812.2(a)). This is the meaning of “experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act.”
- The results of the activity are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

In the above criteria “approved” means “approved by the FDA for marketing.”

Under FDA regulations, individuals are considered “participants” when they become participants in research, either as recipients of the test article or as controls. If the research involves a medical device, individuals are considered “participants” when they participate in an investigation, either as individuals on whom or on whose specimens an investigational device is used or as controls.

The following activities also require IRB approval under FDA regulations:

- Emergency use of an investigational drug, device, or biologic under 21 CFR §56.104(c) and 21 CFR §50.23(c)
- Humanitarian device use under 21 CFR §814.3(n) and 814.124

Human Participant Research Under DHHS or Other Common Rule Regulations

Activities are human participant research under DHHS regulations when they meet the DHHS definition of research:

- Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.
- Under DHHS regulations “human participant” means a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - 1) Data through intervention or interaction with an individual, or
 - 2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant’s environment that are performed for research purposes.

Interaction includes communication or interpersonal contact with a participant or his or her private identifiable information.

Private Information includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of

the participant is or may readily be ascertained by the investigator or associated with the information) in order to be considered information to constitute research involving human participants. This may include identifiable private information obtained from a primary participant about a third party.

3.2 Determining if an Activity Meets the Definition of Human Subjects Research

When the IRB office receives an IRB application the Coordinator will determine if the activity meets the definition of Human Subject Research. If it is not, the Coordinator will inform the PI that he or she does not need IRB approval.

3.3 Activities Requiring Review (This list is not all-inclusive)

3.3.1 Clinical Investigation

- Experiments using a test article (drug or device) on one or more human participants that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the Food and Drug Administration. Products regulated include foods, including dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

3.3.2 Standard Diagnostic or Therapeutic Procedures

- The collection of data about a series of established and accepted diagnostic, therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge.
- An alteration in patient care or assignment for research purposes.

3.3.3 Innovative Procedures, Treatment, or Instructional Methods

- A systematic investigation of innovations in diagnostic, therapeutic procedure, or instructional method in multiple participants in order to compare to standard procedure. The investigation is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.

3.3.4 Repositories (e.g., data, specimen, etc.)

- Preliminary activities typically designed to help the investigator refine data collection procedures. This data is to be included in the publication.
- A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple investigators or multiple research projects.

3.3.5 Retrospective Data

- Retrospective review of participant records with the intent to report and/or publish the summary.

3.3.6 Emergency Use of an Investigational Drug or Medical Device.

- Whenever emergency care is initiated with prior IRB review and approval, under DHHS regulations the patient may not be considered to be a research participant in a

prospectively conceived research study. The data derived from the use of the test article may not be used in a prospectively conceived research study.

3.3.7 Ethnographic Research

- The investigator or his/her staff will participate, overtly or covertly, in people's daily lives for an extended period of time. They will be watching what happens, listening to what is said, asking questions and collecting data to create a broader understanding of a particular environment, ethnic group, gender, etc.

3.3.8 Internet Research

- Online websites are set up for the purposes of collecting data regarding a particular topic. This may include the completion of questionnaires/surveys, personal data, etc.

3.3.9 Pilot Studies

- Activities including those involving only one individual may be participant to the same scrutiny as a full scale research project. Although the data derived from a pilot activity may not be included in the full scale research project, the activity would still need IRB review prior to conducting the activity.

3.3.10 Student-Conducted Research

- Student-conducted research activities that meet the definition of research with human participants and that are conducted by students for work toward a degree. These activities include: (i) all masters' theses and doctoral dissertations that involve human participants; and (ii) all projects that involve human participants for which findings may be published or otherwise disseminated.

3.4 Failure to Submit Project for IRB Review

The implications of engaging in activities that qualify as research that is participant to IRB review without obtaining such review are significant. To do so is in violation of University Policy and each case will be evaluated by the Graduate School.

If an investigator begins a project and later finds that the data gathered could contribute to the existing knowledge base or that he or she may wish to publish the results, the investigator must submit a proposal to the IRB for review as soon as possible.

4. APPLICABLE REGULATIONS AND GUIDELINES

46.102
21 CFR 50, 56, 312, 812

5. FORMS

Determination of Human Participant Checklist
Guidance for Determination of Human Participant

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
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*ORA Director, Chair
or IRB Staff*

Makes determinations whether research activities require IRB Review.

Provide investigators with guidance on appropriate IRB submission requirements.

102 POLICY AND PROCEDURE MAINTENANCE

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1. PURPOSE

The purpose of this section is to state the IRB's commitment to maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles.

2. POLICY

Following regulations and guidance of Office of Human Research Protections (OHRP), FDA, and the International Conference on Harmonization (ICH), and WSU policy, ensures that the rights and welfare of the human participants of such research will be overseen and protected in a uniform manner, regardless of changes in personnel. Written procedures are in place to ensure the highest quality and integrity of the review and oversight of research involving human participants and for the adequate documentation of such oversight.

Standard operating policies and procedures (SOPs) provide the framework for the ethical and scientifically sound conduct of human research.

3. SPECIFIC POLICY

3.1 Review, Revision, Approval of Policies and Procedures

At the minimum, policies will be reviewed by the ORA Director annually. Changes to regulations, federal guidelines, or research practice, as well as the policies and procedures of WSU, may require a new SOP or a revision to a previously issued SOP. Any new information, identified as being pertinent to the protection of research participants, will be disseminated via e-mail and will be available on the website. New information that is considered pertinent to investigators and IRB members will be listed on the IRB website.

3.2 Policy Disseminating and Training

- 3.2.1 When new or revised SOPs are reviewed by the IRB and approved by the ORA Director, they will be disseminated to the appropriate individuals and departments via WSU Announcements and will be available on the IRB website.
- 3.2.2 Training will be provided to all IRB members and ORA staff on any new or revised policy and/or procedure.
- 3.2.3 Each new IRB or ORA staff member must review all applicable Policies and Procedures prior to undertaking any responsibility at the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 103(b)(4)(5), 108
21 CFR 56 108(a)(1), (b)(3), 115(6)

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director</i>	Monitors appropriate sources and contacts for policy updates. Revises and approves policies, procedures and forms as needed.
<i>IRB Coordinator</i>	Updates the website with revised or new SOPs.

103 TRAINING AND EDUCATION

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1. PURPOSE

The purpose of this policy is to describe the training and educational requirements for IRB members and staff.

2. POLICY

Training of ORA staff and IRB members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of research participants in a consistent manner throughout the WSU research community. IRB members, ORA staff and others charged with responsibility for reviewing, approving, and overseeing human participant research should receive detailed training in the regulations, guidelines, ethics, and policies applicable to human participant research.

3. SPECIFIC POLICIES

3.1 Training

- 3.1.1 ORA staff and IRB members who are overseeing research on human participants, as defined in 45 CFR 46.102 (f) and/or 21 CFR 56.102(e), that is managed, funded, or taking place in an entity under the jurisdiction of WSU will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures.
- 3.1.2 The ORA Director establishes the educational and training requirements for IRB members and IRB staff.
- 3.1.3 Members of the IRB will be provided an orientation to the IRB by the IRB Coordinator. Members will be encouraged to participate in initial and continuing training every 5 years in the CITI training program. The Chairpersons will receive additional training in areas relevant to their additional responsibilities.
- 3.1.4 ORA staff will receive initial and continuing training in the areas relevant to their responsibilities. (Continuing education of the IRB members is done through an annual education meeting as well as educational information distributed to members through newsletters and discussions at full board meetings.) The IRB Staff and ORA Director may attend conferences throughout the year for continuing education about regulatory changes and current IRB issues.
- 3.1.5 IRB members and ORA staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions. WSU will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.

3.2 Documentation

Training and continuing education will be documented and added to the ORA personnel files.

3.3 Community Outreach

The WSU IRB provides information to the research community regarding the rights of a research participant as a volunteer. The IRB encourages and promotes community outreach efforts through feedback materials, surveys and presentations on campus whenever possible.

3.3.1 Procedure for Maintaining Community Outreach Efforts Offered

- The Office of Human Participants Protection provides resources for research participants, prospective participants, researchers and community.
- The IRB members or staff conduct trainings or make presentations upon request regarding the rights of research participants.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107, 45 CFR 46.107

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director</i>	Establishes training, educational requirements and content for IRB members and ORA staff. Sets annual budget.
<i>IRB Coordinator</i>	Based on requirements and budget, determines training and education schedule. Schedules speakers, acquires outside publications, schedules attendance at PRIM&R and seminars as budget allows. Notifies IRB members of available training materials and schedule. Maintains documentation of all training and education completed.

104 MANAGEMENT OF IRB PERSONNEL

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1. PURPOSE

The purpose of this policy is to describe management policies and procedures to promote the long-term commitment of IRB staff and employees and ensure the efficient and effective administration and enforcement of IRB decisions.

2. POLICY

Office of Research Assurances (ORA) staff provide consistency, expertise, and administrative support to the IRB and the research community. Thus, the Office staff is the most vital component in the effective operation of WSU human participant protection program. Therefore, the highest level of professionalism and integrity on the part of ORA staff is expected.

3. SPECIFIC POLICIES

3.1 Job Descriptions and Performance Evaluations

ORA staff will have a description of the responsibilities expected of their positions. The performance of the ORA staff will be reviewed by the ORA Director according to University policy.

3.2 Staff Positions

Staffing levels and function allocation will be determined according to WSU policy, management assessment of support requirements, and budget constraints.

3.3 Hiring and Terminating Research Compliance Office Staff

The human resource policies of WSU determine the policies for recruiting, hiring, and terminating staff.

3.4 Delegation of Authority or Responsibility

Delegation of specific functions, authorities, and responsibilities by the Chairperson to an IRB staff member must be documented in writing.

4. FORMS

None

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
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<i>IO</i>	With the input of the ORA Director establishes the requirements for ORA staff. Hires and evaluates the ORA Director in accordance with University policy.
<i>ORA Director</i>	Composes job descriptions. Ensures that ORA staff is adequately oriented and trained. Evaluates the performance of the IRB Staff.

105 CONFLICT OF INTEREST

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1. PURPOSE

The purpose of this policy is to describe the management of financial relationships and possible conflicts of interest (COI) for IRB members, Chairpersons, consultants and ORA staff.

2. POLICY

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively disclosed and managed when they cannot be eliminated.

3. SPECIFIC POLICIES

3.1 Disclosure and Documentation of Conflict of Interest

No regular or alternate IRB member with a conflict of interest may participate in the review of the following (except to provide information as requested):

- Initial Review (full Board or Expedited)
- Continuing Review
- Unanticipated problems involving risks to participants or others
- Non-compliance with regulations or requirements of the IRB.

Definition of Financial Conflict of Interest

A situation in which the IRB member will experience a financial gain or loss that is reliant on the outcome of the Committee's decisions regarding the research.

Definition of Non-financial Conflict of Interest

A situation in which the IRB Committee's decision may have a positive OR negative affect on the individual IRB member's position professionally, personally, departmentally or socially.

It is the responsibility of each voting member or alternate member to disclose any COI in a study submitted to the IRB and recuse him or herself from deliberations and voting. The IRB member with a COI may stay long enough to give requested information but must leave during deliberations and voting.

When an IRB member leaves the room for a conflicting interest, the minutes will state the name of the IRB member, the time he/she left the room and returned; and that the reason he/she was absent from the discussion and voting was due to a conflict of interest. The IRB member will not be counted towards quorum.

3.2 Consultants

Consultants with a declared conflict of interest may provide information as requested after review and determination by the Chair and ORA Director. The IRB members will be notified of

the conflict. The consultant cannot vote (and will be asked to leave the meeting during deliberations and voting). The consultant will not be counted toward quorum.

3.3 Employees

WSU staff whose job status or compensation is affected by research that is reviewed by the IRB must recuse themselves from any meeting at which such a protocol is reviewed.

3.4 Education and Training in COI

Conflict of interest training opportunities are available to IRB members and staff . They include online and classroom trainings.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 46.103, 107
 21 CFR 56.107, 21 CFR 54

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director</i>	Meet in person or by phone with potential consultants to review the COI agreement and assists them in completing the form. Maintain documentation of IRB member COI via meeting minutes.
<i>Chairperson, IRB Coordinator, IRB Members</i>	Ensure that IRB members with a COI do not participate in the IRB deliberations subject to their COI disclosures.
<i>IRB Members</i>	Recuse themselves from IRB deliberations where a COI exists or may appear to exist.
<i>IRB Coordinator</i>	Document in meeting minutes when IRB members have recused themselves for COI issues.

106 SIGNATORY / DESIGNEE AUTHORITY
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1. PURPOSE

The purpose of this policy is to describe signature authority for IRB actions.

2. POLICY

The Chairperson, ORA Director and specifically designated individuals (for example, the IRB Coordinator) are authorized to sign any and all documents in connection with the review and approval of research projects involving the use of humans as participants, which have been reviewed and approved pursuant to WSU policies and procedures.

3. SPECIFIC POLICIES

3.1 Authorization for Signatory Authority

Authorization to sign documents not described in this policy may be made in writing to the ORA Director.

3.2 Chair Designee

The Chair may authorize experienced members of the IRB to act as his/her designee. Authorizations may be made in writing. A designee is an IRB member recognized by the IRB Chair, who has a minimum of six (6) months experience on the IRB. An experienced member is one who has demonstrated a consistent and comprehensive pattern of review of assigned protocols as an IRB member and has demonstrated a dedication to the protection of human participants with his/her actions and comments.

3.3 Results of Reviews, Actions and Decisions

Exempt, Expedited, or Full Board, initial or continuing review as well as amendment approvals may be signed by the ORA Director or the IRB Coordinator.

3.4 Conducting IRB Business

Any letters, memos, or e-mails between the IRB and/or ORA, and/or members of the faculty or staff of the University that provide information concerning the review of research protocols by the IRB or staff may be signed by an IRB staff member. The IRB Staff may correspond with external individuals and agencies on behalf of the ORA Director or IRB chair and/or members. The ORA Director, IRB Chair and IRB Staff will adhere to all institutional signatory authority policies.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.115

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, Chairperson or IRB Coordinator</i>	Establish signature authority delegation based on nature of documents being signed. Sign all documents related to the review and approval of research projects and correspondence with external agencies.
<i>IRB Coordinator</i>	Sign routine internal correspondence or actions taken by Chairperson if authorized to do so by the Chairperson.

200 COMPOSITION OF THE BOARD
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1. PURPOSE

The purpose of this policy is to describe requirements for the composition of the IRBs responsible for reviewing research conducted at, or by agents of WSU.

2. POLICY

The IRB will have sufficient expertise among its members to be able to ascertain the acceptability of proposed research in terms of Institutional commitments and regulations, applicable law and standards of professional conduct and practice. In addition to the members listed below, the ORA Director and IRB Coordinator will serve as an ex-officio voting member of the board.

Therefore, each IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions and of both sexes shall be considered for membership. IRB membership shall not consist entirely of men or of women.

WSU will make every effort to have a diverse membership appointed to the IRBs, within the scope of available expertise needed to conduct its functions.

3. SPECIFIC POLICIES

3.1 Membership Selection Criteria

The IRB members shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. Therefore, the IRB shall include persons knowledgeable in these areas.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural background, clinical experience, healthcare experience, and sensitivity to such issues as community attitudes, to assess the research submitted for review.

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no other affiliation with this institution, either self or family member. For FDA-regulated research, there shall be at least one member who is a licensed physician.

3.2 Regular and Alternate Members

Regular members: The backgrounds of the members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members must include:

- A. **Nonaffiliated member(s):** The IRB will include at least one member from the community. This member will not be affiliated with WSU, other than IRB membership. Nonaffiliated is defined as: The member has no employment or other relationship with the organization and is not otherwise affiliated with the institution or part of the immediate family of a person who is affiliated with the institution. The nonaffiliated member(s), who can be either a scientific or nonscientific reviewer, should be

knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which WSU draws its research participants. The nonaffiliated member(s) should not be vulnerable to influence by the professionals on the IRB, and his/her services should be fully utilized.

- B. **Scientific member(s):** Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a scientific area is required to assess if a protocol adequately protects the rights and welfare of participants.
- C. **Nonscientific member(s):** The intent of the requirement for diversity of discipline is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not primarily in medical or social-behavioral scientific areas.
- D. **Representatives of special groups of participants:** When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. When the IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group, must be included on the IRB.

Clergy: Every effort will be made to include at least one clergy member (non-WSU) or an individual with expertise in ethical practices.

Expertise: Every effort will be made to ensure that at least two of the following fields of expertise will be represented on the IRB: sociology, psychology, and anthropology.

Location: Every effort will be made to include representation from the regional WSU campuses.

Physicians: Every effort will be made to include one or more physicians on the IRB.

- E. **Chairpersons:** The IRB Chairperson should be a highly respected individual from within the WSU community, fully capable of managing the IRB and matters brought before it with fairness and impartiality. The Chair must be an experienced member of the IRB, and can be either a scientific member or nonscientific member. The Chair is elected from the membership of the IRB. The Chair is considered a regular member of the IRB with all applicable responsibilities of voting and motions.
- F. **Alternates:** Alternate IRB members replace regular IRB members who are unable to attend convened meetings. Alternate members have qualifications comparable to the applicable regular member and may be alternates for more than one IRB member. Alternates are not required to attend each meeting, but are encouraged to attend. Alternates will only vote when officially substituting for a designated regular member. Alternates may be asked to attend a meeting when their expertise is needed and/or when they are needed to establish a quorum. Alternates will receive all materials for meetings and general updates so they are able to actively participate in meetings.

3.3 Consultants

Each protocol will be reviewed by the ORA Director, Chair and Coordinator (during the pre-IRB meeting) prior to the meeting to determine if a consultant is needed to provide an expertise review. If the need for a consultant is identified, the ORA Director in consultation with the Chair will contact an appropriate expert (consultant) and arrange for his/her assistance. The consultant will be given all same materials as the Primary and Secondary Reviewer per section 3.4.

The consultant may attend the IRB meeting in person or by teleconference. The consultant may participate in the deliberations and make recommendations, but may not vote. If the consultant is unable to attend the IRB meeting, a written report will be requested and all members will receive a copy prior to the IRB meeting. The consultant's report will become part of the meeting minutes.

If the consultant does not provide a written report, key information from the consultant's verbal report to the IRB will be recorded in the minutes.

3.4 IRB Roster

An IRB roster of regular and alternate members will be maintained for each IRB. The IRB members will be queried at the time of IRB appointment and approximately each year to evaluate any changes.

Any change to the IRB roster will be reported to the ORA Director.

The IRB roster will contain, but not be limited to:

- Name of IRB member
- Earned degrees
- Scientific/nonscientific status
- Representative capacity (e.g. children, prisoners, Native American, pregnant women)
- Experience and credentials
- Affiliation status
- Relationship of the member to the organization
- Membership status
- List of members for whom the alternate member can substitute

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107

21 CFR 56.107

FDA Information Sheets, FAQ section II, questions 14, 15

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IO, ORA Director, Chairperson</i>	Ensures the overall diversity of the IRB membership (gender, race, ethnicity, community affiliation and professional experience) through non-discriminatory selection methods.
<i>ORA Director, IRB Coordinator</i>	Reviews all incoming protocols to determine if consultants are needed. Contacts consultants and follows up as needed.
<i>ORA Director</i>	Reports changes of IRB membership to IO.
IRB Coordinator	Maintains a file on all members, to include their curriculum vita, education, letters of appointment, and other evidence of professional ability. Maintains a roster of all regular and alternate members. Ensures consultants have all study.

201 MANAGEMENT OF THE BOARD

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1. PURPOSE

The purpose of this policy is to describe staff administration and oversight of the IRB to ensure continuity of membership that has the expertise and commitment to meet its regulatory and institutional mandates.

2. POLICY

The management of the membership of the IRB and oversight of member appointments, IRB-related activities, communications, and other administrative details are the responsibility of the ORA.

3. SPECIFIC POLICIES

3.1 Term

Members, including alternates will be appointed to 3 year terms.. Reappointment for additional years or terms may occur. The Chairperson is appointed for one year terms, and may be reappointed.

3.2 Appointments

The IO has the authority (from the President) to appoint regular and alternate members. Members will be solicited from WSU and surrounding Palouse area communities.

The Chair of the IRB will be determined by interest in the position and expertise.

3.3 Resignations and Removals

A member may resign before the conclusion of his/her term. The vacancy will be filled as quickly as possible. A member may be removed by the IO upon recommendation of the IRB. Grounds for removal include failure to attend IRB meetings on a regular basis without reasonable cause, or inability to perform the functions of an IRB member. The Chair or ORA Director will forward the request for removal to the IO along with a recommendation for a replacement.

3.4 Compensation

Participation by WSU faculty or staff as IRB members is considered a component of their job responsibilities as established by their supervisors.

3.5 Evaluation

IRB Committee composition will be evaluated annually to ensure committee composition meets with regulatory and organizational requirements.

IRB Member Evaluation

Annually, the IRB Coordinator will review the activities of the members, including attendance, numbers and types of reviews, and send them summary letters.

Chair Evaluation

The Chairperson will be evaluated by the ORA Director and the IO.

