WSU Manual for the Protection of Human Research Subjects

February 15, 2005

Research Compliance Office (RCO) and Institutional Review Board (IRB)
Washington State University
TABLE OF CONTENTS

Introduction ................................................................................................................. 5

I. The institutional authority under which the IRB is established ...................... 6

II. Purpose of the IRB ............................................................................................... 6

III. Principles which govern the IRB in assuring that the rights and welfare of subjects are protected ................................................................. 6

IV. Authority of the IRB ............................................................................................ 6
    a. Scope of authority defined ................................................................. 6
    b. Authority to disapprove, modify, or approve studies based upon consideration of human subject protection aspects .......................................... 6
    c. Authority to require progress reports from the investigators and oversee the conduct of the study ............................................................... 6
    d. Authority to suspend or terminate approval of a study ......................... 7

V. Membership of the IRB ....................................................................................... 7
    a. Number of members ........................................................................ 7
    b. Qualification of members ................................................................. 7
    c. Diversity of members ....................................................................... 7

VI. Management of the IRB ..................................................................................... 8
    a. The Chairperson .............................................................................. 8
        i. Selection and appointment
        ii. Duties
        iii. Removal
    b. The IRB members ........................................................................... 8
        i. Selection and appointment
        ii. Duties
        iii. Removal
    c. Training of IRB Chair and members ................................................... 9
        i. Orientation
        ii. Continuing Education
        iii. Reference Materials
    d. Liability coverage for IRB members ..................................................... 9
    e. Use of consultants ............................................................................ 10
    f. Administrative support staff ............................................................. 10

VII. Conflict of Interest policy ............................................................................... 11
    a. No selection of IRB members by investigators .................................... 11
    b. Prohibition of participation in IRB deliberations and voting by investigators .............................................................. 11
VIII. Functions of the IRB ................................................................. 12
   a. Conducting initial and continuing review .............................. 12
   b. Reporting findings and actions of the IRB to the investigator ... 12
   c. Determining which studies require review more often than annually ................................................................. 12
   d. Determining which studies require verification from sources other than investigators that no material changes have occurred since previous IRB review ............................................... 12
   e. Ensuring prompt reporting to the IRB of changes in research activities ............................................................................. 13
   f. Ensuring that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards ......................................... 13
   g. Ensuring prompt reporting to the IRB of unanticipated problems involving risks to subjects or others .................................... 13

IX. Operations of the IRB ................................................................. 14
   a. Scheduling of meetings ............................................................ 14
   b. Pre-meeting distribution of IRB review materials to members ... 14
   c. The review process .................................................................. 14
      i. Description of the review process
      ii. Review Levels
   d. Voting requirements ................................................................. 18
      i. Quorum required
      ii. Diversity requirements of quorum
      iii. Full voting rights of all reviewing members
      iv. No proxy votes
      v. Prohibition of conflict-of-interest voting
   e. Communication from the IRB ....................................................... 18
      i. To the investigator conveying IRB decisions
   f. Appeal of IRB decisions ............................................................. 19
      i. Criteria for appeal
   g. Cooperative Agreement between WSU IRB and IRB-Spokane .... 19

X. IRB record requirements ........................................................... 21
   a. IRB membership roster ............................................................. 21
   b. Written procedures and guidelines ........................................... 21
   c. Minutes of meetings ............................................................... 21
   d. Retention of records ............................................................... 21
   e. Communication to and from the IRB ........................................... 21
   f. Adverse reactions reports ......................................................... 22
   g. Records of continuing review .................................................. 22

XI. Investigator responsibilities ..................................................... 22
   a. Education requirements ........................................................... 22
   b. Study protocol ................................................................. 23
   c. Informed consent document ................................................... 23
   d. Assent document and parental consent ................................... 27
   e. Requests for modification in study after initiation ..................... 27
   f. Reports of unexpected adverse events ...................................... 28
   g. Progress reports ............................................................... 28
XII. Health Insurance Portability and Accountability Act (HIPAA) .......... 29

XIII. Discussion of special topics and activities ........................................ 30
    a. Recording (photographs, audio, video) ........................................ 30
    b. “Blanket” classroom approval ...................................................... 30
    c. Research involving children ....................................................... 30
    d. Research conducted in other facilities ........................................ 31
    e. Research involving Native Americans ....................................... 31

XIV. Frequently Asked Questions .............................................................. 31

XV. Definitions ............................................................................................. 39
Introduction

The Washington State University (WSU), *Manual for the Protection of Human Research Subjects* is your reference document detailing the policies and regulations governing research with human subjects 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 proposals to the IRB.