4. APPLICABLE REGULATIONS AND GUIDELINES

None

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IO</i>	In consultation with the ORA Director and other appropriate parties, identify and appoint members of WSU faculty and staff and members of the local community to serve on the IRB.
<i>ORA Director</i>	<p>Discuss the responsibilities and time commitment of IRB membership with the interested parties.</p> <p>Notify the OR of IRB membership</p>
<i>IRB Coordinator</i>	Notify the new member of the next meeting and send a packet of agenda materials to review.
<i>Members</i>	<p>Read information in the New Member packet. Sign and return agreements, and review designated educational materials.</p> <p>Attend the next meeting of the IRB as an observer, in order to meet colleagues and observe the review process.</p> <p>New members are also to be sensitive to conflict of interest and confidentiality issues dealing with their service on the IRB.</p>

*ORA Director, IRB
Coordinator*

Meet with the new member and review the role and responsibilities of being an IRB member, as well as the expectations of the position.

Document that the new member completed required training.

Evaluate IRB membership, Chair and IRB members to ensure that committee meets regulatory and organizational requirements. Provide feedback to IRB members and Chair.

Annually evaluate each IRB member's activity and provide a summary to that member.

202 DUTIES OF IRB MEMBERS

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1. PURPOSE

The purpose of this policy is to define the duties required of IRB members.

2. POLICY

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of that research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the Investigator and the research participants. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human participant protection, biomedical and behavioral research ethics, and the policies of WSU germane to human participant protection. The IRB must be, and perceived to be, fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional or nonprofessional sources.

3. SPECIFIC POLICIES

3.1 General Duties of IRB Members

- Attend all meetings for which they are scheduled; inform the IRB Coordinator of all expected absences as early as possible in order to provide sufficient time to assign protocols to an alternate and ensure a quorum.
- Review all materials related to each item on the agenda in order to participate fully in the discussion and review of each proposed protocol.
- Treat the research protocols and supporting data confidentially
- Expedited reviews: submit review determinations for each expedited submission assigned to them within 3-5 business days of receipt

3.2 Specific Duties

Regular and Alternate Members:

- **Nonaffiliated members:** Nonaffiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.
- **Nonscientific members:** Nonscientific members are expected to provide input on areas relevant to their knowledge, expertise and experience; professional and otherwise.
- **Scientific members:** Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a scientific area is required to assess if a protocol adequately protects the rights and welfare of participants.
- **Chairpersons:** The Chair directs the IRB meetings in accordance with Institutional, state and federal requirements. The Chair works closely with IRB members, the ORA ORA Director, the IRB Coordinator, the Institutional Official, and investigators to ensure the rights and welfare of research participants are protected. The Chair has the authority to

sign for the IRB and conducts all IRB meetings. The Chair helps the ORA Director to designate the reviewers for expedited and full-board applications and may delegate in writing the ability to assign reviewers to the IRB Coordinator and others in the ORA.

Such requests should be in writing, signed by the Chair, and for a period not to exceed one year. The Chair also designates the IRB Coordinator(s) to send official letters, e-mail approval notifications and some IRB related correspondence on behalf of the Chair.

The Chair carries broad responsibilities and an obligation to:

1. Ensure proper conduct and review of all IRB applications
2. Participate in pre-IRB planning meetings with the ORA to ensure optimal review procedures, assignment of duties, and preparation of convened meeting agendas
3. Assist in investigating and resolving complaints, unanticipated events, and adverse events
4. Assist in communications with federal agencies
5. Assist in communicating with faculty and Institutional administration regarding IRB resources and functionality
6. Assist in orientating new members to the board; also delegate the responsibility to ORA staff as needed.

Primary and Secondary Reviewers

In addition to the duties described in sections 3.1 and 3.2, regular members will be expected to act as the Primary Reviewers for their assigned studies at convened meetings. Secondary and Third Reviewers will also be assigned. The Primary Reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB. He or she leads the IRB discussion of the study. The Secondary Reviewer adds to the discussion, as necessary or serves as the discussion leader in the unexpected absence of the Primary Reviewer. The Third Reviewer follows the second.

When reviewing a study, if the IRB reviewing member has issues or questions for the Principal Investigator (PI) to address, the reviewing member will relay the questions to the IRB Coordinator, who will then communicate to the PI. All communications with the PI will go through the ORA.

Members (When Not Assigned as Primary or Secondary Reviewer)

All members attending the convened IRB meeting will receive all submission materials (via Sharepoint). When a reviewer is not assigned as a Primary, Secondary, or Third Reviewer, the reviewer will review the study materials thoroughly enough to provide input into the discussion. All IRB members attending convened meetings are expected to contribute to the Committee discussion including those about other members' assigned protocols.

4. APPLICABLE REGULATIONS AND GUIDELINES

None

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, IRB Coordinator</i>	<p>Maintain up-to-date descriptions of member responsibilities. Answer questions from IRB members as needed.</p> <p>Ensure that members are carrying out their expected functions and that there is adequate staff support to ensure that members are able to function as documented.</p> <p>As needed, make recommendations to the Chairperson regarding changes to descriptions, staffing, meeting schedules, and other factors that affect members' ability to perform their roles.</p>

300 SUBMISSION REQUIREMENTS FOR IRB REVIEW

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1. PURPOSE

The purpose of this policy is to outline the required documents and supporting information required from investigators for IRB review.

2. POLICY

Applications and related documentation will be submitted electronically. Signatures may be electronic, as well.

IRB members often rely solely on the documentation submitted by investigators for initial and continuing review. Therefore, this material must provide IRB members with enough information about a study to assess if it adequately meets the criteria for approval.

A protocol requiring review will be scheduled for IRB review when IRB staff has determined that the information and materials submitted present an adequate description of the proposed research.

3. SPECIFIC POLICIES

3.1 Submission Requirements for Initial Review

3.1.1 Required: Investigators applying for initial approval of a proposed non-exempt research protocol must submit (as pertinent to the research under consideration):

- IRB Submission form
- Research protocol or protocol summary
- Investigator Brochure, or device specifications
- Questionnaires & assessment instruments
- Proposed Informed Consent document/Assent and Permission documents(if applicable)
- Recruitment materials, proposed subject instructions
- Data Safety Monitoring Plan (DSMP) or Data and Safety Monitoring Board Plan (DSMB), if applicable for more than minimal risk research
- IDE or IND FDA assignment letter

In addition, applicants *may* be required to submit:

- Disclosure of Significant Financial Interest
- Documentation of completion of required training
- FDA Form 1572 (drug study) or signed investigator agreement (device study)
- Addendum 7; HIPAA documentation, documentation of approval by another University committee, e.g., Biosafety Committee and Radiation Safety Committee
- Contract of funding agency minus the budgetary pages

3.1.2 Submission Requirements for **Exempt** Research

Required: Investigators applying for acknowledgement of Exempt

Status must submit as part of electronic application (electronic signatures are valid)

- Exempt Application form: with all appropriate signatures
- A protocol summary (abstract)
- Recruitment materials
- If additional IRB review being sought at another institution: name, address and telephone number of IRB

3.2 Submission Requirements for Modification/Amendment and Continuing Review

3.2.1 Modification/Amendment

During the approval period, investigators must submit documentation to inform the IRB about changes in the status of the study *before implementing changes* including, but not necessarily limited to:

- Request for Amendment form
- Current approved consent/assent document if the consent will be changed
- Revised IRB Submission form if change is significant
- Any other relevant documents provided by the investigator

3.2.2 Continuation/Renewal of IRB Approval

At least 14 days prior to the IRB approval expiration date, investigators requesting renewal of an approved research project must submit (but not be limited to) the following materials:

- Completed Continuing Review form
- Courtesy expiration notices will be sent by IRB staff prior to expiration

3.3 Action Taken If Documentation is Not Adequate or Additional Information is Required

If the IRB or staff determines that the submitted documents are not adequate, investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. No incomplete submissions will be reviewed by the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.115
21 CFR 56.108 (a)(4)
21 CFR 312, 812

5. FORMS

Non-Exempt Application
Exemption Determination Application
Request for Amendment
Continuing Review form

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	<p>Ensure that complete submission information is available and provided to all investigators.</p> <p>Date stamp and document receipt of all submissions.</p> <p>Review submission for completeness. Note any missing information.</p> <p>Contacts other committee(s) to check on status of study review and or approval.</p> <p>Evaluate and review claims for exemption from IRB review, document. Evaluate submission that fit requirements for expedited review.</p> <p>Route to Chair or reviewer.</p> <p>Prepare submissions for IRB review.</p> <p>Request from investigator/project ORA Director any missing elements from incomplete submissions.</p> <p>Add new submissions for full IRB review to agenda for next meeting.</p>
<i>ORA Director, Chair, IRB Coordinator</i>	<p><u>Full Board New Studies/Continuations/Modifications</u></p> <p>Review submissions, assigns to Primary/Secondary Reviewers and/or determines if expert consultation is needed.</p> <p>Review high-risk studies –routes to full Board.</p> <p>Review studies involving vulnerable populations –routes to full Board.</p>

301 ADMINISTRATIVE PRE-REVIEW AND DISTRIBUTION OF IRB MATERIALS
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1. PURPOSE

The purpose of this policy is to describe the requirements for document pre-review and distribution prior to IRB review.

2. POLICY

The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed study, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions.

3. SPECIFIC POLICIES

3.1 Exemptions

The IRB Coordinator will review and approve Applications for Exemption submitted by investigators. Such Applications for Exemption will be logged and filed.

3.2 Incomplete Submissions

Incomplete applications will not be accepted for review until the investigator has provided all necessary materials as determined by the ORA Director or IRB Coordinator. The ORA Director or IRB Coordinator will notify the submitting investigator to obtain any outstanding documentation or additional information before the application is scheduled for review. Incomplete submissions will be logged, but not assigned for review and/or approval.

3.3 Scheduling for Review

During the pre-review time, the IRB Coordinator will determine if an application meets the criteria for expedited review under 45 CFR 46.110(b) and the FDA 21 CFR Parts 50 and 56, Washington State regulations and University policy. If an initial application qualifies for expedited review, the Chair (or designee) will select a subcommittee of two members of the IRB to review the application. Each reviewer will have ten working days to review the application and render a decision or comments for clarification.

3.4 Distribution to Members Prior to IRB Meetings

Copies of application materials described in Section 300 (Research Submission Requirements) will be distributed to all IRB members, generally at least ten (10) days prior to the meeting, unless deemed urgent by the ORA Director or Chair. Each regular member of the IRB, and any alternate members attending the meeting in place of a regular member, will receive a copy of the initial application material. Consultants will only receive copies of material that pertain to their requested input.

3.5 Confidentiality

All material received by the IRB will be considered confidential and will be distributed only to meeting participants (regular members, alternate members, and special consultants) for the purpose of review.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109 and 45 CFR 46.109

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Conducts preliminary assessment of submissions claiming exemption from IRB review.
	Distributes expedited review protocols to Chair or designee.
	Requests meeting attendance of PI if requested by Committee.
	Conducts assessment of submission adequacy and contact investigators for any missing elements.
	Assembles reviewers' packets. Sends to all regular members of the IRB.
	Sends pertinent protocols to consultants invited to the meeting.

302 IRB MEETING ADMINISTRATION

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1. PURPOSE

The purpose of this policy is to provide the framework to ensure that IRB meetings are conducted and documented in a consistent manner in order to meet federal and institutional requirements.

2. POLICY

Except when an expedited or exempt review procedure is used, the IRB will review proposed research at convened meetings at which a quorum and appropriate expertise is present. The IRB will meet monthly, or at some other frequency determined by the Chairperson and the ORA Director.

3. SPECIFIC POLICIES

3.1 Quorum

- A quorum is defined as the majority of the voting members.
- A quorum consists of regular and/or their alternate members and includes: at least one member whose primary concerns are in scientific areas, and one member whose primary concerns are in nonscientific areas.
- An alternate member may attend in the place of an absent regular member in order to meet the quorum requirements outlined above.
- IRB members who leave the room due to a conflict of interest cannot be counted towards quorum.
- When the IRB reviews research that involves participants vulnerable to coercion or undue influence, at least one person (member or consultant) who is knowledgeable about or experienced in working with such participants must be present at the convened meeting.
- At least one IRB member who is a licensed physician must be present at the convened meeting.
- For research to be approved, it must receive the approval of a majority of the members present at the meeting.
- If quorum is lost during a meeting, the IRB will not vote until quorum is restored even if that means deferring the vote to next month's meeting.
- Consultants will not be used to establish a quorum and may not vote with the IRB.
- Each member has one vote.
- No proxy votes are allowed. Members may attend the IRB meeting by video conference or by telephone. It is the responsibility of the member to contact the IRB Coordinator to ensure the necessary equipment will be available.

3.2 Primary and Secondary Reviewers (and Third, for full-board applications)

Prior to the meeting, the IRB Coordinator with assistance from the ORA Director and Chairperson will designate Primary and Secondary Reviewers (and Third, for full-board reviewed applications) for each research proposal, including continuations, and amendments, according to their scientific or scholarly expertise, and if there are not IRB members with the appropriate expertise, an expert consultation will be arranged.

If there is not an appropriate scientific or scholarly reviewer (member or consultant) to conduct an in-depth review of the protocol, the protocol will be deferred to the next month's IRB meeting.

3.3 Meeting Materials Sent Prior to IRB Meetings

All IRB members including those attending by conference call and alternates will have access to all required meeting materials at least ten (10) days in advance of the meeting to allow time for adequate review.

All members will have access to all the submission documents as well as the entire study file, via SharePoint.

Agenda Each member will receive an agenda, the agenda will list which members are assigned to be the Primary and Secondary Reviewers (and Third, for full-board reviewed applications) for each study that is to be reviewed. The agenda also includes reporting of exempt and expedited studies and actions.

IRB meeting materials include, but are not limited to:

Initial Review

- IRB application with addendums
- Proposed informed consent document(s) and/or script as appropriate
- Copies of surveys, questionnaires, or videotapes
- Copies of letters of assurance or cooperation with research sites
- Recruitment/advertising intended to be seen or heard by potential participants, including e-mail solicitations and physician letters,
- Reviewer's comment sheet and informed consent checklist
- Translation, if appropriate

Continuing Review Materials

- Completed Continuing/Renewal form
- Current approved consent/assent document(s)
- A copy of the current HIPAA authorization document, if separate from the informed consent, if appropriate
- Any other relevant documents provided by the investigator
- Reviewers' comment sheets

Amendments to the Research

All IRB members are provided and are asked to review sufficient information about the proposed modifications to previously approved research to determine whether the modified research continues to fulfill the criteria for approval. The reviewer materials include:

- Revised application with highlighted changes Reviewers' comment sheets
- Informed consent checklists, if appropriate

3.4 Minutes

- The IRB Coordinator or Staff will take minutes of each meeting. Minutes will be written in sufficient detail to show the following: Attendance at the meeting including:
 - Members or alternate members attending through teleconferencing and documenting that those members have received all IRB materials and can actively and equally participate in the discussion.

- Status of each attendee (regular member, consultant, etc.).
- Alternate members and whom they are replacing
- Names of members who absent themselves due to conflicts of interest along with a notation that the member left due to a conflict.
- Documentation of members leaving and re-entering.
- Actions taken by the IRB on each agenda item requiring full IRB action.
- Separate deliberations for each action.
 - Scientific design
 - Participant selection and recruitment
 - Additional safeguards for vulnerable participants
 - Privacy and confidentiality
 - Minimization of risks to participants
 - Risk/benefit assessment
 - Determination that all required elements of the consent document are present
 - Controverted issues
- Voting results, including the number for, against, abstaining, and abstaining: due to a conflict of interest.
- The basis for requiring changes in research.
- The basis for disapproving of the research.
- Written summary of the discussion of controverted issues and their resolution.
- Determination of level of risk.
- Summary of key information from consultant's verbal in-person report if a written report was not provided.
- Determination of approval period, whether protocols need to be reviewed more than annually (initial and continuing review).
- Determinations required by the regulations, and protocol-specific findings justifying those determinations, for:
 - Waiver of alteration of informed consent.
 - Research involving pregnant women, human fetuses, and neonates.
 - Research involving prisoners.
 - Research involving children as participants.
- The rationale for significant risk/no significant risk device determinations.
- Documentation of approval of research that was contingent on specific minor conditions reviewed and approved by the Chair or designee. This documentation must take place at the first meeting after the date of approval.
- Report on full board protocols approved in the interim
- Follow up on deferred protocols
- Expedited amendment/continuing review approvals for full board protocols
- Report of adverse event(s)
- A list of
 - Expedited applications (New, amendment and continuing review) approved since the last meeting and also for the fiscal year
 - Expedited amendments/renewals for full board applications approved since the last meeting

A majority of members must vote in favor of an action for that category of action to be accepted by the IRB. Only regular and alternate members acting in place of absent regular members may vote. The vote will be recorded in the minutes. Members with a conflict of interest will absent themselves from the discussion and voting and such will be noted in the minutes.

3.5 Distribution of Minutes:

- Minutes must be written and available for review before the next meeting.
- Draft minutes will be distributed to members at the next IRB meeting for review.
- Corrections requested by the IRB will be made by the IRB Coordinator and the minutes will be available in final form on request.
- The recorder will maintain copies of the minutes, as well as the agenda and pertinent materials on file.
- Once approved by the IRB members at a subsequent IRB meeting, the minutes may not be altered by anyone including a higher authority.
- A copy of the final minutes will be forwarded to the Vice President for Research.

3.6 Meeting Conducted Via Conference Calls and Videoconferencing

Meetings may be convened via a telephone conference call and/or videoconference. A quorum (as defined above) must participate for the conference call meeting to be convened. To allow for appropriate discussion to take place, all members must be connected simultaneously for a conference call or videoconference to take place -- "telephone polling" (where members are contacted individually) will not be accepted..

Members not present at the convened meeting, nor participating in the conference call or videoconference may not vote on an issue discussed during a convened meeting (no voting by proxy).

3.7 Voting

Members of the IRB vote motions made and seconded according to the criteria for approval. Members also will determine level of risk, the frequency of review for each protocol, and that the criteria for approval have been met.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.108
 21 CFR 56.108, 56.109

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Complete agenda and ensure that everyone has one prior to start of meeting as well as a copy of the last meetings' minutes
<i>ORA Director, Chairperson, IRB Coordinator</i>	Evaluate each protocol prior to the meeting to ensure that at least one IRB member is knowledgeable about or experienced in working with participants vulnerable to coercion or participants who may be participant to undue influence. If no IRB member is available, obtain consultant.

<p><i>IRB Coordinator/Staff</i></p>	<p>Assemble agenda and upload all applicable study files to secured website. Include in the agenda reporting of exempt reviews, expedited reviews and unanticipated problem reports received since the last IRB meeting. Also include other pertinent or applicable information needed to be reported to IRB members.</p> <p>Record proceedings of the meeting.</p> <p>Complete draft minutes in time to include in the reviewers' packets for the next meeting (within three weeks).</p>
<p><i>Chairperson</i></p>	<p>Ensure that quorum is met, expertise is present and all business is addressed, that proceedings are recorded, and that any member who has a conflict of interest does not participate in the IRB's consideration of the study for determination, except as requested by the IRB, or in voting.</p>

303 DOCUMENTATION AND DOCUMENT MANAGEMENT
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1. PURPOSE

The purpose of this policy is to describe the requirements for document management, retention, and archiving.

2. POLICY

The IRB files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments, and adverse event reports. All IRB records are retained as electronics copies; no paper files are kept. All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy, and be available in case of Freedom of Information Act requests.

Records must be accessible for inspection and copying by authorized representatives of the sponsor, funding departments, or agency, regulatory agencies, and institutional auditors at reasonable times and in a reasonable manner.

Required documents must be submitted to the appropriate funding entity as required.

3. SPECIFIC POLICIES

3.1 Document Retention

The Office of Research Assurances (ORA) must retain all electronic records regarding an application (regardless of whether it is approved) for at least three years.

For all applications that are approved and the research initiated, including studies that did not enroll any participants, the ORA must retain all records regarding that research for at least three(3) years after completion or cancellation of the research.

Applications that do not meet the definition of “research” and “human participant” as defined in DHHS regulations and do not meet the definition of “clinical investigation” in FDA regulations will maintained for three (3) years.

Adequate documentation of the IRB activities will be prepared, maintained and retained in a secure location. Retained documents include but are not limited to:

General office:

- Agendas and minutes of all IRB meetings.
- Protocols closed out or withdrawn without participant enrollment.

Study files:

- Progress reports submitted by investigators.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and investigator.
- Statements of significant new findings provided to participants as submitted by the investigator.
- Approved consent documents, and reports of adverse events, unexpected adverse events, and unanticipated problems occurring to participants and reported deviations or violations from the protocol.

- Copies of all submitted monitoring reports and site visit reports.
- Reports of any complaints received from participants.
- For each protocol's initial and continuing review, the frequency of the next review.
- Protocol violations submitted to the IRB.
- Unexpected adverse events submitted to the IRB.

For initial and continuing review of research by the expedited procedure:

- Specific permissible category on Addendum 1/
- Reviewer's comment sheet.