This manual presents the most current information for reference by investigators, staff, and students. Since the field of human subjects 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 branch campuses at WSU, physicians, researchers, non-scientific members, students, 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 protocols involving human subjects. The dignity and welfare 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 explicit 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 projects reviewed by the IRB conform to the regulations and policies set forth by the Department of Health and Human Services (DHHS) regarding the health, welfare, safety, rights, and privileges of human subjects; and 2) assist investigators in conducting ethical research which complies with the DHHS regulations in a way that permits accomplishment of the research activity.

The mission is accomplished through an educational process of IRB review of protocols, negotiation between investigators and the IRB for approval of research, and IRB outreach to the research community. The process serves to facilitate the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects.

Ethics and ethical review are a potentially dynamic and humanizing element in the search for knowledge. In preparing a protocol, 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.
I. The institutional authority under which the IRB is established
The Washington State University Institutional Review Board (IRB) is a
Presidential Committee. The Institutional Official (IO) for the IRB is the Vice
Provost for Research. The IO signs the WSU Federal Wide Assurance (FWA)
with the U.S. Department of Health and Human Services (DHHS) which among
other requirements assures that all human subject research will comply with 45
CFR Part 46 (Protection of Human Subjects) and all subparts.

II. Purpose of the IRB
The Washington State University Institutional Review Board (IRB) is an
administrative body established to protect the rights and welfare of human
research subjects recruited to participate in research activities conducted under
the auspices of Washington State University. The IRB also assists researchers in
conducting safe and ethically sound research involving human subjects.

III. Principles which govern the IRB in assuring that the rights and
welfare of subjects are protected
The Washington State University Institutional Review Board (IRB) is governed by
the ethical principles put forth in the Belmont Report (The Ethical Principles and

IV. Authority of the IRB
a. Scope of authority defined
The WSU IRB has the authority to approve, require modifications
in, or disapprove all research activities that fall within its
jurisdiction as specified by both the federal regulations and
institutional policy.

b. Authority to disapprove, modify, or approve studies based
upon consideration of human subject protection aspects
Research that has been reviewed and approved by the WSU IRB
may be subject to further review and disapproval by officials of the
institution. However, those officials may not approve research if it
has been disapproved by the WSU IRB.

The WSU IRB also functions independently of other committees
and makes its independent determination whether to approve or
disapprove the protocol based upon whether or not human
subjects are adequately protected. The WSU IRB has jurisdiction
over all human subjects research, thereby providing broader
protection for subjects than required by the regulations.
c. **Authority to require progress reports from the investigators and oversee the conduct of the study**

Any approved research is subject to continuing WSU IRB review and must be reevaluated at least annually (or more frequently, if specified by the IRB).

d. **Authority to suspend or terminate approval of a study**

The WSU IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator.

V. **Membership of the IRB**

a. **Number of members**

The IRB will have no less than five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Washington State University.

b. **Qualification of members**

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. For this reason, the person serving as the Research Compliance Officer will serve as a permanent member of the board.

c. **Diversity of members**

The IRB will be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. When the IRB reviews a project that involves Native Americans or a vulnerable population such as prisoners, one or more individuals who are knowledgeable and experienced with these subjects will be an active part of the review process.

The IRB will include at least one member whose primary concerns are in nonscientific areas.

The IRB will include at least two members from the surrounding community. At least one of these members will not be affiliated with Washington State University.
Every effort will be made to include at least one clergy member.

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.

Every effort will be made to include representation from the urban campuses on the IRB.

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

One graduate student representative may be appointed to the IRB as a voting member.

VI. Management of the IRB
   a. The Chairperson
      i. Selection and appointment
         The Chairperson is appointed by the Institutional Official (Vice Provost for Research) and serves as chair for at least one year.

      ii. Duties
         The Chair directs the IRB meetings in accordance with institutional and federal requirements. The Chair works closely with IRB members, the Research Compliance Officer, the IRB coordinator, institutional officials, and investigators to ensure that the rights and welfare of research subjects are protected. The chair is the designated signatory for the IRB and conducts all IRB meetings.

      iii. Removal
         Chairs may be removed or replaced by the Institutional Official.

   b. The IRB members
      i. Selection and appointment
         WSU faculty members appointed to the IRB will serve on the board for a three-year term. Faculty appointments to the committee begin August 16th of the year appointed and end August 15th three years later.

         Community and/or non-affiliated IRB members will be appointed to the board for a three-year term. Non-affiliated
appointments to the committee begin August 16\textsuperscript{th} of the year appointed and end August 15\textsuperscript{th} three years later.

At the conclusion of their terms a committee member may be appointed to an additional term and/or year of service. There is no limit to the number of terms a member may serve on the IRB.

ii. Duties
WSU IRB members are responsible for protecting the rights and welfare of research subjects by reviewing and approving human research in a manner consistent with federal regulations, state and local laws, and institutional guidelines and policies.

iii. Removal
IRB members may be removed or replaced by the Institutional Official.

c. Training of IRB Chair and members
i. Orientation
When a new member or chair is appointed to the IRB, the Research Compliance Officer or the IRB coordinator will hold a New Member Orientation. This orientation will introduce these new members to the federal regulations, WSU IRB meeting procedures, levels of review, consent requirements, vulnerable populations and they will also be instructed on how to fill out the WSU IRB Protocol Review Sheet.

ii. Continuing Education
Continuing education of the IRB members is done through a yearly training meeting held during the summer months as well as educational information distributed to members through newsletters and discussions at full committee meetings. The IRB coordinator and Research Compliance Officer attend conferences throughout the year for continuing education about regulatory changes and current IRB issues.

iii. Reference Materials
Each IRB member is given a WSU Manual for the Protection of Human Research Subjects which includes the specific WSU IRB Policies and Procedures.

d. Liability coverage for IRB members
State law offers protection for state employees and authorized volunteers who are sued for duties and actions performed in the course of their employment and in good faith.

The IRB performs a vital University function. Thus, a member of the IRB is either a state employee or an authorized volunteer acting for the benefit of WSU. See BPPM 60.81. As such, an IRB member is eligible for state defense of tort and civil rights lawsuits if the acts or omissions of the IRB member which gave rise to the suit were, or were purported to be, performed in good faith within the scope of that person’s official duties. RCW 4.92.060, .070.

e. Use of consultants
The WSU IRB is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be WSU faculty or staff, or may be unaffiliated with WSU. The consultants may present their assessments in writing or in person.

f. Administrative support staff
The WSU IRB has an IRB coordinator to coordinate the privileged and confidential institutional review and approval process of proposed research activities involving human subjects to protect their safety, rights and welfare.

The IRB coordinator serves as ex-officio member, with vote, on Human Subjects Review Committee(s), to present evaluations, recommendations, historical information and precedents regarding compliance with laws, regulations, and ethical and safety standards;

Interpret and apply Federal and State laws, regulations and institutional policies and guidelines relevant to the use of human subjects in research proposals;

Communicate committee requests to investigators for additional information and revisions and review responses;

Prepare correspondence, reports, agendas, and certifications of review for funding agencies related to review and approval process;

Independently review and approve administrative and procedural modifications; facilitate approval for emergency or unique opportunity situations;
Advise faculty, staff, and students in preparation of applications for research proposals involving human subjects and consent documents;

Provide education to the WSU community about the human subjects protection process.