For exempt studies:

- Specific exemption category.
-

Determinations and protocol-specific findings supporting the determinations for:

- Waiver of alteration of the consent process.
- Waiver of documentation of consent.
- Research involving pregnant women, fetuses, and neonates.
- Research involving prisoners.
- Research involving children.

3.2 IRB Documents (Accessibility, Inspection and Copying)

IRB records will be accessible for inspection and copying by authorized representatives of the OHRP, FDA and other authorized entities at reasonable times and in a reasonable manner.

3.3 IRB Administration Documents

The ORA must maintain and retain for at least three (3):

- All records regarding IRB administrative activities that affect review activities three (3) years.
- All records regarding protocols that are approved and the research initiated, three (3) years after completion of the research or termination of IRB approval.

3.3 Destruction of Copies

All materials received by the IRB, which are considered confidential and in excess of the required original documentation will be collected at the end of the meeting and destroyed.

3.4 Archiving and Destruction

All documents and materials relevant to IRB determinations will be archived by the ORA. After three (3) years the documents and materials may be destroyed.

Current and obsolete membership rosters will remain in the ORA and then be archived according to University policy.

Records of Member Appointments, Resignations and Evaluations will be kept indefinitely.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103,115, 21 CFR 56.115

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Ensure study information is entered in the database. Organize the submitted material.
<i>ORA Director, IRB Coordinator</i>	Retain all records regarding a submitted study as required by regulatory requirements and/or institutional policy.

400 EXEMPT REVIEW

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1. PURPOSE

The purpose of this policy is to describe the research process, review, and determinations for exempt reviews.

2. POLICY

All research including that in the exempt categories must meet, at a minimum, the principles outlined in the Belmont Report and meet The University's ethical standards. Determination of exemption will be based on regulatory and institutional criteria (see Appendix [Exemption Determination Application](#)).

3. SPECIFIC POLICIES

3.1 Exempt Project Submission Requirements

Research activities that meet the requirements for one or more exempt research categories must be reviewed by the IRB staff.

The investigator must complete the appropriate Exempt Application and submit the application along with (if appropriate or requested by the IRB staff):

- Research tools: questionnaires, surveys, etc.
- Consent statements, informed consents, assents (recommended).
-
- Recruitment materials.
- Translations (not required for exempt reviews but reflect Best Practice per Belmont Principles).

3.2 Exemption Categories and Determinations

Research activities in which the only involvement of human participants will be in one or more of the exempt categories (see Appendix) may be approved as exempt. The Chair, designee, ORA Director, or IRB Coordinator will review the Exempt Application and make a determination.

Policies do not allow exemption of research involving audio, video or digital recordings or photography, unless it is only for transcription purposes. Surveys or interviews that are extremely sensitive or personal will not be exempted.

3.3 Approval Period

Studies receiving an exemption certification from the IRB staff will not receive an expiration date. During the active research, the investigator will keep the IRB informed of any changes in the study, so that the IRB can ensure that the study continues to meet the exempt criteria. Any change to the study will be submitted as an amendment.

The investigator may close out the study when data collection has ended or when contact with participants is complete.

3.5 Documentation of Exempt Review

If the study qualifies for exempt review, the reviewer will complete the Exemption Determination Checklist, which will be used as documentation.

3.6 Investigator and IRB members Notification

The investigator will be notified by e-mail of the exemption determination.

Each month exempt certifications will be listed on the IRB meeting agenda.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56. 104, 105

5. FORMS

Exemption Determination Application

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
IRB Staff	Reviews submitted projects to determine claims of exemption using the Exemption Determination Checklist. The Staff may: <ul style="list-style-type: none"> • Approve the request • Request revisions and/or additional documentation from PI • Disapprove claim of exemption and send for expedited or full Board review. • Email determination of exemption. Document approval of exemption category on Exemption Application.
IRB Staff	Report exemption determinations on IRB meeting agenda. Maintain documentation of exemption application submissions and determinations.

401 EXPEDITED REVIEW

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1. PURPOSE

The purpose of this policy is to describe and outlines the process to determine if the research meets criteria for expedited review.

2. POLICY

During the pre-review, the IRB Coordinator will determine if an application meets the criteria for expedited review under 45 CFR 46.110(b) and the FDA 21 CFR Parts 50 and 56, Washington State regulations and University policy. If an initial application qualifies for expedited review, the Chair (or designee) will select two members of the IRB to review the application. Each reviewer will have ten working days to review the application and render a decision or comments for clarification. If any changes are requested, the reviewers will notify the IRB Coordinator who will contact the researcher. In most cases, the IRB Coordinator will act as a liaison between the reviewer and the researcher. This policy pertains to both initial, continuing review, and modifications to previously-approved research.

The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that (1) present no more than minimal risk to human participants (2) do not involve identification of participants and/or responses that would reasonably place them at risk of criminal or civil liability or be damaging to the participant's 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 no greater than minimal, (3) are not classified, and (4) involve only procedures listed in one or more the specific categories on the Addendum 1 Expedited Categories and Determination.

2.1 Expedited Categories

The expedited categories are listed on Addendum 1 of the Non-Exempt Application. See Appendix.

3. SPECIFIC POLICY

3.1 Initial Review

In reviewing the research, the reviewers may exercise all of the authorities of the full IRB except that the reviewers may not disapprove the research. In the case of a split decision by the reviewers, the Chair will act as a third reviewer, or the application will be brought before the full board IRB meeting.

- The reviewer(s) will have access to the entire study file including the following documents (if applicable):
 - IRB application with any required addendums
 - Research protocol, if applicable.

- Investigator brochure or device specifications.
- Questionnaires and assessment instruments.
- Proposed informed consent documents (including assent).
- Proposed participant instructions, recruitment materials, and advertisements.
- Letters of permission.
- Recruitment materials (flyers, posters, etc.).
- Translations of materials.
- Documentation of completion of required training.
- FDA Form 1572 (drug study) or signed investigator agreement (device study).
- HIPAA documentation.
- If additional IRB review is sought at another institution: name, address and telephone number of the IRB.
- If additional review is being sought at another WSU committee, the approval, if it is completed (included on application)

3.2 Continuing Review

Studies which have been approved as expedited may be reviewed via expedited review.

A study that received full Board review may be determined by the full Board, to be minimal risk and thus, if the Board so determines, can be annually reviewed by the expedited procedure. This determination will be documented in the minutes.

The reviewers at continuation will have access to the entire study file including the following documents:

- Completed Continuing Review form
- Copy of the current approved protocol and all intermediate amendments
- Copy of the current consent document(s)
- A copy of the current HIPAA authorization document, if separated from the informed consent Any other relevant documents
- Background information.

3.3 Minor Modifications to Previously Approved Research

Unless it will change the level of the review, Expedited Amendments are reviewed in the IRB office. The IRB Coordinator may approve minor modifications of previously approved research during the period for which approval is authorized.

Minor modification is defined as a change and is considered minor when it does not materially affect an assessment of the risk and benefits of the study, does not change the aims of the study design, and is not directly relevant to the determination required for approval.

Examples of minor modifications include, but are not limited to:

- Protocol revisions that entail no more than minimal risk.
- Changes to the informed consent documents that do not affect the rights and welfare of study participants, or do not involve increased risk, or significant changes in the study procedures.
- Changes in research personnel or contact information.

3.4 Additional Items that May Be Reviewed by the Expedited Review Process

- **IRB Meeting Determination: Minor Modifications**
The IRB will stipulate specific revisions that require simple concurrence or agreement by the investigator. These stipulations must be clear so that the IRB Coordinator can determine whether the protocol, consent, advertisement, or other document was modified as requested by the IRB.
- **Advertisements**
New or revised recruitment advertisements or scripts.

3.5 Documentation of Expedited Review

The IRB Coordinator will document the expedited review (initial, continuing review, amendments) by use of the reviewer’s comment sheet, which will become part of the study file.

4. EXPEDITED APPROVAL NOTIFICATIONS

Once both designated reviewers have approved the application, the IRB Coordinator will notify the researcher of approval, on behalf of the Committee. The IRB attempts to complete expedited reviews within ten working days from receipt of the application.

When the expedited review procedure is used (initial, continuing review, modifications) all regular members shall be informed of actions taken by the IRB Staff at the next convened meeting. The expedited actions will be listed in the IRB agenda.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.102, 46.110
21 CFR 56.102, 56, 110
OHRP IRB Guidebook

6. ATTACHMENTS

Addendum 1 Expedited Categories and Determination

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, Chairperson, IRB Coordinator</i>	Make initial determination regarding qualification for expedited review. Refer to checklists as needed.
<i>Reviewers</i>	Review study using appropriate Expedited Reviewer’s Comment Sheet and any other appropriate checklist. Ask the IRB office to make the contact for clarifications or revision.

<i>IRB Coordinator</i>	If study qualifies for expedited review, assemble reviewer's materials and assign to reviewers. Enter study into the database. Report all expedited reviews on IRB meeting agenda. Ensure reviewer(s) turn in checklists and add to study file. Send out correspondence of action or approval to investigator.
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402 AMENDMENTS/STUDY UPDATES

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1. PURPOSE

The purpose of this policy is to describe exempt, expedited and full board amendment processing and determinations.

2. POLICY

Minor changes that do not increase the risk to research participants may receive review and approval at expedited or administrative review levels. An amendment may require full IRB review if the amendment is significant and impacts the risks and benefits to participants in the research.

3. SPECIFIC POLICIES

3.1 Amendments/Project Updates

Investigators or sponsors must submit requests for changes to the IRB in writing. Each update/amendment will include:

- Description of the changes.
- Reason for the change.
- Whether or not changes are needed to the informed consent document.
- The impact the changes will have on the study and/or the participants: risk/benefit rationale.
- All appropriate documents:
 - Revised informed consent (changes underlined or tracked)
 - Sponsor correspondence concerning the amendment.
 - Amended protocol (if appropriate).

3.2 Full Board Amendment Review

Minor administrative changes (adding personnel, updating phone numbers, minor editorial changes to consent documents, cover letters, advertising, etc.) may be reviewed and approved by the Chair and/ or the IRB Coordinator.

Amendments to approved applications that may affect the risk to participants may be forwarded to the full IRB for review. Reviewers will receive the Request for Amendment and any modified items such as consent forms, applications, investigator brochures, study instruments, recruitment tools, background materials, etc.

Changes in the risks or benefits to participants may require amendments to the consent form and re-consenting of participants.

The IRB approval of an amendment does not extend the approval period. For example, if the new or continuing review is approved on January 1, 2015 it will have an expiration date of December 31, 2015. If an amendment is approved during this time, the approval still lasts only until December 31, 2015.

If possible, the prior Primary and Secondary Reviewers of the initial IRB submission will be assigned as the reviewers. All other members will receive all the materials.

3.3 Expedited Amendment Review

If the project amendment/update is a minor change, involving no more than minimal risk to the participant, it will be reviewed by the expedited review process and will be reported to the IRB on the next month's agenda. See 401 Expedited Reviews.

Exempt Amendment Review The investigator must inform the IRB of any changes to the scope or design prior to implementation to ensure that the study continues to meet the exempt criteria.

3.6 Investigator Notification

All approvals for requested revisions will be reported to the investigator via e-mail.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812.64
 21 CFR 56.108, 56.109, 56.113
 45 CFR 46.103, 46.109, 46.115
 FDA Information Sheets, 1998

5. ATTACHMENTS

Request for Amendment

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Prepare all information received from Investigator and prepare reviewer packet. Determine whether amendment can be reviewed via expedited review and which are to be placed on the agenda for the next meeting. Assign to Primary and Secondary Reviewers Process Amendments and project updates.
<i>Reviewers</i>	Review amendment or change in the research at a convened IRB meeting.
<i>IRB Coordinator</i>	Complete processing of amendment/project update.

403 CONTINUING REVIEW – CRITERIA FOR RENEWAL

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1. PURPOSE

The purpose of this policy is to describe the procedure for the renewal of approved research at the expiration of the IRB approval period.

2. POLICY

The IRB conducts continuing review (renewal) of research taking place within its jurisdiction at intervals appropriate to the degree of risk, but not less than once per year including:

- Research which remains active for long term follow-up of participants even when research is permanently closed to enrollment of new participants and all participants had completed all research-related interventions.
- The remaining research activities include collection or analysis of private identifiable data.

3. SPECIFIC POLICIES

3.1 Interval for Review for Continuing Review

3.1 Criteria for Continuation/Renewal

The IRB reviews all active expedited and full-board applications at least annually. The IRB may determine the frequency of the review based on the nature and/or risk of the research. In general, continuing reviews are conducted at the level of the initial review, but the review level can be changed as necessary to conform to the risk level, law and policy. In order to ensure continuing reviews are substantive and meaningful, the IRB members designated as the primary and/or secondary reviewers will receive the continuing review form, consent form, as well as the full application (back ground material containing previously approved protocol and/or activities) and any additional information that is necessary. Any IRB member who is not a designated reviewer can receive a complete application packet upon request. All material is available to all members via SharePoint.

Approved applications determined to present more than minimal risk category can be reviewed under expedited review category where:

- The research is permanently closed to the enrollment of new participants; and
- all participants have completed all research-related interventions; and
- the research remains active only for long-term follow-up of participants; or where no participants have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

Research activities that were originally reviewed using expedited criteria may receive continuing review on an expedited basis, unless the research activities no longer meet the expedited criteria for review and approval.

Research activities that had previously met criteria for expedited review may change with the review and approval of amendments, such that IRB Committee review would be required at the time of continuing review (e.g., risk has changed to be greater than minimal).

3.3 Possible Outcomes of Review for Continuation

As an outcome of continuation review, the IRB may authorize continuation of the research, require that the research be modified or halted altogether.

Appropriate continuing review intervals are addressed with each review conducted by the IRB. The following factors are taken into consideration when determining the appropriate review interval, but are not limited to:

- Involvement of vulnerable populations.
- Involvement of recombinant DNA or other types of gene transfer protocols.
- Use of waiver of informed consent procedures.
- Classified research.
- Research for which participants would be exposed to additional risks, e.g., breach of confidentiality, phase I studies, disproportionate number or severity of adverse events, and
- Previous suspensions of the research due to compliance, record-keeping, or other concerns.

Any changes required to obtain continued renewal approval shall be provided to the investigators by the IRB staff.

3.4 Date of Continuing Review Approval

If the IRB grants a one year approval of the continuation, the date of continuation will be determined by the date the protocol was approved by the convened IRB. If the study is reviewed by expedited review, the approval date will be determined by the date the study is approved.

3.5 Expiration and Extensions of Approval Period

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. If a Continuing Review form is not received as scheduled, the IRB approval expires and the investigator must stop all research procedures, screening, recruitment, enrollment, interventions, advertisements, consent, interactions, and collection of private identifiable data.

Investigators, who believe that currently enrolled participants will be at risk if the research project is discontinued, must immediately submit to the IRB Chair, a list of participants for whom suspension of the research would cause harm. The IRB Chair or an experienced IRB member designated by the Chair will determine whether it is in the best interest of individual's participants to continue to take part in the research interventions or interactions.

At the discretion of the reviewers, the matter might be brought to a convened meeting. However, new participants CANNOT be enrolled. Prospective research data cannot be collected, and no procedures that are only being performed for the purpose of the protocol may be performed until a Continuation Form or other progress report is reviewed and approved.

Failure to obtain renewal of an approved study in the required time frame may be considered serious non-compliance and may be reported to the appropriate institutional officials and regulatory authorities when applicable.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108,111

45 CFR 46.111

OHRP Guidance on Continuing Review 7/11/02

6. FORMS

Continuing Review Form

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Generates and e-mails correspondence notification letters and continuing review forms Reviews the report and associated materials to determine the status of continuation of the study. Full Board studies will be put on next meeting agenda. Assigns expedited studies to reviewers. Notifies the investigator of the outcome of the review.
<i>Member(s)</i>	Review continuations.

404 STUDY COMPLETION

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1. PURPOSE

The purpose of this policy is to describe how to close a research protocol or project.

2. POLICY

The completion or termination of an expedited or full-board study is a change in activity and must be reported to the IRB. Although participants will no longer be "at risk" under the study, a final report to the IRB allows it to close the file.

3. SPECIFIC POLICIES

3.1 Determining When a Project Can Be Closed

- Participant enrollment is complete. All data collection is complete and the only remaining activity is analysis of the data. The data are de-identified; there is no identifying link or code to the de-identified data and there are no active financial transactions to be completed (if funded).
- Multi-site industry studies may be closed when the investigator submits a final report.
- Exempt studies may be closed when there is no longer any contact with the participants or data collection is complete.

3.2 Administrative Closure of an Exempt Project

The IRB may close an exempt project if several documented attempts have been made to contact the investigator or student investigator and there has been no response. Project Closure notification will be sent to the investigator or advisor of the student investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109
 45 CFR 46.103, 46.109

5. FORMS

Closeout Report Form

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
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IRB Coordinator

Instruct investigators to submit a Closeout Report Form
Review Project Closure Report and obtain any outstanding information or documentation from the investigator to close the study. If there are inconsistencies or if clarification is needed, request additional information.

405 IRB MEETING DETERMINATIONS

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1. PURPOSE

The purpose of this policy is to describe potential meeting determinations.

2. POLICY

As a result of its review, the IRB may decide to approve, defer (pending minor clarifications), defer (pending additional full board review) or disapprove the protocol. Except when the expedited review procedure is used, the determination will be made by a vote of a majority of the quorum. When reviewed via expedited review, the reviewers may approve or defer pending changes or they may determine that a full board review is required. Expedited reviewers cannot disapprove a protocol; if they do not agree on approval it will be reviewed by the full board.

3. SPECIFIC POLICIES

3.1 Determinations

The IRB may make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

Approve: The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or Chair, or designee of the IRB and expire within one (1) year of the approval date, but not later than the day preceding the date of review.

Approvals are always conditional on conditions being met by the investigator. The conditions for continued approval and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

Defer Pending *Minor Clarifications and/or Modifications*: The IRB will stipulate specific revisions that require simple concurrence or agreement by the investigator. These stipulations must be clear enough so that the reviewer needs minimal judgment to determine whether the protocol, consent, advertisement, or other document was modified as requested by the IRB.

Clarifications and/or modifications will be discussed and voted upon during the IRB meeting, as well as terms of approval, duration of approval, any other determinations that need to be discussed, and level of risk.

The IRB Chairperson will assign the reviewers (IRB Chair, Primary or Secondary Reviewer, or IRB Coordinator) the task of reviewing the information provided by the investigator. If the designated IRB reviewer determines that the investigator has not made the appropriate responses to the IRB's request, the reviewer may request additional information or send the response back for full IRB review at a convened meeting. Upon satisfactory review, approval will be issued.

Approval Periods:

Approval Date: The approval date is issued as of the date that the requested information or materials are verified.

Expiration Date: The expiration date will be one year (minus one day) from the date of the convened meeting, e.g. July 27, 2007 to July 26, 2008.

Approval is usually one year, but may be given for a lesser period of time (less than one year) based on the relative perceived high level of risk to the participant population, previously reported issues with the drug, biologic or device, previous issues with the PI, nature and location of the study, or the vulnerability of the study participant population.

Participants must not be recruited into the study until final approval has been issued.

VA research cannot commence until R&D gives final approval.

Defer Pending Major Clarifications and/or Modifications: The IRB requests any additional information, any clarifications, or any modifications that *cannot* be described as specific revisions that require simple concurrence by the investigator. The convened IRB must review the responsive materials. If the convened IRB approves the research based on the responsive materials, the following apply:

Approval period:

The approval date is issued as of the date of the IRB meeting in which the study was approved.

Expiration date: The expiration will be one year (minus one day) from the approval date, but may be given for a lesser period of time (less than one year) based on the relative perceived high level of risk to the participant population, previously reported issues with the drug, biologic or device, previous issues with the PI, nature and location of the study, or the vulnerability of the study participant population.

Participants will not be recruited into the study until final approval has been issued.

Tabled: Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the investigator and/or sponsor. Tabling cannot be given through the expedited review mechanism and may only be given by a majority vote at a convened meeting of the IRB.

Disapproval: The proposal fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111, 56.113
45 CFR 46.109

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
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<i>IRB Coordinator</i>	Documents all IRB decisions in the minutes.
<i>Chair</i>	Ensures all determinations are discussed and voted upon.
<i>Chair or Designee</i>	Reviews and signs all IRB decision letters.

406 NON-COMPLIANCE WITH IRB POLICIES AND PROCEDURES

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1. PURPOSE

The purpose of this policy is to establish procedures for handling the reports of non-compliance and serious and continuing non-compliance with IRB policies and procedures. This policy also applies to routine and for cause audits conducted by the ORA.

The policy applies to all University investigators and research personnel who conduct research involving human participants as well as University designees responsible for the oversight of human research.

2. POLICY

All members of a research team are required to conduct research projects in accordance with the protocol as approved by the IRB, and in accordance with federal regulations, state law, and University policy. Failure to do so constitutes noncompliance in the research endeavor, irrespective of the magnitude or intent of the deviation from the approved protocol. Principal Investigators are responsible for reporting incidents of serious or continuing noncompliance to the IRB along with any proposed corrective action plan to ensure the safety of research participants and others and future compliance with the approved protocol and to prevent reoccurrence.

Other entities responsible for the oversight of human research and University personnel, who believe in good faith that they are aware of an instance of noncompliance, also are required to report such incidents to the IRB office.

Reports of noncompliance which are reported to the IRB will be promptly reviewed and resolved in a fair process and in accordance with all applicable regulatory requirements and WSU policies.

Reports and allegations of serious noncompliance must be reported to the Office of Human Participants Protection (OHRP) or FDA within 5 working days. Studies conducted by researchers from WSU should be reported to the ORA Director of the Office of Research Assurances. Reports of noncompliance involving the conduct of any of the IRBs or their staff should be reported to the Institutional Official.

2.1.1. Definitions:

Noncompliance: Failure to comply with applicable federal regulations, WSU IRB policies and procedures, WSU policy, or the determinations of the WSU IRB.

Serious non-compliance: An action or omission taken by an investigator, study personnel or individual in the ORA that any other reasonable individual would have foreseen as compromising the rights and/or welfare of the participant.

Examples of serious non-compliance:

1. Failure to adhere to the federal regulations governing the use of humans in research:
 - Failure to obtain IRB approval prior to initiation of research procedures;
 - Failure to notify the IRB of changes in approved procedures;

- Failure to obtain informed consent;
 - Failure to document informed consent;
 - Failure to maintain complete record of informed consent;
 - IRB approval expires due to failure to renew;
 - Failure to notify the IRB of changes in the scope/intent of the study; or
 - Failure to obtain renewal of an approved study in the required time frame.
2. Failure to adhere to institutional policies where participant's well-being or rights have been affected.

Continuing non-compliance: A pattern of repeated actions or omissions taken by an investigator or individual, which indicates a lack of ability or willingness to comply with federal regulations, WSU IRB policies and procedures, or the determinations of the WSU IRB.

3. SPECIFIC POLICIES

3.1 Receiving Reports of Non-compliance

Reports of non-compliance may be provided to the IRB Chair, IRB members and ORA staff from anyone inside or outside of the University community who has reason to believe that non-compliance with human subject research regulations and/or IRB policies and procedures has occurred. These complaints will be accepted verbally or in writing.

- Receipt of verbal reports: Allegations that are presented via telephone or in person to the ORA office will be directed to the ORA Director.

The recipient of the call should take care to record all relevant information in a thorough manner and request that the caller provide a contact number for follow-up calls, unless the caller desires to remain anonymous.

- Anonymous callers: The person making the allegation may choose to remain anonymous. The recipient of an anonymous call should inform the caller that the matter will be investigated to the extent possible, given the information provided. The recipient of the call should ask the caller for any available evidence that the caller is willing to give that will facilitate an investigation into the matter, but should not encourage the caller to provide a name or contact information if the caller has expressed a desire to remain anonymous. ORA staff may advise the caller to provide additional information at a later date if new information becomes available or if the caller remembers details that were not presented originally.

3.2 Investigation

Report to IRB of Pending Investigation. If investigation of the allegation has not been completed prior to the next scheduled meeting of the appropriate IRB, the IRB will be notified that an allegation of non-compliance has been received and that an investigation has been initiated. This information will be presented in a manner that does not identify the investigator, study or facility. However, if the allegation will impact other IRB business at that or another meeting, the IRB will be informed as needed to ensure effective decision-making by the IRB relative to that investigator, protocol or facility.

Report of allegation/investigation complete: If the allegation was received and the investigation completed prior to the next scheduled meeting of the appropriate IRB, the IRB will be presented with the allegation and findings.

Investigation. The ORA Director and/or IRB Chair and, if necessary, the IO will investigate the allegation upon notification of the alleged non-compliance. The matter will be reported to the full IRB at its next scheduled meeting.

Determinations: After the investigation, the ORA Director and/or IRB Chair will determine whether:

1. The non-compliance is not serious and not continuing, or
2. The non-compliance is serious or continuing.

Not serious and not continuing: If it is determined by the ORA Director and/or IRB Chair that the allegation is not serious and not continuing, the investigator/study personnel will be notified by the IRB Coordinator. In addition, the IRB Coordinator will discuss the issue with the investigator/study personnel and an action plan will be drafted. The final action plan will be forwarded to the investigator/study personnel via letter or e-mail and will be included in the IRB agenda as an information item.

Non-compliance that may be serious or continuing: The investigator/study personnel will be notified by the ORA Director and/or Chair of the findings and/or requests for information by phone call, letter or e-mail.

The investigator will be asked to respond in writing to the allegation and/or finding and/or request for information. The individual will have 14 business days to respond. If the individual needs more time, an extension may be granted by the ORA Director or Chair.

Note: During the investigation, the ORA Director, Chair and/or IO may impose restrictions to the research study until satisfactory answers are received from the PI.

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

- No action.
- Suspension: Suspend enrollment and/or all research procedures for the specific research study in question; (in accordance with P&P on Suspension and Termination of IRB approval).
- Termination of the research; (in accordance with P&P on Suspension and Termination of IRB approval).
- Require a response from the investigator with a plan for corrective action.
- Initiate audits of all or some part of the investigator's active protocols.
- Modification of the research protocol.
- Modification of the information disclosed during the consent process.
- Provide additional information to past participants,
- Modification of the continuing review schedule.
- Obtain more information pending final decision.
- Conference with other IRBs involved with the research;
- Requirement that current participants re-consent to participation.
- Provide information to current participants whenever such information might relate to the participants' willingness to continue to take part in the research.

- Monitoring of the research.
- Monitoring of the consent process.
- Refer to other organizational entities.

3.3 Notification of Relevant Parties of Reports and Findings of Serious or Continuing Non-Compliance.

Upon determination by the ORA Director, IRB Chair and IO that an incident of non-compliance was either serious or one of continuing non-compliance, the incident will be reported according to Reporting Requirements for Unanticipated Events, Serious and Continuing Non-compliance, and/or Suspensions or Termination of IRB approval.

If the identity of the person who reported the allegation, complaint, or concern is known, a summary of the findings of the investigation will be forwarded to this person as well.

3.4 Record Keeping and Further Reporting Requirements

Whenever an allegation or complaint of noncompliance warrants inquiry and further action involving an investigation, notice of the allegation(s) will be provided to the investigator at the start of the investigation. Throughout the investigation, the investigator will be provided the opportunity to respond. In instances of noncompliance, an investigative report and any appropriate corrective action taken with the investigator (such as retraining or modification to research procedure) will be documented in the study file. The investigator will be provided written notification of the outcome of the investigation.

Allegations which are determined to not actually constitute noncompliance will nonetheless be documented in an IRB compliance file and an explanation of this determination may be provided to the complainant when the reviewer deems it appropriate.

For all incidents determined to be serious or continuing noncompliance the IRB will notify the following individuals within 7 days: the PI and his or her Department Chair. Where applicable, the IRB will also notify the Office of Grant and Research Development, OHRP; the FDA; the funding agency and for other institutions participating in the research, the IRB Chair(s) of those institutions.

When the IO makes a decision to suspend or terminate approval of any research for any reason, the following individuals will be notified within five working days: the PI and his or her Department Chair; the Office of Grant and Research Development; OHRP; FDA; the funding agency and for other institutions participating in the research; and the IRB Directors of those institutions.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108(b)(2), 56.113
45 CFR 46.113

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
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<i>ORA Director, IRB Coordinator</i>	Receive notification of (alleged) non-compliance and initiate the process. Notify the investigator of the IRB's determination and corrective action. Notify all appropriate parties of the allegation and outcome.
<i>IO, ORA Director, IRB Chair</i>	Conduct investigation into (alleged) non-compliance. Determine if the allegation has a basis in fact. Keep IRB notified as appropriate. Present the facts and findings to the IRB upon completion of the investigation.

407 SUSPENSION AND TERMINATION

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1. PURPOSE

The purpose of this policy is to establish procedures for documenting the requirements for suspension or termination of IRB-approved research projects.

2. POLICY

The IO shall have the authority to suspend or terminate approval of research that is not conducted in accordance with IRB requirements, federal, state or local requirements, or has been associated with unexpected serious harm to participants. A project may be suspended or terminated for the following reasons, including, but not limited to:

- Serious and continuing non-compliance with federal regulations and IRB policy.
- Repeated failure to submit a Continuation form in sufficient time to allow for an appropriate review to be conducted.
- Repeated failure to obtain appropriate informed consent.
- Change in the risk benefit ration of the research.
- New information regarding the increased risk to the participant.

2.1 Definitions:

Suspension: An action issued by the IO that all or some of the research activities must stop until issues have been satisfactorily resolved. Suspended projects still have IRB approval.

Termination: An action issued by the IO that all or some of the research must stop permanently except for the continuation of follow-up activities necessary to protect the participants' safety.

3. SPECIFIC POLICIES

3.1 Procedures for Suspension and Termination

The IO may act alone to suspend or terminate previously approved human research or an investigator's privilege to conduct human participant research if the alleged serious or continuing non-compliance with the requirements or determinations of the IRB, or any incidence that has been associated with the unexpected serious harm to participants appears to pose imminent threat to participant safety.

The IO, ORA Director and IRB Chair may request a consult from an independent source with expertise in the type of research being conducted or expertise in the specific area of concern.

The IO, ORA Director and IRB Chair will decide on a course of action and establish a time line for the completion of that action.

The IO will notify the investigator in writing of the decision by letter within five (5) working days. The letter will include:

- Reason and rationale for the suspension or termination.
- If appropriate, require the investigator to submit:
 - Procedure for the withdrawal of currently enrolled participants that considers the participants' rights and welfare.
 - Letter or script notifying all currently enrolled participants who are affected by the suspension or termination.
- A reminder that all study activities such as reporting adverse events, revisions to investigator brochures, and updated package inserts must still be reported to the IRB.

To reinstate a project that has been suspended, the investigator must satisfactorily resolve any pending issues required by the IRB.

To reinstate a project that has been terminated, the investigator must submit the project to the IRB as a new and past issues must be resolved to the satisfaction of the IRB.

3.2 Reporting Suspension and Terminations

All suspensions and terminations will be reported to the appropriate individuals and agencies per 409 Reporting Requirements.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.113 and 21 CFR 56.113

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>Coordinator</i>	Document all actions and decisions made by the IO, the ORA Director and the IRB Chair.
<i>IO, ORA Director, IRB Chair</i>	Review the facts and make determination, establish an action plan and timeline for the investigator.
<i>IO</i>	NotifY the investigator within five (5) business days of IRB determination and all relevant agencies and sponsors within the timeframes required by law.

408 ADVERSE EVENTS AND UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS

[Back to Index](#)

1. PURPOSE

This policy establishes the process to determine which unanticipated problems involve risks to participants and others.

2. POLICY

2.1 Definitions:

Unanticipated Problems Involving Risks to Participants or Others: Unanticipated problems indicating that the participants or others are at increased risk of harm.

Risks: The occurrence of harm or the probability that harm or an increased risk of harm might occur. The harm may be physical, psychological, financial, social, economic, or legal.

Others: Individuals who are not research participants.

2.2 Investigator's Responsibility

Investigators must report to the IRB as soon as possible, but in all cases within seven (7) working days after the event had been made known to the investigator, any of the following:

1. Adverse events which, in the opinion of the investigator, are serious, unexpected and related:
 - An adverse event is "unexpected" when its specificity and severity are not accurately reflected in the informed consent document or study protocol.
 - An adverse event is "related to the research procedures" if, in the opinion of the investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.
2. Serious Adverse Event
 - Event that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect.
3. Serious Problem that results in:
 - Substantive harm or damage (or risk of substantive harm or damage) to the safety, rights, or welfare of research participants, research staff, or others: or
 - An adverse event or problem in the research is also considered serious when medical, surgical, behavioral, social, or other intervention is needed to prevent above #2.
4. Information that indicates a change to the risks or potential benefits of the research; for example:
 - An interim analysis indicates that the participants have a lower rate of response to treatment than initially expected.

- Safety monitoring indicates that a particular side effect is more severe or more frequent than initially expected.
 - A paper is published from another study that shows that an arm of the research study is of no therapeutic value.
5. A breach of confidentiality.
 6. Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
 7. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
 8. Incarceration of a participant in a protocol not approved to enroll prisoners.
 9. Event that requires prompt reporting to the sponsor.
 10. Complaint from a participant when the complaint indicates unexpected risk or cannot be resolved by the research team.
 11. Protocol violation (which an accidental or unintentional change to the IRB- approved protocol) caused harm to participants or others or indicates that the participants or others are at an increased risk of harm.
 12. Sponsor-imposed suspension for risk.
 13. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application [including a supplementary plan or application], or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of participants).

The investigator must complete the Adverse Event Form and attach any associated documents such as MedWatch form, medical record notations, and correspondence from the sponsor, etc.

The investigator is responsible for the documentation, investigation and follow-up of unanticipated problems that occur at the site in which the investigator is responsible for the conduct of the research.

2.3 Review of the Event or Problem

The ORA Director will review the event or problem within 5 days of receiving the event or problem. If appropriate to the event or problem the Chair and/or IO will also review. One of the following determinations will be made.

1. The event is NOT an unanticipated problem involving risk to participants or others (because the event is either anticipated or does not indicate that the participants are at increased risk of harm).
 - Take no action, document review, and put on IRB agenda for reporting purposes.

OR

2. The event or problem is considered an unanticipated problem involving risks to participants or others because the problem (1) is unanticipated and (2) indicated that the participants are at increased risk of harm.

The ORA Director, IRB Chair and/or IO may determine that immediate action is needed to ensure the participants' safety and request that the investigator suspend some or all of the

research pending review of the event at the next convened IRB meeting. Suspensions will follow IRB procedures for suspension and termination.

Actions that may be taken during or after the investigation of an adverse event or unanticipated problem:

- Modification of the research protocol.
- Modification of the information disclosed during the consent process.
- Additional information provided to past participants.
- Notification of current participants (required when such information may relate to participants' willingness to continue to take part in the research).
- Requirement that current participants re-consent to participation.
- Modification of the continuing review schedule.
- Modification of the inclusion/exclusion criteria.
- Monitoring of the research.
- Implementation of additional procedures to monitor the participants.
- Monitoring of the consent.
- Suspension of the research.
- Termination of the research.
- Request for more information pending final decision.
- Refer to other organizational entities (e.g., legal counsel, institutional official), or
- Other actions appropriate for the local content.

The determination will be reported in the minutes and the investigator will be notified.

2.4 Notification

No action required: If the event is determined not be an unanticipated problem involving risks to participants or others, no action will be required.

The investigator will be notified within five (5) business days of the ORA Directors, IRB Chair and/or IO's determination and action(s). If the event is determined to be an unanticipated problem involving risks to participants or others, the event will be reported to the appropriate individuals. A copy of this report will also be disseminated to the IRB members at the next convened IRB meeting.

3. Research Sponsored by the Department of Energy

When following DOE regulations and guidance: Researchers must promptly (within 2 working business days) report the following to the ORA Director of Human Participants Protection:

- Any significant adverse events, unanticipated risk and complaints about the research, with a description of any corrective actions taken or to be taken.
- Any suspension or termination of IRB approval of research
- Any significant non-compliance with HIRPP procedures or other requirements
- The timeframe for promptly is defined as within 48 hours

Any compromise of personally identifiable information must be reported immediately (within one working business day).

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103(b) (5)(i)

- 21 CFR 56.108(b)(1)
- 21 CFR 312.32
- 21 CFR 812.3(s)

5. FORMS

See Appendix
Adverse Event Form

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, IRB Chair</i>	Review all reports of Serious Adverse Events & Unanticipated Problems Involving Risks to Participants or Others Form and immediately triages as appropriate. Determine if the event is (1) serious, (2) unanticipated and (3) related; within 5 days of receipt. If applicable, present the facts to the IRB at a convened IRB meeting
<i>IO</i>	If reportable, notifies within 30 business days all appropriate individuals and agencies.

409 REPORTING REQUIREMENTS

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1. PURPOSE

This policy describes the reporting requirements for reporting:

- unanticipated problems involving risks to participants and others,
- serious and continuing non-compliance and/or
- termination or suspension of a study by the IRB.

2. POLICY

One or more of the following will be notified, as appropriate, of any serious and continuing non-compliance, unanticipated problem involving risks to participants or others, suspension or termination of IRB approval of a study within 15 days.

- Institutional Review Board
- Principal investigator
- Sponsor, if the study is sponsored
- Contract research organization , if study is overseen by one
- Department Chair or supervisor of principal investigator
- Head or appropriate designee of the funding department or agency
- Appropriate designee of the sponsoring company or organization
- Vice President for Research
- FDA, when the research is FDA-regulated
- OHRP, in all cases
- Other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP.
- Local agencies as required by institutional officials

3. SPECIFIC POLICIES

All serious and continuing non-compliance, serious adverse events, suspensions, terminations or unanticipated problems and involving risks to participants or others will be reported within 15 days to OHRP and/or FDA. The ORA Director will draft a letter that outlines;

- Nature of the event.
- Name of institution conducting the research.
- Title of the research project and/or grant proposal in which the problem occurred.
- Name of principal investigator.
- Number assigned by the IRB and number of applicable federal awards.
- Detailed findings of the IRB.
- Actions taken by the IRB.
- Reasons for the IRB's action.
- Plans for continued investigation or action.
- Plans, if any, to send a follow-up report or final report.

The letter is sent to the Institutional Official for review, approval and signature. The letter is sent to the appropriate persons as outlined in section 2 of this policy.

All unanticipated problems involving risks to participants or others need to be reported to the FDA by the investigator when the research is FDA-regulated. Copies of the reports must be sent to the IRB.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108(b)(1), 56.108(b)(2), 56.108(b)(3)
VHA Handbook 1200.5 Section 7.c.13 and 1605.1

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, IRB Coordinator</i>	Report to appropriate internal and external agencies.
<i>IO</i>	Reviews, approves and signs letter.

410 INVESTIGATIONAL DRUG OR DEVICE

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1. PURPOSE

The purpose of this policy is to establish procedures for investigators and investigators who also may be sponsors holding an Investigational New Drug (IND) or Investigational Device Exemption (IDE) for the test article under study.

2. POLICY

If the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, an Investigational New Drug (IND) or Investigations Device (IDE) may be required. If an IND or IDE is required, the investigator proposing to conduct the study must first obtain FDA approval of an IND or IDE application either directly or indirectly via a device or pharmaceutical sponsor. It is also the responsibility of the investigators to meet the requirements of regulations in 21 CFR 312 and 21 CFR 314 (investigational drugs) or 21 CFR 812 and 21 CFR 814 (investigational devices).

3. SPECIFIC POLICIES

3.1 Investigator Responsibilities

- For research involving the use of a drug other than the use of a marketed drug the investigator will need to determine if an IND is necessary.
- The investigator will need to submit the IND or IDE assignment letter to the IRB. If there is debate regarding the need for an IND, the IRB will require that the PI contact the FDA to obtain written documentation that an IND is not necessary and conditions stated in 21 CFR 312.2(B)(1) have been met. Then an IND is not necessary.
- If the investigator plans on holding the IND or IDE, the investigator will be required to meet with the ORA Director and Chair to review how the investigator plans to meet the sponsors requirements according to 21 CFR 312 and 21 CFR 314 for an IND and 21 CFR 812 and 21 CFR 814 for an IDE. The investigator will need to put the plan into writing and submit it to the IRB for final approval. The plan needs to include, but not be limited to: good manufacturing practices, test article storage, labeling, distribution, accountability, site study monitoring, conflict of interest, and periodic reports to the FDA.
- The investigator is responsible for assuring the IRB that the investigational drugs and devices are stored in a safe and secure manner and are only used in the IRB approved research study and under the direction of the study investigator.
- The investigator is responsible for assuring the IRB that there are appropriate plans for inventory control, storage, monitoring and dispensing of the test articles (drugs, biologics, or devices).
- The investigator will obtain informed consent for studies involving an IND or IDE. The consent form will identify the test article as investigational and will inform the participants that the FDA may inspect the research records.

3.2 IRB Review

- The IRB will review each protocol that uses drugs and biologics to see if an IND or IDE has been received or required. If one is required, it is the investigator's responsibility to obtain the FDA assignment letter.

The reviewer(s) will determine if an IND is required, and if an IND is required, the PI must provide documentation of a valid IND number on the IRB application.

- Studies involving an IND or IDE will undergo initial and continuing review at a convened meeting of the IRB that includes at least one physician or pharmacist unless the study meets the criteria for expedited review.

The pharmacist reviewer will review the application to determine if the plan for storage, control and dispensing of the drug is adequate and to ensure that only the investigators will use the drug on participants who have provided informed consent.

- Studies involving an IND or IDE will be reviewed according to policy and procedure and, in addition, the IRB will confirm that the investigator's plans for inventory controls for storage, monitoring, dispensing of investigational drugs or devices meet appropriate standards.

3.3 Emergency Use of a Test Article

A one-time emergency use of an investigational drug, device, or biologic "test article" by an investigator without prior IRB review and approval is permitted under 21 CFR 56.104(c).

When an investigator conducts an emergency use of a test article in a life-threatening situation without prior IRB review, the activity is research under FDA regulations and the patient is a subject under FDA regulations. FDA may require data from an emergency use of a test article in a life-threatening situation to be reported in a marketing application.

Emergency Use: The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval 21 CFR 56.102(d).