VII. Conflict of Interest policy

When an investigator involved in a research project enrolling human subjects has disclosed a potential financial conflict of interest, a representative of the IRB will be present at the Conflict of Interest Committee meeting to gain a complete understanding of the nature of the financial interests. The Conflict of Interest Committee will review the financial disclosure, and consider the potential conflict of interest (as outlined in OGRD Memorandum No.3, WSU Policy and Procedures for Managing Conflict of Interest in Sponsored Research and Scholarship). The IRB representative will collect the information necessary to fully inform the rest of the IRB as cited in the Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRB’s to Consider when Dealing with Issues of Financial Interests and Human Subject Protection, Section 4.3.

After the Conflict of Interest Committee determines an investigator has a potential conflict of interest that cannot be eliminated, and must be reduced or managed in some way, the Institutional Review Board will carefully consider the specific mechanisms proposed to minimize the potential adverse consequences of the conflict in an effort to optimally protect the interests of the research subjects. In general, if there are any financial conflict of interest issues on the part of the researcher, he or she should not be directly engaged in aspects of the trial that could be influenced inappropriately by that conflict. These could include: the design of the trial, monitoring the trial, obtaining the informed consent, adverse event reporting, or analyzing the data. The IRB will also consider if the source of funding and funding arrangements should be included in the consent form.

In all cases good judgment, openness of process and reliance upon objective, third party oversight can effectively minimize the potential for harm to subjects and safeguard the integrity of the research.

a. No selection of IRB members by investigators

Principle investigators are not able to select which IRB member will review their protocol. Additionally, any IRB member must recluse themselves from a review if they have any potential conflicts.
b. Prohibition of participation in IRB deliberations and voting by investigators

Reviews of applications will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IRB on actions concerning projects or activities in which they have an active role or conflict of interest related to any person or entity connected with the protocol. Failure to abide by these provisions may be cause for removal of a member from the IRB.

IRB members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol. The IRB member must make any conflict of interest known to the IRB Chair. The member may provide information to the IRB if requested. The fact that a protocol is submitted by another investigator from an IRB member's Department or Section does not, in and of itself, constitute a conflict of interest.

VIII. Functions of the IRB

a. Conducting initial and continuing review

The WSU IRB is responsible for the review of all projects involving human subjects conducted under the auspices of Washington State University regardless of funding source.

b. Reporting findings and actions of the IRB to the investigator

The IRB coordinator will report findings and actions of the IRB to the investigator.

c. Determining which studies require review more often than annually

The IRB reviews all active protocols annually, unless the IRB has determined the nature and/or risk of the research requires more frequent review. In general, continuing reviews are conducted at the level of the initial review. In order to ensure continuing reviews are substantive and meaningful reviewing members will receive a completed status report and consent form. The IRB member designated as the primary reviewer will receive the status report and consent form as well as the full protocol and any modification or reports to the IRB since the last date of review. Any IRB member can receive a complete protocol packet upon request.
d. **Determining which studies require verification from sources other than investigators that no material changes have occurred since previous IRB review.**

For exempt studies, the IRB coordinator will determine if a study needs to have outside verification that no changes have occurred since the previous review. For expedited reviews, the two reviewers will make this determination. For full board reviews, the full committee will make this decision.

e. **Ensuring prompt reporting to the IRB of changes in research activities**

All modifications to currently approved research are required to have IRB review and approval prior to implementation. Minor changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved protocols that may affect the risk to subjects may be forwarded to the full IRB for review. Reviewers will receive a request for modification and any modified items such as consent forms, protocols, investigator brochures, study instruments, recruitment tools, etc.

A modification may require full IRB review if the modification is significant and impacts the risks and benefits to subjects in the research. Changes in the risks or benefits to subjects may require modifications to the consent form and re-consenting of subjects.