3.3.1 Investigator Responsibilities

- Whenever possible, the investigators are to contact the IRB in advance of the emergency use.
- The investigator must submit written certification to the IRB within five (5) working days after the use of the test article.

3.3.2 IRB Responsibilities (Prior notification)

- If the IRB Chair determines that the circumstances meet regulatory criteria, the IRB Chair will inform the investigator and clears them to proceed without IRB review.
- If the IRB Chair determines that the circumstances DO NOT meet regulatory criteria, the IRB chair will inform the investigator and indicates that proceeding with the use without IRB approval will be serious non-compliance.

3.3.3 IRB Responsibilities (Without prior notification)

- If the IRB Chair determines that the circumstances meet regulatory criteria, the IRB Chair will inform the investigator in writing.
- If the IRB Chair determines that the circumstances DO NOT meet regulatory criteria, the IRB chair will inform the investigator in writing that the use without IRB approval is serious non-compliance, and refers the matter to the convened IRB for review under the Non-Compliance with IRB Policy and Procedure

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR parts 50 and 56, 50.24
 21 CFR 312.2(b), 312.7
 21 CFR 312, 314, 812, 814

5. FORMS

See Appendix

Addendum 8 Investigational Drugs, Other Drugs & Devices

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director</i>	Meet with the investigator (who plans on holding the IDE or IND) to ensure that the investigator understands and puts into writing the plan that he/she is to act as the “sponsor” and will adhere to the sponsor responsibilities outlined in 21 CFR 312, 314, or 812, 814.
<i>IRB Members</i>	Review the IRB submission, including the plan (if investigator holds the IND) for covering the responsibilities outlined in 21 CFR 312, 314, or 812, 814.
<i>ORA Director or IRB Coordinator</i>	Check IDE or IND FDA number and assignment letter to ensure validity.

411 INTERNATIONAL RESEARCH

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1. PURPOSE

This policy describes the standards and parameters for the review of international research.

2. POLICY

The University is committed to upholding the standards for ethical research and informed consent expectations for all research conducted outside the United States. Research conducted outside the U.S. creates areas of concern for both the investigator and IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants compared to the same research conducted within the U.S. Other countries and institutions within foreign

countries may have IRB or Ethics Committees which require review of the research before research can be conducted in that country.

The IRB shall require the investigator to provide to the IRB, the local applicable laws, regulations, customs, and practices for the country where the proposed study will occur, along with an outline of how the investigator will follow those laws, regulations, customs, and practices. The IRB will require the investigator to provide to the IRB evidence of the qualifications of the researchers and the research staff for conducting research in the country.

All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries as appropriate even if the governing laws of the other country are less stringent.

3. SPECIFIC POLICIES

3.1 Review of the Research by the Foreign Ethic Committee

Approval by the foreign local IRB or Ethics committee where the research is taking place prior to WSU IRB approval is optimal. If there is no equivalent board or group, investigators must rely on local experts or community leaders to provide insight into local context.

It is important that all research with living human beings adequately protects the rights and welfare of the research participants, irrespective of whether the research is conducted in the United States or at foreign sites. In the international setting, special attention should be given to the involvement of local participants in the design and conduct of the research to ensure respect for differences in language, education, cultural and social history, and social mores, as well as compliance with local law. In addition, national policies such as the availability of national health insurance, philosophically different legal systems, and social policies distinguish international research from U.S. research and must be considered carefully by investigators and the WSU IRB when contemplating conducting and reviewing such research

3.3 Exempt and Expedited Review

International studies that are minimal risk, do not ask sensitive questions, and fall under the exempt or expedited categories may be reviewed by the IRB Coordinator. A consultant familiar with local context may be sought out to provide guidance to the reviewer.

3.4 Institutional Review Board Considerations

In addition to obtaining IRB approval, the principal investigator (PI) must seek review of his/her human subject research protocol by a local IRB, Ethics Board or Independent Ethics Committee (IEC) whenever possible. The local IRB, Ethics Board, or IEC must be knowledgeable about and sensitive to local community composition, mores, laws, and standards of conduct. In the event that no such local IRB, Ethics Board, or IEC exists or when such a local ethics board is unable or unwilling to review the research, the PI should seek to identify a review board within the general region or to identify a local institution that can serve in a comparable capacity (e.g., a tribal council, school board, town committee, or hospital board). A copy of the local IRB or IEC approval must be submitted to the IRB. The IRB should have contact information of this organization and work with this committee via e-mail for regular updates. This committee should also be listed in the protocol as an area reference for participants to communicate problems and complaints.

If WSU IRB approval is required before the foreign IRB approval can be obtained the IRB may either:

1. Require an expert consultant to address issues of local context.
2. Review the study and make a motion, "Approved, pending review and approval of the foreign IRB." The investigator will be required to submit to the WSU IRB all correspondence and approval document.

The protocol must provide evidence of sufficient local resources and facilities to support the proposed human participant protocol in compliance with this policy and local law. The PI and the foreign site are responsible for ensuring that the resources and facilities are appropriate for the nature of the research, and are responsible for the ongoing monitoring of the research including the ability to submit the initial review, continuing reviews, amendments, all unanticipated events as well as regular communication with the WSU IRB.

In order to approve a protocol being carried out at a foreign site and to make an informed judgment about the level of risk to potential research participants, the IRB must demonstrate that it has sufficient information about the local research context and local law by its review of written material, or through discussions with either IRB members knowledgeable about the local context or appropriate expert consultants. The level of knowledge about the local context and local law required for approval is based on the degree of risk to potential research participants. Higher risk studies require more thorough considerations of local context and inclusion of strategies to mitigate harm than do minimal risk studies.

3.5 Informed Consent

The informed consent process, as well as the document, must be in the participants' native language or they must be fluent enough in English to fully understand the information and ask appropriate questions.

4. APPLICABLE REGULATIONS AND GUIDELINES

Office of Human Research Protections (OHRP) – International Issues

5. FORMS

None

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator, IRB Members</i>	Determine if local context consultant is needed. Review IRB application and all associated documents.

500 PREGNANT WOMEN, FETUSES AND NEONATES

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1. PURPOSE

The policy describes the requirements concerning review of research that involves pregnant women, human fetuses, and neonates. This group could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

2. POLICY

Research involving women who are pregnant should receive special attention from the IRB because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. Special attention is justified because of the involvement of the fetus that may be affected but cannot give consent.

3. DEFINITIONS

Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Fetus: the product of conception from implantation until delivery.

Neonate: newborn (birth to four (4) weeks).

Nonviable neonate: a neonate after delivery that, although living, is not viable.

Pregnancy: the period of time from implantation until delivery. A woman shall be assumed pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Viable, as it pertains to a neonate: being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

3.1 Pregnant Women and Fetuses

Pregnant women or fetuses prior to delivery may be involved in research. The IRB members will confirm that all the conditions and determinations are met.

3.2 Neonates

Neonates may be involved in research. The IRB members will confirm that all the conditions and determinations are met.

3.3 VA Policy

Research involving fetuses and *in-vitro* fertilization cannot be conducted by VA

investigators.

3.4 Research Sponsored by the Environmental Protection Agency

- For research conducted or supported by the EPA
 - Research involving intentional exposure of pregnant women or children to any substance is prohibited and not approved by the IRB
- For Research intended for submission to the EPA
 - Research involving intentional exposure of pregnant women or children to any substance is prohibited and not approved by the IRB.
- The EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance
- The IRB will review observational research involving pregnant women and fetuses using 40 CFR 26 and 45 CFR 46 Subpart B
- EPA policy requires submission of IRB determinations and approval to the EPA Human Participants Research Review official for final review and approval before the research can begin.
- For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:
 - EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance
 - EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.

4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
 45 CFR 46: Subparts B,
 45 CFR 46.305, 45 CFR 46.122
 21 CFR 56.111
 OHRP IRB Guidebook

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Select appropriate Primary and Secondary Reviewers or obtains expert consultant.

501 CATEGORIES OF RESEARCH

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1. PURPOSE

The policy describes the review of specific types of research that require additional considerations by the IRB.

2. POLICY

The categories of research defined in these policies involve either methodologies that might require additional considerations or for which there are federally mandated determinations that IRB are required to make and document. These categories of research include, but are not limited to:

- Clinical research involving devices.
- Genetic research.
- Prospective research in emergency settings.
- Emergency use of an investigational article.
- Medical records and chart review.
- Residual body fluids, tissues, and recognizable body parts.
- Biomedical research.
- Radiation materials.
- Oral history.
- Prospective tissue banking.
- Alcohol.
- Classroom projects/activities.
- Graduate student research.
- Internet (or on-line, computer) based research.
- Recording (photographs, audio, video).
- Suicide/Depression.
- Undergraduate student activities.

3. SPECIFIC POLICIES

3.1 Genetic Research

Genetic research may require special considerations. At first consideration, much genetic research may appear to meet the criteria for expedited review. This includes:

- Pedigree studies, which look for a pattern of inheritance of a gene.
- Positional cloning studies, which are conducted to identify particular genes.
- Diagnostic studies, which gather samples to develop techniques to determine the presence of specific DNA mutations.

However, these studies may create a vulnerable population and participants' autonomy may be compromised. Therefore, the ORA Director, IRB Chair or the ORB Coordinator may request the full IRB to review these studies to answer the following questions:

- Will the samples be made anonymous to maintain confidentiality? If not, to what extent will the results remain confidential and who will have access to them?

- Will the samples be used for any additional studies not made explicit at the time of donation, or will the samples be destroyed after specified, one-time use?
- Will the donor be informed of any and all results obtained from his or her DNA?
- Will the sample be sold in the future?
- Will the donor be paid for his/her sample now or in the future?
- Will the donor be informed of the results of the entire study?
- Will family members be implicated in the studies? If so, they are participants.

Gene therapy research (administration of recombinant vectors), which is carried out to develop treatments for genetic diseases at the DNA level, presents obvious and not so obvious questions, including considerations of delivery methods, target population, required follow-up. Such protocols require use of external consultants to provide independent guidance to the IRB. If the project involves gene therapy to human participants for other than clinical purposes, the study must be reviewed and approved by the National Institutes of Health Recombinant DNA Advisory IRB prior to IRB approval. Monitoring must be adequate, and a DSMB will be required.

Because there is still little regulatory guidance and relatively few ethical precedents, genetic research will require close scrutiny, and the input of experts in this area.

3.2 FDA-Regulated Prospective Research in Emergency Settings

WSU and its affiliates do not currently do prospective FDA- regulated research in emergency settings. When and if The University does do research in emergency settings, a procedure will be developed.

3.3 HHS-Regulated Prospective Research in Emergency Settings

WSU and its affiliates do not do prospective research in emergency settings. When and if The University does do research in emergency settings, a procedure will be developed.

3.4 Emergency Use of Test (Investigational) Articles

WSU and its affiliates do not currently do research involving emergency use with a test article. When and if The University does do research involving emergency use of a test article, a procedure will be developed.

3.5 Medical Records and Chart Review

Studies involving the use of existing publicly or privately held records may qualify for exempt status or expedited review. However, if the nature of the research could reasonably put participants' confidentiality at risk, the study will be reviewed by the full IRB. Studies that involve only chart and record review can sometimes pose significant risk to patients.

The most common breach of confidentiality is exposure of possible embarrassing information without the knowledge or consent of the patient. Such studies may also lead to recruitment of patients into future non-therapeutic studies in a manner, which may provoke the patient to ask how his/her record was revealed to someone not part of his/her therapeutic team. The present policy is to require IRB review of studies involving chart review or data collection and analysis.

If identifiers were to be recorded, the research would require IRB review to ensure that, among other things, procedures for protecting privacy and confidentiality are adequate. Furthermore, the investigator studying cancer risk factors may propose to go on to contact the participants (if

still living) or family members (if the participant is deceased) to gather additional information, which may or may not be participant to the federal regulations.

3.6 Residual Body Fluids, Tissues and Recognizable Body Parts

Body fluids and tissues: Research on existing specimens ("on the shelf" or frozen) without identifying information (e.g., names, initials, hospital number, etc.) may be submitted to the IRB for exempt or expedited review.

3.7 Biomedical/Biohazard Research

In addition to IRB approval, the principal investigator will be required to obtain approval from the WSU Institutional Biosafety Committee, if necessary.

3.8 Radioactive Materials

In addition to IRB approval, the principal investigator will be required to obtain approval from the WSU Radiation Safety Committee, if necessary.

3.9 Oral History

Historians and social scientists sometimes conduct interviews, or oral histories with sources (knowledgeable people) to supplement written documents and artifacts in attempting to preserve information about past events. Like journalists, historians interview sources to obtain eyewitness accounts of events.

Oral histories do not meet the definition of research and do not require IRB review and approval under the following conditions:

- Focus is exclusively on past events, and
- Purpose is conducted to understand or explain a particular past or unique event in history (and not contribute to generalizable knowledge or be applied to future activities).

There are additional considerations when reviewing oral history research proposals. Principal investigators should be familiar with the Oral History Association's standards of ethics and should review John Neuenschwander's *Oral History and the Law*. The following statements must be addressed in the proposal, if applicable:

- The interviewee is given an opportunity to review and to approve of the conditions of use or publication of the data.
- The interviewee is given an opportunity to provide informed consent to the interview. The consent form must state that the interviewee can refuse to answer any questions, can limit the time of the interview, and has the right to suggest topics that are not to be discussed during the interview.
- The interviewee is given an opportunity to provide informed consent to the disposition of the records and/or access to the recordings. The consent form should indicate the rights of the participants with regard to editing, access, copyright, prior use royalties, and the expected dissemination of all forms of the record. It should be noted that if the recordings are archived outside the researcher's control, the research may not be able to anticipate all the uses of the record.
- There must be adequate means provided for the protection of the privacy of any third parties (such as disguising the identities) of those who may be named in the interview. The researcher and the repository will follow conditions that the interviewee stipulates regarding dissemination of the interview, such as not publishing until after death or after a specific period of time. The repository must accept the interviewee's conditions provided they are

reasonable and legally acceptable. The accepted conditions must be noted in the cooperating repository's letter.

- The researcher must state any arrangement made to deposit interviews. The repository must be capable of preserving the interviews and making them available for general research. A letter of acceptance from the repository must be submitted with the research proposal.

3.10 Prospective Tissue Banking

A proposal must be submitted to the IRB describing the policies and procedures for the collection and handling of stored specimens. The IRB must be able to evaluate the procedures to ensure confidentiality and protection of the participants. The proposal must address the following items:

- How the specimens will be obtained, processed and stored.
- How the specimens will be labeled.
- How the clinical data will be associated with the specimen, and how the clinical data will be collected.
- What identifying information will be collected.
- How identifiers will be linked to specimens.
- What steps will be followed to maximize the confidentiality of linked identifiers.
- How specimens will be distributed.
- How the secondary distribution of specimens will be controlled.
- How the participants' rights will be protected with any future use of specimens not previously approved by the IRB;
- If results will be shared with participants, how will they be shared?
- If minor participants are used, how will future adult consents be secured?
- A separate consent form must be used to obtain permission for specimen banking.

3.11 Alcohol

Consistent with the National Advisory Council on Alcohol Abuse and Alcoholism, the University recognizes the legitimate and important need for research involving on the biological and behavioral effects of the ingestion of ethyl alcohol on human subjects.

It is essential that such research conform to the (ethical) principles that govern all research involving human subjects. These principles are elaborated upon in the latest report prepared for the National Institute on Alcohol Abuse and Alcoholism by the National Advisory Council on Alcohol Abuse and Alcoholism. The NIAAA website <http://www.niaaa.nih.gov/> provides information on research involving the administration of alcohol and also contains the latest NIAAA guidelines <http://www.niaaa.nih.gov/Resources/ResearchResources/job22.htm>.

The IRB refers to and is guided by the NIAAA guidelines when reviewing research involving alcohol and researchers are strongly encouraged to review these guidelines prior to submitting applications to the IRB.

Depending on the nature of the research and the perceived risk to the participants the IRB may require frequent blood alcohol level (BAL) measurements, based on time intervals or numbers of participants. The IRB also may approve a limited number of initial human participants and require submission of BAL measurements for review before approving additional participants.

The WSU IRB may also request input/review from an outside expert in this area of study.

3.12 Certificate of Confidentiality

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. These certificates are issued by the NIH. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for Certificate. For more information: <http://grants.nih.gov/grants/policy/coc/index.htm>.

3.13 Classroom projects/activities

The IRB does not review classroom projects/activities. Classroom projects/activities are generally considered to be conducted for a class assignment and turned in to the faculty/instructor. If the class assignment involves subjects from vulnerable populations or if the subjects are members of the populations listed in section IX.c.i, the ORA should be contacted for advice and assistance and the Non-Regulatory Review form completed. In certain situations where a class project will be used as part of larger research, IRB review and approval may be required. Contact the IRB Coordinator for help and assistance in determining the need for and completing the appropriate application. See additional guidance on IRB web page at: http://www.irb.wsu.edu/class_projects.asp

3.14 Graduate student research

IRB policy requires the PI on an IRB application be a WSU faculty or staff member. Student-initiated research involving human subjects, whether dissertation, thesis, or other research, should include the student as a Co-PI or “other study personnel” when submitted to the IRB for review. Regardless of whom fills out the form (e.g. PI, student, research assistant, etc.), the PI is responsible for the content.

IRB review and final approval should take place during the proposal stage of a dissertation or thesis and IRB approval and determination will not be granted retrospectively. Prior to graduation, the Graduate School will require a copy of the graduate student’s IRB approval letter. If it comes to the attention of the IRB that IRB approval has not been obtained for a thesis or dissertation prior to initiation of research involving human subjects, the IRB will refer the student researcher/advisor(s) to the Graduate School.

3.15 Internet (or on-line, computer) based research

Use of the internet and other computer based research methods are evolving rapidly and offering many new methods for researchers to contact research participants and collect data for research (including opportunities for large numbers of participants, ease of data collection, possibilities for anonymity, etc.). All of the same IRB considerations and federal regulations apply; however, use of the internet also creates challenges for the IRB.

Recruitment:

- There are many methods of recruitment. Indirect recruitment would include using flyers and announcements which direct individuals to websites to participate in the research. Direct recruitment may include sending e-mails or letters directly to individuals whom the

researcher would like to recruit. Researchers should ask themselves the following questions: For direct recruitment, would the participants reasonably expect the research to contact them regarding the research topic? Authentication can be a major challenge for internet based research. How does the researcher know who they are actually communicating with/recruiting?

- Informed consent:
- Minimal risk research may qualify for a waiver of consent or a waiver of documentation of consent. The IRB would generally require the information normally contained in the consent be provided to participants so participants may make an informed decision as to whether to participate. Greater than minimal risk research may require more traditional methods, such as mailing an informed consent document and receiving the participant's signed copy, although, researchers may present suggestions to the IRB. Again, authentication may be a challenge for internet based consent.
- Anonymity/confidentiality:
- The internet and computer based research can offer a "false sense" of anonymity/confidentiality. The researcher will be required to explain to the IRB how anonymity/confidentiality will be maintained. This will often rely heavily on server administration/security. The use of encryption should be considered and may be encouraged or required by the IRB. Whenever possible, identifiable data should be de-identified. Any code linking data to identities should not be stored on the same server as the data.
- Data collection:
- Depending on the type of data being collected, encryption may be suggested or required.
- Data storage/disposal:
- Whenever possible, personal identifiers should be stored separately from the data and/or the codes linking the data to individuals. Back-up storage is always a consideration with electronic media. The IRB will be as concerned with security of the back-up material as it is with the original material. Final data destruction of electronic media can be complex. The IRB will want assurance that data deleted is truly not recoverable.

The above discussion is meant as a brief overview. In general minimal risk research may be well suited for internet-based activities. Greater than minimal risk research will require careful consideration by the IRB. There may be certain activities that the IRB will not be comfortable approving as internet based.

3.16 Recording (photographs, audio, video)

The federal regulations (45 CFR Part 46) require that whenever voice, video, digital, or image recordings are made the application must be reviewed at the expedited review level (provided that the other requirements for expedited review are met) or full board review.

The type of recording must be disclosed in the informed consent document. When the recording is deemed necessary to the research the informed consent must clearly indicate such. When recording is not absolutely necessary to the researcher a separate signature line for the recording acceptance should be included on the consent form so that a participant could choose to participate in the study but decline the recording of their participation.

The IRB considers recording for purposes of transcription only not to be part of the research that would automatically require expedited review.

3.17 Suicide/Depression

Research involving depression indexes and scales can reveal information or disclosures that carry additional responsibilities for the researchers. Studies with suicide or suicidal ideation related questions also require additional safeguards and responsibilities on the part of the researcher. The consent document will also need to contain specific information regarding the risks, resources for counseling, and reportability of certain information.

The IRB will consider to the following:

- What is the level of risk? A brief depression index or a detailed questionnaire on suicidal ideations?
- Is the individual obtaining consent or administering the survey/interview qualified to provide counseling? If not, how will counseling be made available?
- Does the informed consent provide specific phone numbers or locations where counseling services can be accessed by participants?
- If a participant expresses the potential to harm themselves or others how will the situation be handled? Who will be contacted? Such situations may require mandatory reporting to law enforcement (this should be disclosed in the informed consent).

3.18 Undergraduate student activities

Undergraduate students may be involved with classroom activities or other research involving human subjects (i.e. surveys, observing behavior, etc.). In general classroom activities are not included in the IRBs purview. The IRB Coordinator is available to help and assist faculty/instructors. The IRB Coordinator is also available to present full or abbreviated human subject education to undergraduate classes.

3.19 Non-regulatory reviews

The trained ORA staff reviews certain activities that involve human participants but are outside of the federal regulations. Such activities are identified on the flowchart and table found on the IRB website, <http://www.irb.wsu.edu>. If WSU faculty, staff, or students have questions on the process they should contact the ORA for assistance. Activities that require review in this category will be submitted to the ORA using the Non-Regulatory Application.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 812.66
21 CFR 50.24
21 CFR 56, 102, 56.104
45 CFR 46.101, 46.103, 46.118, 46.119

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Genetic Research

Who	Task
<i>IRB Coordinator</i>	If necessary, identifies and invites appropriate consultant(s) who may assist the IRB in its deliberations.
<i>ORA Director, IRB Coordinator</i>	Determines whether the research is exempt from IRB review, eligible for expedited review, or subject to full IRB review.

502 RESEARCH INVOLVING HUMAN PARTICIPANT UNABLE TO CONSENT

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1. PURPOSE

This policy describes the requirements designed to protect human participants from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent, or who have impaired decision-making capacity.

2. POLICY

Research involving participants who are mentally ill, or participants with impaired decision-making capacity, warrants special attention. Research involving these populations frequently presents greater than minimal risk, may not offer direct medical benefit to the participant, and may include a research design that calls for washout, placebo or symptom provocation. In addition, these populations are considered to be vulnerable to coercion. The investigator and IRB need to ensure that provisions are made to obtain legally effective informed consent prospectively from each research participant or permission for the participants legally authorized representative (LAR).

3. SPECIFIC POLICY

3.1 Definitions:

Surrogate Consent: obtaining from a surrogate decision maker (*a person appointed to represent or act on behalf of another—legally authorized representative-LAR*), the valid informed consent to participate in research for an adult participant who is cognitively impaired, lacks decision-making capacity, or suffers a serious or life-threatening disease.

Health Care Agent: The health care agent is the individual named in a durable power for health care decision maker (DPAHC) executed by the participant while the participant had decision-making capacity. The health care agent acts on the participant's behalf to make health care decisions, including enrolling the participant in a research study, when the participant is unable to provide consent. A health care agent is considered a legally authorized representative.

Court-Appointed Guardian: A legal guardian is one who has been appointed by a court to make decisions for an individual who has been judicially judged to be incompetent. A court-appointed guardian is considered a legally authorized representative.

Next-of-Kin:

- **VA Research:** VHA Handbook 1200.5 describes next-of-kin in the following order: spouse, adult child, parent, adult sibling, grandparent, adult grandchild, and adult close friend.

Legally Authorized Representative (LAR) as defined by FDA and DHHS Regulations:

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedures(s) involved in the research.

FDA regulation at 21 CFR 50.20 states that no investigator may involve a human being as a participant in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative.

HHS regulation 45 CFR 46.116 states that if a participant is not legally competent to consent to participate in a study, the federal regulations require that a legally authorized representative consent for the participant.

Legally Authorized Representative in Washington: A LAR is one of the following in order of priority: a designated proxy (such as a durable power of attorney for health care), court-appointed guardian, or next-of-kin.

3.2 Investigator's Responsibilities

3.2.1 Investigators must apply to the IRB for use of surrogate consent that is specific to the particular study being reviewed.

- Surrogate consent may be considered only in research studies relating to cognitive impairment, lack of decision-making capacity, or serious or life-threatening disease as conditions of the research.
- Upon approval of the IRB for use within a specific protocol, the investigator shall apply the use of surrogate consent on a case-by-case basis.

3.2.2 If an adult participant is identified and is incompetent or lacks decision-making capacity for healthcare decisions and consent:

- The treating physician, the consulting physician(s), and others involved as members of the healthcare team must document in the medical record:
 - The basis for their determination that the patient lacks decision-making capacity.
 - The identity of the legal authorized representative and if none, the next-of-kin. (A copy of the legal form authorizing the durable power of attorney, etc. must be maintained in the research records.
 - The process by which the participant was enrolled or declined to be enrolled in the research.

3.2.3 VA Investigator Requirements

Surrogate consent may be requested and accepted only when the prospective research participant is incompetent or has impaired decision-making capacity, as determined and documented in the person's medical record in a signed dated progress note. The determination must be made in accordance with the following requirements:

- The practitioner, in consultation with the chief of service, or chief of staff, may determine after appropriate medical evaluation that the prospective research participant lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
- Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research participant's lack of decision-making capacity is based on a diagnosis of mental illness.
- Disclosures required by IRB to be made to the participant by the investigator must be made to the participant's surrogate.
- If feasible, the practitioner must explain the proposed research to the prospective research participant even when the surrogate gives consent. Under no circumstances may a participant be forced or coerced to participate in a research study.
- If someone other than the investigator explains the proposed research and obtains consent, the investigator must formally delegate this responsibility. The designee must receive appropriate training to perform this activity.

3.3 IRB Guidelines

3.3.1 Surrogate consent (using an LAR) is a protocol-specific request of the investigator, and must be reviewed and approved accordingly by the IRB:

- Surrogate consent may be considered only in research studies relating to the cognitive impairment, lack of decision-making capacity, or serious or life-threatening disease and conditions of the research.
- The IRB membership shall include at least one member who is familiar with the population to be recruited.
- The IRB will consult the WSU AG office to determine that the appropriate LAR is used for the research study being reviewed. This includes any research conducted in another state.
- The IRB shall utilize consultants as necessary to ensure appropriate expertise. Such consultants may not vote with the IRB or contribute to the quorum.
- The IRB will consider whether and when to require a reassessment of the participant's decision-making capacity, periodic re-consenting of the participants, and the study's renewal period.

3.4 Criteria for IRB Approval:

Incompetent persons: or persons with impaired decision-making capacity are the only suitable research participants. Competent persons are not suitable for the proposed research.

The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants.

Incompetent persons or persons with impaired decision-making capacity must not be participants in research simply because they are readily available.

Favorable risk/benefit ratio: The proposed research entails no significant risks, tangible or intangible or, if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant.

Incompetent people or persons with impaired decision-making capacity will not be participants of research that imposes a risk of injury unless that research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.

Voluntary participation: In situations where the potential research participant is incompetent to provide informed consent, the investigator should still attempt to obtain assent from the potential participant.

Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may participants be forced or coerced to participate.

Well-informed representatives: Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision-making capacity. Health care agents (appointed under durable power of attorney for health care) and guardians must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the participant would do if competent, or if the participant's wishes cannot be determined, what they think is in the incompetent person's best interest.

3.5 IRB Determination and Documentation

The IRB shall make a determination in writing of each of the criteria listed above. If these criteria are met, the IRB may approve the inclusion of incompetent participants or participants with impaired decision-making capacity in research projects on the basis of informed consent from legally authorized representatives or, if none exists, next-of-kin.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111

45 CFR 46.116 and 46.117

38 CFR 16 and 17

OHRP Guidance Document: Informed Consent, Legally Effective and Prospectively Obtained

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
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<i>IRB Coordinator</i>	Provides guidance to investigators as needed. Selects appropriate Primary and Secondary Reviewers. Obtains consult if needed.
<i>Primary and Secondary Reviewers and Tertiary Reviewers</i>	Review study and determine if all safeguards are in place. Determine if study meets criteria for using an LAR.

503 RESEARCH WITH CHILDREN

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1. PURPOSE

The policy describes the requirements concerning review of research that involves children in regard to autonomy, and who present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

2. POLICY

Enrolling children into research studies presents especially difficult considerations for the IRB. Two factors make a case for research in children.

1. Children differ markedly from adults; and therefore, adult participant research cannot substitute for testing in children.
2. Lack of appropriate research in children will increase their risk of harm from exposure to practices and treatments untested in this population. In addition, new therapies could not be developed for diseases that specifically affect children.

However, research in children requires that the IRB carefully consider assent and parental permission, beneficence, and justice.

The determination of risk (possible harms) and possible benefit to the child is at the core of the concept of beneficence when considering research in a pediatric population.

Therefore, the IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB has the authority to approve the study.

2.1 Definitions

Children:

DHHS (45 CFR 46.402(1)): Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted .

FDA (21 CFR 50.3(o)): Children are persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

The following exceptions to the general rule apply, where a person underage of 18 does not meet the federal definition of “child” and may provide legally effective consent to participate in research if:

- The child is emancipated;
- The child (a) has entered into a valid marriage, whether or not the marriage is terminated by dissolution;
- Is on active duty with the armed forces of the United States; or
- Has received a declaration of emancipation from a court.

Guardian:

DHHS(45 CFR 46.402(e)): Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

FDA (21 CFR 50.3(s)): Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of subpart D of this part, a guardian also means an individual who is authorized to consent on behalf of a child to participate in research.

3.1 IRB Review

The IRB members will use the Checklist: Research Involving Children to determine risk, benefit assessment, and requirements for permission by parents or guardians and assent by children and all other determinations.

When reviewing research conducted on children, risk is defined in terms of minimal and greater than minimal risk, and may only be approved by the IRBs as follows:

Risk determination	Benefit assessment	IRB’s action
Minimal	With or without direct benefit	Approvable
More than minimal risk*	Potential benefit to child	Approvable
Greater than minimal risk	No direct benefit to child, offers general knowledge about the child’s condition or disorder	Approvable case-by-case*
Greater than minimal risk	No direct benefit to child, offers potential to “understand, prevent, or alleviate a serious problem affecting the health and welfare of participants.”	Not approvable**

*IRB will make determination if consent of one or both parents is required.
 * Respect for persons require oral communication with children younger than age seven (7) about the research and what they will experience to the extent their development permits.
 **Approval to proceed with this category of research must be made by the IRB Coordinator of the HHS with input from selected experts, and following opportunity for public review and comment.

The IRB will determine that adequate provisions are made for soliciting the permission of the child’s parents or guardian.

If the research includes enrollment of participants in other states or countries, the investigator is responsible for providing the IRB with sufficient information to verify the age at which participants in such jurisdictions have the ability to consent to participation in research, including any medical treatment or procedures, if applicable.

In general, research involving children will be reviewed at the expedited or full board level. When the research involves observation of public behavior and the investigator does not participate in the activities being observed an exempt review may be utilized.

The No Child Left Behind Act of 2001

The Act identifies eight (8) categories of protected information for surveys, questionnaires, interview materials, or other testing instruments responses. Research involving any of the eight (8) identified categories requires written parental informed consent prior to participation of a child.

1. Political affiliations of student or student's parents.
2. Mental or psychological problems of student or student's family.
3. Sex behavior or attitudes.
4. Illegal, anti-social, self-incriminating or demeaning behavior.
5. Critical appraisals of others with whom students have close family relationships.
6. Legally recognized privileged or analogous relationships.
7. Religious practices, affiliations or beliefs of student or student's parents.
8. Income.

Known or Suspected Child Abuse

Investigators are required to report known or suspected child abuse. This must be disclosed on the informed consent form.

Policy on EPA Supported Research on Children

The IRB may review and approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provision are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 40 CFR 26.406.

The IRB may review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB finds and documents that:

- The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
- The risk is justified by the anticipated benefit to the participants.
- The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40 CFR 26.406

4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
45 CFR 46: Subparts D
45 CFR 46.122
21 CFR 56.111
OHRP IRB Guidebook

5. FORMS

See Appendix

Parent/Child Informed Consent Checklist

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, IRB Coordinator</i>	Select appropriate Reviewers or obtain expert consultant.
<i>IRB Coordinator</i>	Provide reviewers with appropriate checklists.
<i>Reviewers</i>	Present recommendations during convened meeting. Complete checklists to ensure all determinations are met. Determine who met the DHHS and State Law definitions of child, guardian and ward, if applicable.

504 RESEARCH WITH PRISONERS

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1. PURPOSE

The policy describes the requirements concerning review of research that involves prisoners who could be potentially vulnerable to coercion in regard to autonomy and who present conditions that may affect risk/benefit determinations or bear unequal burden in research.

2. POLICY

Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and non-coerced decision whether or not to participate in research. To safeguard their interest and to protect them from harm, special ethical and regulatory considerations apply when reviewing research involving this population.

3. Definitions

For Prisoners, “minimal risk” means the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examination of a healthy person.

4. SPECIFIC POLICIES

4.1 IRB Composition

The IRB shall meet the following requirements:

- A majority of the Board shall have no association with the prison(s) involved, apart from their membership on the IRB.
- A least one member of the IRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

4.2 Additional Duties of the IRB When Reviewing Research with Prisoners

If an investigator indicates in the study submission that prisoners will participate in the research, or that participants may reasonably be expected to be incarcerated at some time point during the study, the additional requirements will apply to IRB review of the project:

1. If the research involving prisoners is neither conducted nor supported by DHHS, then the IRB will include in its minutes that the research falls into one of the four categories of research[45 CFR 46.306(2)(A)-(D)].
2. If the research involving prisoners is either conducted or supported by DHH, then the IRB will certify to OHRP that the duties of the IRB have been fulfilled.

Minor modifications to research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification

- Modification involving more than a minor change reviewed by the convened IRB
 - Must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting
- Continuing review
 - Must use the same procedure for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting
 - If no participants have been enrolled, the research may receive continuing review using the expedited procedure under expedited category #8.

Local regulations: In addition to meeting federal regulations, the project must comply with local and state requirements for inclusion of prisoners as participants.

4.3 When Participants Become Prisoners during a Research Protocol

This policy applies whenever any human participant in a research protocol becomes a prisoner at any time during the protocol, *e.g.*, after the research has commenced. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of the participant.

- If a participant becomes a prisoner after enrollment in research, the principal investigator is responsible for reporting this situation in writing to the IRB immediately.
- At the earliest opportunity after receiving the investigator's notice or otherwise becoming aware of the prisoner status of a participant, the IRB should review the protocol again with a prisoner representative as a member of the IRB. The IRB should take special consideration of the conditions of being a prisoner.
- Upon this review, the IRB can either (a) approve the involvement of the prisoner-participant in the research in accordance with this policy or (b) determine that this participant must be withdrawn from the research.
- If involvement of the prisoner participant is approved, a special addendum to the consent document must be created that informs the participant of the impact incarceration may have on his or her continued participation.

If a participant becomes a prisoner while enrolled in a research study that was not Reviewed according to Subpart C:

- When subpart C applies:
 - Before terminating the enrollment of the incarcerated participant the IRB should consider the risks associated with terminating participation in the study
 - If the participant cannot be terminated for health or safety reasons
 - Keep the participant enrolled in the study and review the research under Subpart C.

- If some requirement of Subpart C cannot be met, but it is in the best interest of the participant to remain in the study, keep the participant enrolled and inform OHRP of the decision along with the justification.

5. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
 45 CFR 46: Subparts C, 45 CFR 46.305, 45 CFR 46.122
 21 CFR 56.111
 OHRP IRB Guidebook

6. ATTACHMENT

See Appendix
 Addendum 3

8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Maintain and update checklist to conform to applicable regulations and guidelines. Secure prisoner representative for the IRB’s meeting
	Select appropriate Primary, Secondary and Tertiary Reviewers and/or obtain an expert consultant.
<i>ORA Director</i>	Certify to the OHRP that the IRB has reviewed and approved the research under CFR 46.305I.

600 COMMUNICATIONS

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1. PURPOSE

The policy describes the IRB actions that must be communicated to the investigator and the importance of open communication among IRB, investigators, ORA staff and officials.

2. POLICY

It is important that staff, participants, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that IRB members, department heads, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution. The researcher and his/her research staff interact with participants; therefore, it is vital that open and frequent communication with the investigative team be maintained.

3. SPECIFIC POLICIES

3.1 Investigator Notifications

- **Initial submission (full Board):** The investigator will be notified by e-mail of the IRB decision as soon as possible after the meeting. If the approval is withheld or deferred pending receipt and review of requested materials or responses from the investigator or sponsor, the IRB must receive the response within 180 days of the date of notification. Studies received after 60 days will be reviewed as a new initial review.
- **Exempt and Expedited:** The investigator will be notified by e-mail of the decision as soon as possible after review of the project. If the approval is pending upon receipt and review of requested materials or responses from the investigator, the IRB must receive the response within 60 days of the date of notification. Studies received after 180 days will be reviewed as a new initial review.
- **Renewals and Revisions:** Investigators will be notified by e-mail as soon as possible as to the action taken by the IRB for any continuing reviews or revisions.
- **Notification of Final Approval:** Investigators will be notified by e-mail of the final approval. The IRB-approved consent form will be stamped with the approval and expiration date and submitted to the investigator with the final approval letter.
- **Disapproval:** Correspondence will provide the reason(s) for disapproval and instructions to the investigator for appeal of this decision.
- **Table:** Correspondence will provide reason(s) for tabling and instructions to the investigator to respond to this decision.
- **Expiration:** If a project expires and the investigator does not respond to continuation notices, a letter of expiration will be sent to the investigator and appropriate institutional

and regulatory officials. If the investigator does not respond in five (5) business days, the IRB will not accept future research proposals from the investigator or from students for whom he/she serves as advisor until all submitted research is current.

3.2 Investigator Appeal of IRB Action

An investigator may appeal the revisions required by the IRB in the protocol and/or informed consent form. This appeal must be in writing, signed by the investigator, and submitted to the IRB.

Investigators may also appeal an IRB decision to disapprove a study. Any such appeal must be in writing, signed by the investigator, and must be reviewed by the full IRB at a convened meeting. The investigator may request or be asked to attend the convened IRB meeting.

In response to an appeal, the IRB may reverse its decision, table consideration in order to obtain more information, or affirm its original decision.

If the appeal is denied, the investigator's institution cannot override the IRB's decision. A declined appeal is final.

3.3 Investigator and IRB Communications

The investigator and his/her staff can call or e-mail the IRB office at any time with questions, concerns, or suggestions. The phone call or e-mail will be triaged to the appropriate personnel. All attempts will be made to respond to messages or e-mails within 48 hours.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.113, 45 CFR 46.109, 46.113

5. ATTACHMENTS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director</i>	Ensure that all communications follow established procedures and format.
<i>IRB Coordinator</i>	Ensure that the determinations and requirements of the IRB are communicated to the investigator as soon as possible. File documents electronically according to established filing procedures.

<i>ORA Director</i>	Review and signs IRB decision communications. Ensure that documentation, either electronic or paper, of any communication of determinations, requirements, or actions of the IRB or representatives of the IRB, when acting in a regulated capacity, are maintained, according to procedures in section 305: Documentation and Document Management.
<i>IRB Coordinator</i>	Triage questions, concerns, and/or suggestions as appropriate. Distribute correspondence as directed.

700 INFORMED CONSENT

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1. PURPOSE

This policy describes the general requirements for obtaining informed consent and documentation of consent.

2. POLICY

Informed consent must be legally effective and prospectively obtained. Except as described in Section 701, no investigator may involve a human being as a research participant unless he or she has obtained legally effective informed consent of the participant or the participant's legally authorized representative. Consent shall be sought only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The informed consent of a participant is a privilege freely granted by a participant. He or she is under no obligation to participate no matter how worthy the research objectives. Furthermore, while obtaining the signature of a participant is an event, obtaining consent is a process that leads to the signature and that is to be continued throughout the project as may be required by respect for persons.

The IRB requires documentation of informed consent by use of a written informed consent form approved by the IRB and signed and dated by the participant or the participant's legally authorized representative. In studies involving children, the legally authorized representative is the parent or court-appointed guardian.

2.1 Legally Authorized Representative (LAR)

In studies involving cognitively impaired adults, the legally authorized representative is a designated proxy (such as a durable power of attorney for health care), court-appointed guardian, or next-of-kin, in that order. For a more detailed explanation on LAR see P&P 502 3.2.

3. SPECIFIC POLICIES

3.1 Informed Consent Document:

A written consent document is one that embodies the elements of informed consent described in 21 CFR 50.25 and 45 CFR 46.116(a). This form may be read to the participant or the participant's legally authorized representative; but, in any event, the investigator shall give either the participant or the representative adequate opportunity to read and reflect upon it before it is signed.

The participant or the participant's legally authorized representative signs and dates the consent document. The participant must be given a copy of the signed form.

3.2 Required and Additional Elements of Informed Consent

The IRB reviewers will use the Informed Consent Checklist when reviewing informed documents to ensure that the consent contains the required elements and additional elements, if appropriate.

3.2.1 General Guidance for Informed Consent

Information must be presented to enable persons to voluntarily decide whether to participate as a research subject. The language and process used in obtaining informed consent should be culturally appropriate and use language the subjects can understand. Informed consent language and its documentation must be written in "lay language", (i.e. understandable to the people being asked to participate). Generally, a 6th-8th grade reading level is appropriate for average adults.

Consent documents are more understandable if they are written just as the investigator would give an oral explanation to the subject, that is, the subject is addressed as "you" and the investigator as "I/we." This second person writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of the first person may be interpreted as presumption of subject consent, i.e., the subject has no choice. Also, the tone of the first person "I understand" style seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension. In this manual, the word "subject" is used to refer to the people who will take part in the study. Depending on the nature of the research, the word "participant" may be more applicable. Generally, one term or the other is used consistently throughout the consent according to the investigator's preference and the research purposes.