The IRB may only approve modifications submitted during a current approval year to the end of that period. For example, if the new, renewal, or continuing approval is issued on January 1, 2008 it will have an expiration date of December 31, 2008. If a modification is approved during this time, the approval still lasts only until December 31, 2008.

f. **Ensuring that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards**

There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to relieve an apparent immediate hazard to research subjects. In these situations, the principal investigator may implement a change necessary to protect the welfare of the research subjects. Investigators are encouraged to contact the IRB if this type of situation arises prior to implementation of the protocol change. Investigators are required to notify the Research Compliance Office in writing of the change, within 72 hours, and include a written description of the change and events which necessitated immediate implementation.
g. Ensuring prompt reporting to the IRB of unanticipated problems involving risks to subjects or others
The IRB coordinator or the Research Compliance Officer will report in writing within 10 working days to the IRB Chairperson, Vice Provost for Research, relevant Department or Agency Head (sponsor), any applicable regulatory body and OHRP, any report of adverse events as mandated in the Federal Regulations.

IX. Operations of the IRB

a. Scheduling of meetings
The full IRB will convene monthly during the academic year and at least once during the summer. Additional full meetings, or subcommittee meetings may be called by the chair.

Monthly meetings will be arranged by the IRB coordinator after the second week of the semester. The IRB coordinator will work with the Washington Higher Education Telecommunication System (WHETS) to make meeting sites available at each urban campus with a representative on the committee, as well as any urban campus with a researcher having a protocol on that month’s agenda.

IRB meetings are open to the public and meeting dates for the current semester are published on the Research Compliance Office’s website.

b. Pre-meeting distribution of IRB review materials to members
Ten calendar days prior to a monthly meeting the IRB coordinator will send to each committee member who will be in attendance at the next meeting:

1. Meeting agenda
2. Minutes from the previous meeting
3. A list of exempt protocols approved within the past month
4. All new protocols to be reviewed by the full board
5. Review forms for each new protocol
6. Adverse Event Reports
7. Modification Requests
8. Renewal Requests
9. Continuing Education Materials

One week prior to the monthly meeting the IRB Coordinator will contact via e-mail each researcher submitting a protocol for initial review inviting them to attend. An electronic copy of the agenda will be attached to the e-mail.
c. The review process

i. Description of the review process

The WSU IRB is responsible for the review of all projects involving human subjects conducted under the auspices of Washington State University regardless of funding source. The IRB will consider the following issues when reviewing requests to involve human participants in research.

Study Design:
The IRB will examine the study design insofar as it may impact the rights and welfare of the human subjects. The OHRP indicates in the, *Protecting Human Subjects, Institutional Review Board Guide Book*, that, "...if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even inconvenience them through participation in such a study." Many experts agree that the IRB should approve only research that is both valid and of value. The Committee may request an expert consultant review in order to determine whether a study design places subjects at unnecessary risk.

Risks and Benefits:
The IRB will assess whether the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects and to society as well as the importance of the knowledge reasonably expected to result from the research. The IRB will consider only those risks and benefits that may result from the research. The federal regulations do not allow the IRB to evaluate the possible long range effect of applying the knowledge gained through the research. [45 CFR 46.111]

The IRB is required to review any possible benefits a subject may derive from participation in research, and/or the benefits of new knowledge that may justify asking a person to undertake the risks of the study. Payment for participation in research is not considered a benefit.

Equitable selection of subjects:
The selection of subjects should be equitable and free of coercion. The IRB will consider the purpose of the research and the setting of the research. The IRB will closely examine research involving Native Americans or vulnerable subject populations, such as children, prisoners,
subjects with cognitive disorders, or economically or educationally disadvantaged subjects.

Identification of Subjects and Confidentiality:
The IRB is required to review the method for prospective identification of subjects. They will examine the means of identifying and contacting potential subjects and the methods for ensuring the subjects’ privacy and confidentiality. Investigators are required to submit plans for ensuring the confidentiality of subjects.

The Informed Consent Process:
The IRB will carefully review the informed consent process: when, where, and how consent is obtained and any provisions for the ongoing consent of subjects.

Additional Review:
The IRB will determine whether a project requires more than annual review and may require an appropriate monitoring procedure that could include monitoring of the consent process, observation of the research procedures, and review of research related records.

ii. Review Levels
pre-Review
This is an administrative review completed by the IRB Coordinator and not part of the regulatory review process. Upon receipt of a protocol, the IRB coordinator will pre-review the protocol for signatures and completion. The IRB coordinator will also verify the review level. The coordinator will contact the investigator via phone or email if any additional materials are required.