3.2.2 Required Elements for Informed Consent

Informed consent disclosures must include all of the following 8 elements, when applicable, as required by 45 CFR 46.116 (a) or 21 CFR 50.25 (a) as applicable.

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, the number of participants and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if

injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

3.2.3 Additional Elements

When applicable, one or more of the following elements of information shall also be provided to each subject per 45 CFR 46.116 (b) or 21 CFR 50.25 (b):

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

3.2.4 WSU Elements on the Informed Consent Form (ICF)

1. Study title and name(s) of researcher(s) at the beginning of the consent form;
2. A statement that the study has been approved for human subject participation by the Washington State University Institutional Review Board;
3. Consent document written at a reading and comprehension level appropriate for the age and/or background of the participant (6th-8th grade for most);
4. The language and its documentation (especially explanation of purpose, duration, experimental procedures, alternatives, risks, and benefits) written in "lay language," (i.e. understandable to the people being asked to participate);
5. Signature block include participant, researcher(s), witness if appropriate, and date of signature;
6. When appropriate, check box or signature provided to indicate agreement to audio or videotape is included;
7. A statement that the participant will receive a copy of the consent form if appropriate; and
8. Consent form free of exculpatory language through which the subject is made to waive, or appear to waive, any of the subject's legal rights.

3.3 Other Requirements

- A. FDA-regulated test articles: For all research involving test articles regulated by the FDA, informed consent documents must include a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article. The consent form must also include a statement that the FDA has access to the participant's medical records.
- B. Compensation: Payment or compensation to research participants should not be considered a benefit, but a recruitment incentive. The compensation should not be such that it would be considered coercive or unduly influence participants to enroll into a study or stay in a study. All information concerning the compensation, including the amount and schedule of payments, should be included in the consent document. The compensation should not be contingent upon completion of the study, but should be prorated.

If compensation is class extra-credit, an alternative means of obtaining extra credit must be made available to the students who wish not to volunteer as research participants. The alternative means of obtaining extra credit needs to be comparable in time and effort.

3.4 Translations of Consent Documents into a Foreign Language

Translations of consent documents will also be submitted for IRB approval. There are two options available to obtain approval of translated consent forms.

- A. Option #1: The IRB-approved consent form is translated by the sponsor or site and submitted to the IRB. The IRB will have a member or consultant fluent in the language of the consent review the translated document for accuracy. In his/her opinion it must match the English version.

If the IRB does not have a consultant available, the investigator will need to obtain and pay for translation services.

- B. Option #2: The investigator (or sponsor) may submit the IRB-approved version of the consent to an IRB-approved, certified translator. A second translator may then back translate the consent to the original English. Both original and back-translated consent must be submitted.

3.5 Observation of the Informed Consent Process

The IRB may observe the informed consent process in ongoing research, when appropriate. As part of the IRB oversight options, an IRB may require that a staff member, IRB member, Post Approval Reviewer or outside third party observe the consenting of research participants to determine whether the informed consent process has been appropriately completed and documented.

An IRB may require that selected protocols have one or more informed consent process situations be observed. IRB considerations used to choose such protocols include:

- High risk studies.
- Studies that involve particularly complicated procedures or interventions.
- Studies involving vulnerable populations.
- Studies involving study staff with minimal experience in administering consent to potential study participants.
- Other situations when the IRB has concerns that the consent process is not proceeding well.

3.6 Withdrawal from a Clinical Trial

The IRB considers the following issues regarding data retention when participants withdraw from a clinical trial:

- When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
- A research may ask a participant who is withdrawing whether the participant wished to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
 - The researcher must obtain the participants' informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). The IRB must approve the consent document
- If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participants collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50
45 CFR 46.116, 46.117
FDA Information Sheets, 1998

5. FORMS

See Appendix
Informed Consent Checklist

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>Primary, Secondary and Tertiary Reviewers</i>	Reviews proposed ICFs and confirm that all required elements are present and the consent includes the six (6) additional elements, if appropriate.
<i>IRB Coordinator</i>	If elements are missing, return consent document to investigator with request for revision and suggested language (where appropriate).

701 WAIVERS OF INFORMED CONSENT
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1. PURPOSE

This policy describes the requirements for waiver of some or all the elements of informed consent procedures and waiver of requirements for obtaining informed consent.

2. POLICY

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria.

3. SPECIFIC POLICIES

3.1 IRB Waives One or More Requirements of Informed Consent

The IRB may approve a consent procedure that does not include or which alters some or all of the elements of informed consent, or waives the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or participant to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs.
 - Procedures for obtaining benefits or services under those programs.
 - Possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs,
2. The research could not practicably be carried out without the waiver or alteration, as in prospective emergency research conducted under 21 CFR 50.24, when time may not permit informed consent.
 - Note: The IRB does not approve waiver of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations.

Or that:

1. The research involves no more than minimal risk to the participants.
2. The waiver or alteration will not adversely affect the rights and welfare of the participants,
3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
5. The research is not FDA-regulated.

3.2 Alteration of Informed Consent Process

Some research studies (i.e. medical record review, deception research, or collection of biological specimens) would not be possible if all of the elements of informed consent from participants were required.

The IRB may consider waiving the requirements for some or all of the informed consent (45 CFR 46.116 (d)) elements when the research meets *all* of the following conditions (the researcher needs to explain for each condition how it applies to his/her research):

- The research involves no more than minimal risk to the subject;
- The rights and welfare of subjects will not be adversely affected;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever relevant the subject will be provided with additional pertinent information after they have participated in the study.

Note: The investigator needs to describe which elements of consent will be altered, and /or omitted, and justify the alteration. IRB does not approve alteration of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations.

3.3 When Obtaining Informed Consent from a Parent is Not Reasonable

If the IRB determines that a research protocol is designed for conditions or for a participant population for which parental or legally authorized representative permission is not a reasonable requirement to protect the participant (e.g., abused or neglected children), it may waive the consent requirements provided that:

- The research was designed for conditions or for a participant population for which parental or guardian permission was not a reasonable requirement to protect participants.
- An appropriate mechanism for protecting the children who would participate as participants in the research was substituted.
- The research was not FDA-regulated.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

The IRB may waive parental permission by determining that:

1. The research involves no more than minimal risk to the participants.
2. The waiver or alteration will not adversely affect the rights and welfare of the participants.
3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.
5. The research is not FDA-regulated.

4. RESPONSIBILITY

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.23, 50.24
 21 CFR 56.109(c), 56.109(d)
 45 CFR 46.116

6. FORMS

See Appendix
 Addendum 6 Waiver of Informed Consent Process

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator, IRB Members</i>	Review and approve waiver. Document waiver determinations using appropriate checklist(s).
<i>IRB Coordinator</i>	Review submission to determine if waiver is requested. If so, indicate on the IRB agenda/minutes template that waiver is requested.

702 DOCUMENTATION OF INFORMED CONSENT
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1. PURPOSE

This policy describes the requirements for documentation of informed consent and circumstances when the IRB may waive the requirement to document informed consent.

2. POLICY

Unless specifically waived by the IRB, all participants, or their legally authorized representatives, must document that they are consenting to participate in any research project that is conducted at WSU.

3. SPECIFIC POLICIES

Each participant or his/her legally authorized representative must sign and date a copy of the current IRB-approved consent form prior to enrollment or any participation in any phase of the study, and be given a copy of the signed document, unless the requirement is waived by the IRB.

The IRB may approve procedures for documentation of informed consent that involve (a) a written consent form signed by the participant, or (b) in limited circumstances, a waiver of the requirement for a signed written consent form. Each of these two options is described in detail below. It is the responsibility of the IRB to determine which of the procedures described below is appropriate for documenting informed consent in protocols that it reviews. Usually, only option (a) will be appropriate.

3.1 Written Consent Form Signed by the Participant

- 3.1.1 Mentally disabled or cognitively impaired participants: Studies involving participants who may have impaired decision-making capabilities may take place over extended periods. The IRB should consider whether periodic re-consenting of individuals should be required to ensure that a participant's continued involvement is voluntary. The IRB may require investigators to re-consent participants after taking into account the study's anticipated length and the condition of the individuals to be included. Additionally, the IRB should consider whether and when to require a reassessment of decision-making capacity.
- 3.1.2 Participants who do not understand English should be presented with an informed consent document written in a language understandable to them.

3.2 Waiver of Documentation

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if the IRB finds either:

- That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality and the research is not FDA-regulated,

Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant's wishes will govern, **OR**

- That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with:

- A cover letter explaining the research.
- Consent statement with all the elements that states consent is implied by returning the survey.

The investigator must provide the IRB with a completed written consent document containing all the elements of consent and study information that will be provided to the participant.

3.3 ConsentS for Mail, Telephone and Internet Surveys

When research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context, the following may be considered:

- 3.1.3 **Fax or Mail:** The IRB may approve informed consent sent by mail in one of two ways. (1) The investigator mails or faxes the consent document along with a letter requesting participation. The participant signs the consent and returns it with his/her survey. If the study is to be anonymous, the consent form is separated immediately upon opening the package. (2) The investigator sends a consent statement to the participant which includes a statement that by returning the completed survey, the participant is providing and documenting his/her consent.
- 3.1.4 **Telephone:** The IRB may approve telephone consent for survey research. The investigator must use a script when obtaining consent by telephone. (The investigator must include the script in his/her IRB submission.) The script must contain a comprehensive, succinct description of the study and include the relevant elements of informed consent in narrative form. (All possible efforts should be made to mail the informed consent document in advance to the participant.) The interviewer solicits any questions the potential participant may have and answers them. The investigator needs to document that the script was read, the individual was offered the opportunity to ask questions, and whether the participant agreed to or declined participation in the study. If an investigator is taping his/her phone conversations with the participant, the interviewer must immediately inform the participant that he/she is being taped.
- 3.1.5 **For Anonymous Internet-Based Surveys:** It is sometimes appropriate to use a consent statement. Participants would still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey and/or clicking on an "I agree" or "I do not agree" button on the website. The website needs to be designed to allow the participants to print a copy of the consent statement for their records.

4. APPLICABLE REGULATIONS AND GUIDELINES

5. FORMS

Addendum 5 Waiver of Documentation of Informed Consent

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>Chairperson, IRB Members</i>	Reviews submission to determine if circumstances warrant that the IRB may waive the requirement to document informed consents. Reviews the consent documents using the appropriate checklists to capture all determinations.

703 ASSENTS

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1. PURPOSE

This policy describes the requirement for assent of children and cognitively impaired adults.

2. POLICY

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of clinical research, this is accomplished by soliciting the informed consent of the prospective research participant. In the case of the cognitively impaired adult or non-autonomous child, applying the principle of respect for persons is problematic. However, any individual capable of some degree of understanding (generally, a child of seven or older, or a cognitively impaired adult) should participate in research only if they assent. When assent is required by the IRB, however, the decision of the individual assenting is binding.

3. SPECIFIC POLICIES

3.1 Use of Assent

In instances in which the participant is not legally capable of giving informed consent (e.g., children) or in which the participant is cognitively impaired, the IRB must find that adequate provisions are made for soliciting the assent of the participant when, in the judgment of the IRB, the participant is capable of providing assent.

- Assent means a participant's affirmative agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as assent.
- In determining whether participants are capable of assenting, the investigator and the IRB shall take into account the age, maturity, and psychological state of the participant involved. This judgment may be made for all participants to be involved in research under a particular protocol, or for each participant, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the participants is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participant and is available only in the context of the research, the assent of the participant is not a necessary condition for proceeding with the research. Even when the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.
- When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Subpart D

5. FORMS

See Appendix

- Assent Template (Ages 7-10)
- Assent Template (Ages 11-14)
- Assent Template (Ages 15-17)
- Parent Permission Form Template
- Parental Permission & Child Assent Checklist

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>Reviewer</i>	Reviews assent and confirm that language level and content are appropriate. Uses appropriate checklist for review.

800 IRB-REQUIRED INVESTIGATOR ACTIONS
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1. PURPOSE

This policy describes what the IRB requires of investigators in the conduct of research, whether it is single site or multi-site.

2. POLICY

It is the investigator's responsibility to keep the IRB informed of unexpected, protocol- related, non-serious and serious adverse events and other unexpected findings that could affect the risk/benefit ratio of the research. An investigator is responsible for the accurate documentation, investigation and follow-up of all possible study related adverse events. Investigators are also responsible for informing government and other sponsors of any unanticipated or serious adverse events, as appropriate.

3. SPECIFIC POLICIES

3.1 IRB Review of Research

All human participant research that is conducted by or under the direction of any employee, faculty, staff, student, agent, or affiliate of WSU in connection with his or her institutional responsibilities must be reviewed by the IRB.

3.2 Investigator Expectations

It is an expectation that the investigator will:

- Disclose any conflict of interest (financial or other) that may affect the relationship with the research participant or the outcome of the research.
- Have sufficient time to conduct and complete the research.
- Ensure that all persons assisting in the research are adequately trained and informed about the protocol.
- Consider whether other procedures involving less risk are more appropriate when designing the research and will employ sound scientific design in the conduct of research.
- Minimize risk to the participant.
- Monitor participants for potential harm and takes steps to minimize or lessen those harms when possible.
- Modify his/her research designs to mitigate potential injuries in on-going research.
- Develop and implement appropriate recruitment techniques.
- Equitably recruit and select participants for the research.
- Obtain and document informed consent.
- Quickly respond to requests of information or complaints.
- Keep current on policies and procedures that affect human participant protections.
- Seek guidance from IRB or other areas as appropriate.
- Maintain research records, such as signed and dated consent documents, correspondence with IRB, supporting data, and any medical records associated with the research.

3.3 Informed Consent

The investigator must obtain informed consent from participants prior to their enrollment into the research. The investigator must use the informed consent document approved by the IRB. Approval and expiration dates are indicated on the first page of the consent document. Consent documents are valid only during the dates indicated on the form, and the investigator may use the forms only during the period for which they are valid. Investigators must follow federal guidelines and University policy for obtaining informed consent.

3.4 Reports of Unanticipated Problems Involving Risks to Participants or Others

The IRB must be informed of any serious, unexpected, or unanticipated problems involving risks to participants or others that occur during the approval period. See *410-Unanticipated Problems* for more information.

3.5 Changes in Approved Research/Amendments

Changes in approved research during the period for which approval has already been given may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to human participants.

Investigators or sponsors must submit requests for changes to the IRB in writing using an Amendment form if the change represents more than a minimal risk to participants, it must be reviewed and approved by the full IRB. Minor changes involving no more than minimal risk to the participant will be reviewed by the expedited review process. Changes in exempt projects can be approved by the IRB Coordinator. See *403 Amendment/Project Updates* for more information

3.6 Continuations/Renewals and Project Closure

Continuations: The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for requesting renewal in anticipation of the expiration of the approval period. Investigators or their designees and/or sponsors are required to provide a periodic report regarding their investigation prior to the end of the approval period, or upon completion of the study. For renewal of approval, a Continuing Review Form will be provided to the investigator 45 days before study expiration date. A second reminder will be sent one (1) to two (2) weeks before the expiration date.

Project Closure: All studies need to be closed once completed. A Closeout Report Form needs to be filled out and sent into the IRB office.

- **Exempt Studies:** May be closed when all contact with the participants is completed.
- **Expedited:** May be closed when all participant contact is complete and the study does not involve a FDA-regulated drug or device.
- **Full Board Studies:** may be closed when data analysis is completed or sponsor indicates of close the study.

See *P&P 403 Continuing Review* and *P&P 404 Project Closure* for more information.

3.7 Student-Conducted Research

The IRB does not review classroom projects/activities. Classroom projects/activities are generally considered to be conducted for a class assignment and turned in to the faculty/instructor. If the class assignment involves subjects from vulnerable populations or if the subjects are members of the populations listed in section IX.c.i, the ORA should be contacted

for advice and assistance and the Non-Regulatory Review form completed. In certain situations where a class project will be used as part of larger research, IRB review and approval may be required. Contact the IRB Coordinator for help and assistance in determining the need for and completing the appropriate application. See additional guidance on IRB web page at: [Class Projects](#).

3.8. Education Requirement (CITI Human Participant Training)

Non- Exempt (expedited and full board reviews) Applications: All researchers (PIs on the non-exempt IRB application) must complete human subject protection education prior to (or concurrent with) submitting a non-exempt human subject research application to the IRB. In addition, refresher education will be required every five years.

3.8.1 WSU uses human subject education provided by CITI (Collaborative Institutional Training Initiative) which can be accessed from the IRB website; <http://www.irb.wsu.edu>. The CITI program is widely accepted as an industry standard among university IRBs and by the federal government. The IRB requires the completion of the CITI Social/Behavioral modules identified with WSU. The researcher may submit a certificate indicating completion of human subject education from the CITI program along with their application. The researcher is responsible to maintain records of their human subject education and provide copies or relevant information of completion along with their application submissions.

3.8.2 The IRB will verify the CITI program requirement for the PI on the non-exempt IRB application only. A non-exempt IRB application may not be approved until the PI has completed the CITI program. The PI on the IRB application is responsible to ensure that all other research personnel are properly trained (preferably through CITI) and have the experience necessary to perform the research.

3.8.3 Exempt Application: All researchers (PIs on the exempt applications) should complete human subject protection education preferably prior to submitting the application to the IRB. WSU uses human subject education provided by CITI (Collaborative Institutional Training Initiative) which can be accessed from the IRB website; <http://www.irb.wsu.edu>.

- Note: Funding agencies may require all personnel be having documentation of human subject training for exempt and non-exempt applications.

For more information about the CITI training, go to the [WSU IRB CITI](#) page.

3.9 Record Keeping

It is the **responsibility** of the PI to maintain records of:

- All correspondence with the IRB.
- Copies of forms submitted to the IRB.
- Original IRB stamped consent document (all versions).
- Signed consent documents.
- Protocols and amendments (all versions).
- Any other documentation requested by sponsor (for funded research).

3.10 Case Histories: VA Research Requirement

A case history is a record of all observations and other data pertinent to the investigation on each research participant. An investigator is required to prepare and maintain adequate and accurate case histories. Cases histories include the case report forms, and supporting data including signed and dated consent forms, any medical records including, but, not limited to: progress notes of the physician, the participant's hospital chart(s), and nurses' notes. The case history for each participant must document that informed consent was obtained prior to participation in the study.

The investigator's research records must be retained for a minimum of five (5) years after the completion of the study and in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors.

3.11 Finder's Fees and Bonus Payments

Finder's fees pose a potential conflict of interest for the conduct of the research and, therefore, are not allowable. Faculty, staff, students, and all others conducting human research under the purview of WSU are strictly prohibited from offering or receiving any finder's fee or other inducement, in cash or in kind, for the purpose of referring patients as candidates for participation in research.

Likewise, no individual or organization conducting human research under the auspices of The University may receive "bonus payments" from sponsors that are tied to the rate or timing of participant enrollment. Examples are; an additional payment of \$5,000 to sites if they can recruit an additional five (5) participants in a week, or additional payment to sites that reach their recruitment goals.

3.12 VA Reporting

Unfounded classification of an SAE as "anticipated" constitutes serious non-compliance and should be promptly reported to the ORA Director.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111, 21 CFR 54
 45 CFR 46.109, 46.111
 VHA Handbook 1200.5

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>IRB Coordinator</i>	Provide investigators with complete information package on preparing IRB submissions, securing initial and ongoing approval of research, and providing all required reports.

	Secure all necessary information for ongoing IRB review and approval.
	<p>Provide guidance to investigators on IRB process.</p> <p>Check all incoming studies to confirm if PI and key personnel have completed the CITI training and, if not, e-mail PI reminder to complete the training before study approval can be given.</p> <p>Distribute communications to and from investigators to appropriate IRB staff and members in a timely manner.</p>
<i>ORA Director, IRB Coordinator</i>	Provide investigators with appropriate training in preparing IRB submissions, conducting the informed consent process, fulfilling ethical obligations and investigator responsibilities.

801 CONFLICT OF INTEREST (INVESTIGATOR)

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1. PURPOSE

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

2. POLICY

It is the policy of WSU Institutional Review Board (IRB) that all conflicts of interest be disclosed and reviewed by the IRB to ensure elimination of any conflict of interest, or to appropriately manage and disclose the conflict of interest to the participants in human participants research.

3. SPECIFIC POLICIES**3.1 Conflict of Interest**

The protection of human participants requires objectivity in communicating risks, selecting participants, promoting informed consent, gathering, analyzing, and reporting data. Therefore, the IRBs consider financial and other conflict of interest issues in their deliberations on applications.

3.2 Reporting

All investigators whose projects require Full Board or Expedited review must reveal on their application to the IRB whether they or any other person responsible for the design, conduct, or reporting of the research has an economic interest in, or acts as an officer or a ORA Director of any outside entity whose financial interests would reasonably appear to be affected by the research.

When a COI is reported, the WSU Conflict of Interest Committee will review the conflict. If, upon review, there is a decision of a conflict the committee will design a conflict management plan. The plan will be reviewed by the IRB, at which time the IRB will decide whether the research can be approved.

WSU Investigators

WSU investigators are required to adhere to the WSU Policy on Financial Conflict of Interest (Objectivity in Research).

If a conflict exists the WSU Significant Financial Interest Form needs to be completed and submitted with the initial IRB application. The process for review and management will be conducted according to the WSU and IRB policy.

- Note: All investigators are required to complete an Annual Disclosure of COI by principal investigators. This form is reviewed by the COI Committee. If a conflict of interest is identified, the IO or the COI Coordinator notifies the ORA Director. The ORA Director checks all open studies to determine if the COI needs to be addressed. This process is in addition to completing the COI questions on the IRB application.

VA Investigators

If a financial interest is disclosed on the Disclosure Form B, the form will be forwarded to the VA research coordinator. The research coordinator will disseminate according to VA policy. The IRB will review the management plan according to 3.3 of this policy.

3.3 Management

The IRB, at a convened meeting, will review the management plan and will consider:

- Risks to participants.
- Anticipated benefits, if any, to participants,
- The scientific or the scholarly integrity of the research.
- The selection of participants.
- The possibility of coercion or undue influences during the consent process.
- The information provided to participants.
- Provisions for monitoring the data collected to provide for safety of participants.
- Provisions to protect the privacy interests of participants.
- Provisions to maintain the confidentiality of identifiable data.

The IRB may accept the management plan or require additional management including, but not limited to:

- Public disclosure of significant financial interest.
- Monitoring of research by independent reviewers.
- Modification of the research plan.
- Disqualification from participation in all or a portion of the research.
- Divestiture of significant financial interests.
- Severance of relationships that create actual or perceived conflicts.

3.4 Approval

The IRB will withhold approval until the determination and/or management plan is reviewed by the convened IRB. The IRB has the final authority to approve the research or to require modification to the research given the management plan. A copy of the IRB approval and any additions to the management plan will be sent to the COI Committee Chair.

3.5 Changes in the Conflict of Interest Status during the Course of the Study:

If there is a change in the conflict of interest status of an investigator during the course of a study, the investigator is required to notify the IRB within ten (10) working days of the change. The IRB will review the change as a modification to the protocol.

3.6 Annual Review

At the time of continuing review, the investigator will be asked whether there has been any change in the conflict of interest status relating to the research. The IRB will review conflict of interest as part of its continuing review.

4. APPLICABLE REGULATIONS AND GUIDELINES

WSU Financial Conflict of Interest (Objectivity in Research)
 NIH Guide – Objectivity in Research
 OHRP COI Policy Draft

5. FORMS

See Appendix
 Significant Financial Interest Disclosure Form

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director</i>	Review potential conflicts of interest and forwards to WSU Conflict of Interest Committee or other individuals as appropriate.
<i>COI Committee</i>	Review COI and make determination and/or recommends management plan.
<i>IRB Members</i>	Review COI determination, management plan, and all supplemental materials at convened IRB meeting.
<i>IRB Coordinator</i>	Distribute communications to and from investigators to appropriate IRB staff and members in a timely manner.

900 POST APPROVAL REVIEW

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1. PURPOSE

The policy describes procedures to assist Office of Research Assurances (ORA) personnel in maintaining and ensuring continuing quality and standards for all IRB procedures.

2. POLICY

The quality assurance and improvement program exists to heighten awareness of regulatory requirements and improve the ethical conduct of research in the Institutional Review Board's approved research. Therefore, the PAR program consists of four areas of focus:

- Evaluation of the effectiveness of the human participant research protection program (HRPP)
- Evaluation of how investigators implement protocols as approved by the IRB
- Identification of issues to be addressed in HRPP education and training
- Evaluation of the informed consent process to determine if it meets standards or can be improved

3. SPECIFIC POLICIES

3.1 Site Visits and Third Party Verification

The IRB has the authority to observe, or have a third party observe, the informed consent process of research it has approved, and to verify that the study is being conducted as required by the ORA and within the institutional policies and procedures and site-specific procedures, as appropriate. The Post Approval Reviewer, a representative of the IRB, will conduct site visits, inspect records, observe consents and interview PIs and study staff as described in the [Post Approval Review Guidance](#).

The criteria for selecting studies to be audited may include:

- Studies that involve more than minimal risk to participants
- Studies that involve vulnerable populations
- Studies that involve large numbers of participants

Sponsors may be asked to submit copies of monitoring reports.

The Post Approval Reviewer will conduct a minimum of 1 not-for-cause audit per month. For-cause investigations will be conducted by the IO.

5. APPLICABLE REGULATIONS AND GUIDELINES

None

6. FORMS

- [Post Approval Review Guidance](#)
- [Self Evaluation Tool](#)
- [WSU Post Approval Review Program](#)

7. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>Post Approval Reviewer</i>	Call Investigator or contact key site personnel to set up a day and time to conduct a site visit.
<i>Post Approval Reviewer</i>	Review and bring to site visit complete IRB file. Confirm that the study is being conducted in compliance with the information provided on these documents by observation if possible. Complete the Site Visit Report and send to IRB Coordinator
<i>IRB Coordinator</i>	Communicate with PI to follow up on action items
<i>ORA Director</i>	Develop and implement quality improvements as indicated by audits

1000 HIPAA WAIVERS/AUTHORIZATION/DECEDENTS/REVIEW PREPARATORY TO RESEARCH

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1. PURPOSE

To define the HIPAA requirements and the procedures necessary to conduct full board review and expedited review of HIPAA Waivers of Authorization, Authorizations for use and disclosure of PHI for research.

2. POLICY

Researchers should be aware of the Privacy Rule because it establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research. Although not all researchers will have to comply with the Privacy Rule, the manner in which the Rule protects PHI could affect certain aspects of research.

Applications must include Addendum 7 when the study will be accessing PHI. In order to render PHI anonymous, all 18 identifiers must be removed. Visit the IRB website for more information or contact the IRB Coordinator.

3. SPECIFIC POLICIES

3.1 Full/Partial Waivers of Authorization, Reviews of PHI of Decedents and Reviews Preparatory to Research

Full Waiver: Covered entities may use and disclose identifiable health information for research without an authorization from the individual if the researcher has a waiver issued by an Institutional Review Board (IRB) or a Privacy Board. Before the IRB can issue a waiver of authorization, it must determine that ALL of the following criteria are met:

1. The use or disclosure of the PHI involves no more than minimal risk to the individuals, based on the following elements:
 - An adequate plan to protect identifiers from improper use and disclosure;
 - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law); and
 - Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.
2. The research could not be practicably conducted without access to and use of the PHI; and
3. The research could not practicably be conducted without the waiver.

Partial Waiver: A partial waiver of the individual's authorization may be used for recruitment purposes if the IRB determines that the treating physician's direct approach to the individual or

obtaining the individual's prior authorization is impracticable. The request for waiver of authorization may include several possibilities:

- A partial waiver of authorization for treatment personnel to refer individuals to the researcher or share PHI with the researcher without first speaking to the individual about the referral.
- A partial waiver of authorization for the researcher to look at medical records, or schedules, patient lists, etc., and then contact potential participants.

3.1.1 PHI of Decedents: Investigators wishing to use the PHI of participants who are deceased must certify that:

- That the PHI sought is only that of decedents
- You can document the death of each individual if asked to do so, and
- The PHI is necessary to the research purposes. However, the researcher must represent to the IRB/Privacy Board that (1) the use/disclosure is requested solely for research on the PHI of decedents, (2) the PHI sought is necessary for the research, and (3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought.

Reviews Preparatory to Research: the Investigator submits to the IRB/Privacy Board that (1) the PHI is requested solely to review PHI as necessary to prepare a research protocol, (2) the PHI will not be removed from the covered entity during the course of review and (3) the PHI sought is necessary for the research.

3.2 Review of Full and Partial Waivers at covered entities

Full/Partial Waivers, PHI of Decedents and Review Preparatory to Research will be reviewed by the Privacy Officer of the covered entity. The Privacy Officer will and make a recommendation that the IRB either approve or disprove the waiver, or preparatory to research request. The IRB will review the waiver or request along with the Privacy Officer's recommendation and will vote on a final ruling.

3.3 Review of Full and Partial Waivers at a VA Facility,

Full/Partial Waiver, PHI of Decedents and Review Preparatory to Research at a VA facility will be reviewed by the IRB.

3.4 Authorizations

HIPAA authorizations must be obtained by the investigator for prospective use or disclosure of PHI within a covered entity.

3.5 Review of Authorizations

The IRB/Privacy Board reviews will review all VA stand-alone authorizations.

3.6 IRB Review and Approval

The IRB reviews HIPAA authorizations for all research requests and follows all policies and procedures regulating Institutional Review Boards.

There will be two types of review of HIPAA related research requests:

- Full Board Review, where the entire IRB/Privacy Board reviews Full/Partial Waiver, PHI of Decedents and Review Preparatory to Research.
- Expedited Review, where the Chairperson or designee reviews the Full/Partial Waiver, PHI of Decedents and Review Preparatory to Research

3.7 Documentation and Correspondence

IRB actions will be recorded in the meeting minutes including:

- Full and Partial Waivers of Authorization justification/determinations.

Expedited reviews of Full and Partial Waivers of Authorization will be documented on the reviewer checklists and will be reported to the IRB.

Documentation of approval will be sent to the Investigator as per notification policies.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 164.512 (i)
RCW 70.02

5. FORMS

See Appendix

Addendum 7 HIPAA Authorization Form and Appendix A
RCW 70.02 Washington State Health Care Information Access and Disclosure

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task	
<i>IRB Coordinator</i>	Review expedited HIPAA research related requests	
<i>IRB Members</i>	Review HIPAA research related requests	
<i>IRB Coordinator</i>	Notify PI of committee decision	

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1. PURPOSE

The purpose of this policy is to define the procedures as they apply to human research that is funded by the Department of Defense (DoD). Research supported by the Department of Defense requires compliance with additional federal regulations, directives and instructions.

2. Definitions

Research Involving a Human Being as an Experimental Participant:

The Department of Defense definition is: An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR.210.102 (f) reference (c)). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the participant or participant's environment, the withholding of an intervention that would have been undertaken if not for the research purpose.

3. SPECIFIC POLICY

3.1 Education

Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human participant research. There may be specific DOD educational requirements or certification required.

Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support or manage human research supported by the DOD or its components. The WSU Human Participant Protection Training and Education policy (103 SOP) requires initial and continuing education of research personnel and IRB members every five years. Note however, individual DOD components may have stricter or specific educational requirements. Researchers should contact their project coordinator at the DOD, or DOD component, to ensure adherence to any unique requirements. IRB Coordinators assigning reviewers to protocols funded by the DOD will ensure that training requirements are current at the time of review. Regular education at IRB meetings will include DOD components when appropriate.

3.2 Research Monitor

Appointment of an independent research monitor is required for research involving greater than minimal risk. The monitor must be a provider capable of overseeing the progress of the research protocol. The monitor must be independent of the investigative team and possess sufficient educational and professional experience to serve as the participant/patient advocate. The Principal Investigator is responsible for providing the name, contact information and responsibilities of the Monitor to the IRB in the IRB application. The IRB may require a monitor for a portion of the project or for studies involving no more than minimal risk when appropriate.

The research monitor has the authority to:

- Stop a research study in progress
- Remove individuals from the study
- Take any steps to protect the safety and well-being of participants until the IRB can assess

3.3 International Research

When DoD sponsored research involves human participants who are not U.S. citizens or DoD personnel and the research is conducted outside the United States, and its territories, the investigator must obtain the permission of the host country. The laws, customs, regulations and practices of the host country and those required by *414 International Research*, will be followed. Evidence of permission to conduct the research in the host country by certification of local ethics review must be submitted to the IRB prior to initiation of the project.

3.4 Multi-site Research

When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.

3.5 Studies Involving Department of Defense Personnel

When research involves Department of Defense personnel, including U.S. military personnel, the following requirements to minimize undue influence will apply:

- Officers cannot influence the decisions of their subordinates
- Officers and senior non-commissioned officers need to have a separate opportunity participate in the research.
- When recruitment involves a percentage of a unit, an independent ombudsman must be present during the recruitment.
- Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB.

The following limitations on dual compensation for U.S. military personnel apply:

- In individual may not receive pay for more than one position for more than 40 hours of work in one calendar week. This limitation on dual compensation includes temporary, part-time and intermittent appointments.
- Individuals may be compensated for research if they participate in the research when not on duty.

3.6 Serious or continuing non-compliance

For any research sponsored by the DoD where there is a report of serious or continuing non-compliance, a report will be made to the Department of Defense.

The DoD components may have stricter requirements than the Common Rule requirements for research-related injury

3.7 Scientific Review

New research and substantive amendments to approved research must undergo scientific review prior to the IRB review.

3.8 Informed Consent

If the research participant of a study funded by the DoD meets the definition of “experimental participant,” then a waiver of consent by the IRB is prohibited unless a waiver is obtained from the Secretary of Defense. If the research participant does not meet the definition of “experimental participant,” the IRB may waive the consent process

3.9 Provisions for Research-Related Injuries

For DoD sponsored research, DoD components may have stricter requirements than the Common Rule requirements for research-related injuries. The IRB shall apply the stricter requirements for research-related injuries as outlined by the DoD component conducting or supporting the research

3.10 Archiving

Research sponsored by the DoD may require submitting records to the DoD for archiving.

4. APPLICABLE REGULATIONS AND GUIDELINES

- 32 CFR 219
- DOD Directive 3216.2
- DOD Instructions 3210.7
- DOD Instructions 6200.02

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, Chairpersons of IRB’s, IRB members, IRB Coordinator, and IO</i>	<p>Ensure compliance with federal regulations, policy and procedures to guarantee the protection of human participants participating in research.</p> <p>Report to the IO any inappropriate attempts to influence the IRB process.</p>

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1. PURPOSE

The purpose of this policy is to define the procedures as they apply to human research that is funded by the Department of Justice (DOJ). Research supported by the Department of Justice requires compliance with additional federal regulations, directives and instructions.

2. SPECIFIC POLICY

2.1 Bureau of Prisons

For Research conducted within the Bureau of Prisons, the university, IRB, and researchers and research staff must follow the requirements of 28 CFR 512, including:

- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing
- The research design must be compatible with both the operation of prison facilities and protection of human participants. The researcher must observe the rules of the institution or office in which the research is conducted.
- Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- All research proposals will be reviewed by the Bureau Research Review Board in addition to the IRB.

A Research project conducted within the Bureau of Prisons must have an adequate research design and contribute to the advancement of knowledge about corrections.

Implementation of Bureau programmatic or operational initiative made through pilot projects is not considered to be research.

2.1.1 Research Participation

- Selection of participants within any one organization must be equitable
- Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
- Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both
 - No longer in Bureau of Prisons custody
 - Participating in authorized research being conducted by Bureau employees or contractors.

2.1.2 Researchers Responsibilities

- A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency
- Except as noted in the consent statement to the participant, the researchers must not provide research information that identifies a participant to any person without that

participant's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding with the written consent of the individual to whom the data pertain.

- Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, and electronic retrieval system
- If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.
- The researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.
- At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
- At least 12 working days before any report of findings is to be released, the researcher shall distribute on copy of the report to each of the following along with the report of finding:
 - The chairperson of the Bureau Research Review Board
 - The regional ORA Director
 - The warden of each institution that provided data or assistance
- In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
- The researcher shall expressly disclaim approval or endorsement of the published materials as an expression of the policies or views of the Bureau.
- Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons

Researchers must design their study in a manner that minimizes risk to participants
For research conducted within the Bureau of Prisons, the researcher must have academic preparation or experience in the area of study of the proposed research
For research conducted within the Bureau of Prisons, when submitting a research proposal, the applicant shall provide the following information:

- A Summary statement which includes:
 - Names and current affiliations of the researcher
 - Title of the study
 - Purpose of the study
 - Location of the study
 - Methods to be employed
 - Anticipated results
 - Duration of the study
 - Number of participants (staff or inmates) required and amount of time required from each
 - Indication of risk or discomfort involved as a result of participation and a discussion of the likelihoods that the risks and discomforts will actually occur
- A comprehensive statement, which includes:

- Review of related literature
- Detailed description of the research method
- Significance of anticipated results and their contribution to the advancement of knowledge
- Specific resources required from the Bureau of Prisons
- Description of steps taken to minimize any risks
- Description of physical or administrative procedures to be followed to:
 - Ensure the security of any individually identifiable data that are being collected for the study
 - Destroy research records or remove individual identifiers from those records when the research has been completed.
- Description of any anticipated effects of the research study on organizational programs and operations
- Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules
- A statement regarding assurances and certification required by 28 CFR 46, if applicable.

2.2 Disclosure

For research conducted within the Bureau of Prisons required elements of the disclosure include:

- Identification of the researchers
- Anticipated uses of the results of the research
- A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable)
- A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
- A statement that participation in the research project will have no effect on the inmate participant's release or parole eligibility.

3.0 National Institute of Justice (NIJ) funded research

For research funded by the National Institute of Justice (NIJ):

- All projects are required to have a privacy certificate approved by the NIJ Human Participants Protection Officer
- All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.
- All projects are required to have a privacy certificate approved by the NIJ Human Participants Protection Officer.
- The confidentiality statement on the consent document must state that confidentiality can only be broken if the participant reports immediate harm to participants or others

For National Institute of Justice-funded research, a copy of data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or their relevant research materials.

4. APPLICABLE REGULATIONS AND GUIDELINES

28 CFR 512

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
<i>ORA Director, Chairpersons of IRB's, IRB members, IRB Coordinator, and IO</i>	<p>Ensure compliance with federal regulations, policy and procedures to guarantee the protection of human participants participating in research.</p> <p>Report to the VP for Research any inappropriate attempts to influence the IRB process.</p>
<i>IO and ORA Director</i>	<p>Evaluate on an on-going basis the HRPP program for adherence and compliance with federal, state, and local policy and regulations.</p>

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1. PURPOSE

The purpose of this policy is to define the procedures as they apply to human research that is funded by the Department of Education (ED). Research supported by the Department of Education requires compliance with additional federal regulations, directives and instructions.

2. Definitions

FERPA – Family Educational Rights and Privacy Act – 34 CFR 49

PPRA – Protection of Pupil Rights Amendment – 34 CFR 98

Schools that receive funding from the US Department of Education are required to comply with FERPA as well as PPRA.

Under FERPA, schools may not release identified student academic information without authorization for the student (if over 18) or parent/guardian. PPRA requires that consent be obtained for any surveys involving sensitive information and that such surveys be available for review by parents prior to their administration to the student. Investigators are reminded to take these regulations into account with planning research involving schools.

Prior Consent means:

Prior consent of the student, if the student is an adult or emancipated minor: or

Prior written consent of the parent or guardian, if the student is an un-emancipated minor.

Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.

Access to instructional material used in a research or experimentation program:

All instructional material - - including teachers' manuals, films, tapes, or other supplementary instructional material - - which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research

Research or experimentation program or project:

Research or experimentation program or project is any project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

Children:

Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

3. SPECIFIC POLICY

3.1 FERPA

An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

- Develop, validate, or administer predictive test
- Administer student aid programs
- Improve instruction

A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the university or researcher conducting the research that specifies:

- The determination of the exception
- The purpose, scope, and duration of the study
- The information to be disclosed
- That information from educational records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31 (a)(6) on re-disclosure and destruction of information.
- That the study will be conducted in a manner that does not permit personal identification of parents and student by anyone other than representative of the university with legitimate interests.
- That the university is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study
- The time period during which the university must either destroy or return the information.

Education records may be released without consent under FERPA if all personally identifiable information has been removed including:

- Student's name and other direct personal identifiers, such as the student's social security number or student number
- Indirect identifiers, such as the name of the student's parent or their family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina or iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

3.2 Protection of Pupil Rights Amendment (PPRA)

For research funded by the U.S. Department of Education:

No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

- Political affiliations
- Mental and psychological problems potentially embarrassing to the student or his or her family

- Sex behavior and attitudes
- Illegal, anti-social, self-incriminating and demeaning behavior
- Critical appraisals of other individuals with whom the student has close family relationships
- Legally recognized privileged and analogous relationships, such as those with lawyers, physicians, and ministers
- Religious practices, affiliations, or beliefs of the student or student's parent
- Income, other than required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

3.3 Research Not Funded by the US Department of Education

The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to student.
- Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the same eight items of information noted above.
- The right of parents to inspect, upon request, any instructional material used as part of the educational curriculum for students
- The administration of physical examinations or screens that the school may administer to students

3.4 Requirements of Researchers

Researchers are required to follow Department of Education requirements for the protections of personally identifiable information by completing and complying with the requirements of the "Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with Department of Education Requirements."

4. APPLICABLE REGULATIONS AND GUIDELINES

34 CFR 49
34 CFR 98
32 CFR 219

5. FORMS

None

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY & ASSIGNMENT OF RESPONSIBILITY

Who	Task
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<i>ORA Director, Chairpersons of IRB's, IRB members, IRB Coordinator, and IO</i>	Ensure compliance with federal regulations, policy and procedures to guarantee the protection of human participants participating in research.
<i>IO and ORA Director</i>	Evaluate on an on-going basis the HRPP program for adherence and compliance with federal, state, and local policy and regulations.

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