Exempt Review
The IRB coordinator will determine if a protocol meets the criteria for exemption under 45 CFR 46.101(b) and university policy. If a protocol is exempt under federal regulations, the protocol will be reviewed within the Research Compliance Office for the protection of human subjects. The IRB coordinator will be responsible for the review. The IRB coordinator will notify the researcher by phone or email of any required changes and will issue approval once the reviewer is confident the protocol meets university requirements for the protection of human subjects. The WSU IRB attempts to complete exempt reviews within 10 working days from receipt of the application.
Expedited Review
The IRB coordinator will determine if a protocol meets the criteria for expedited review under 45 CFR 46.110(b) and university policy. If an initial protocol qualifies for expedited review, the IRB coordinator will select a subcommittee of two members of the IRB to review the protocol. Each reviewer will have ten working days to review the protocol and render a decision. 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, although a reviewer is always able to work with a researcher directly.

Once both reviewers have approved the protocol, the IRB coordinator will notify the researcher of approval, on behalf of the committee. The WSU IRB attempts to complete exempt reviews within 10 working days from receipt of the application.

Either reviewer can request that the protocol be reviewed at a convened meeting of the IRB.

A protocol will not be disapproved through expedited review. In the case of a split decision by the reviewers, the chair will act as a third reviewer, or the protocol will be brought before the full IRB at a convened meeting for discussion.

In the case of a protocol modification or continuing review that falls under the expedited review category, the review may be carried out by one or more experienced reviewers designated by the IRB chairperson from among members of the IRB. The IRB chairperson, IRB coordinator, program assistant (when an IRB member or alternate), and the Research Compliance Officer are qualified to be reviewers under this procedure.

The full IRB will be informed of all protocols approved through expedited review at the next convened meeting of the IRB. The name of the researcher and title of the protocol will appear on the agenda for the meeting.

Full Board Review
All protocols that do not qualify for exempt or expedited review will be reviewed at a convened meeting of the IRB. Each protocol undergoing initial review will be discussed individually.

Protocols that require full board review have the potential for high risks to subjects (physical, psychological or social) or those that have special population consent considerations (e.g. research involving Native Americans or vulnerable subject populations such as prisoners, children, persons with cognitive disorders, or economically or educationally disadvantaged subjects).

Each full board protocol will be assigned at a minimum to primary and secondary reviewers (third or alternate reviewers may also be utilized). The reviewers may contact the researcher prior to the convened full board meeting and clarify any issues or questions that may arise.

The IRB coordinator will notify the researcher of the committee’s decision and, in the case of approved protocols, issue written approval on behalf of the committee.

d. Voting requirements
  i. Quorum required
     A quorum of more than half of the voting membership is required to conduct business.

  ii. Diversity requirements of quorum
     At least one member whose primary concerns are in non-scientific areas must be present.

  iii. Full voting rights of all reviewing members
     Each member has one vote.

  iv. No proxy votes
     No proxy votes are allowed.

  v. Prohibition of conflict-of-interest voting
     IRB members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol.

e. Communication from the IRB
  i. To the investigator conveying IRB decisions
IRB actions that occur during meetings are promptly conveyed to the Principal Investigator in writing by the IRB coordinator. Communications include deferred pending clarification/modification and its conditions, deferred pending rereview, or disapproval including the reasons for non-approval.

f. Appeal of IRB decisions
   i. Criteria for appeal
      If an IRB application is disapproved, the reasons for disapproval will be conveyed to the investigator in writing. The investigator may request the IRB to reconsider by responding in writing, and may request an opportunity to appear before the IRB.

g. Cooperative Agreement between WSU IRB and IRB-Spokane
   The Cooperative Agreement replaces the previous requirement that WSU-affiliated researchers submit IRB forms separately to both the WSU IRB and the IRB-Spokane. Prior to this agreement, researchers were required to receive independent approval from both IRBs before initiating research activities.

Effective September 7, 2004, the Institutional Review Boards (IRBs) of Washington State University (WSU) and the Inland Empire Hospital Services Association (IEHSA) entered into a cooperative agreement. The Cooperative Agreement is intended to ensure that human research subjects are protected while at the same time allowing WSU researchers conducting research in five Spokane hospitals under the jurisdiction of IRB-Spokane (Deaconess Medical Center, Holy Family Hospital, Sacred Heart Medical Center, St. Luke’s Rehabilitation Institute, and Valley Hospital & Medical Center) to submit to only one IRB protocol. IRB-Spokane’s web site is (http://www.spokane.wsu.edu/research&service/HREC/IRB/). The WSU IRB (http://www.irb.wsu.edu/) represents all WSU faculty, staff, students, and researchers.

Procedure

The following procedure applies to all WSU researchers conducting research in hospitals under the jurisdiction of IRB-Spokane:
1. WSU researchers will complete an IRB-Spokane application form and associated study documents (consent form, HIPAA addendum) per directions on the IRB-Spokane website.

2. WSU researchers will submit the IRB-Spokane application form and associated documents to the WSU IRB per directions on the WSU IRB website. The WSU IRB must keep copies and records of all research conducted by WSU researchers. This is an administrative review and for file copies only.

3. The WSU IRB Coordinator will contact IRB-Spokane immediately to place the application on the next available IRB-Spokane meeting agenda if full board review appears to be required. The WSU IRB Coordinator will forward the IRB-Spokane application materials to the IRB-Spokane Administrator.

4. The IRB-Spokane Administrator will review the application materials, make the final determination of the review level, and coordinate requests (if any are required) for clarification or additional information. The IRB-Spokane Administrator will determine when the application is complete and ready to be sent to reviewers and/or presented at an IRB-Spokane meeting or receive expedited review (if applicable).

5. IRB-Spokane will review the application at a convened full-board meeting or conduct expedited review.

6. Following the review, any requests for changes, modifications, additions, etc. will be coordinated through IRB-Spokane.

7. The final approval letter will be sent by the IRB-Spokane Administrator.

8. Copies of all correspondence and approval letters will be sent to the WSU IRB Coordinator from the IRB-Spokane Administrator.

9. IRB-Spokane will coordinate annual renewals, investigator-initiated protocol modifications, monitoring, and adverse event reports and reviews for the approved protocols. Copies of all materials will be forwarded to the WSU IRB.
10. WSU researchers will close out projects (terminate IRB approval) through the IRB-Spokane.

11. The IRB-Spokane Administrator will forward copies of the final documentation to the WSU IRB Coordinator.

**Exception**

One exception to this Cooperative Agreement is research involving Native Americans. WSU IRB policy requires that any protocols submitted by WSU faculty, staff or students conducted on tribal lands or which target Native Americans as the principle study population will be reviewed at a convened full board WSU IRB meeting with special committee representation. These protocols will also need to be reviewed by the IRB-Spokane.

X. IRB record requirements

a. **IRB membership roster**
   In the fall of each year, the IRB coordinator will submit to NIH a copy of the membership roster and curriculum vitae demonstrating the qualifications of each committee member.

b. **Written procedures and guidelines**
   Written procedures and guidelines are contained in the Manual for the Protection of Human Research Subjects. For a copy of this manual, please contact the Research Compliance Office.

c. **Minutes of meetings**
   The IRB Coordinator will take minutes at each meeting of the IRB. The minutes will contain:

   1) members present
   2) others present (guests/consultants/researchers)
   3) summary of discussion on debated issues
   4) motions made and seconded
   5) record of voting

d. **Retention of records**
   All protocols reviewed, consent documents and related materials will remain on file at the Research Compliance Office (RCO) for three years after the completion of data collection.
Meeting minutes and IRB rosters will remain on file at the RCO as a permanent record of the committee’s activities.

Policy guidance and forms will be disseminated from and stored at the RCO until replaced by new and/or revised documents.

e. Communication to and from the IRB

The Application to Involve Human Subjects in Research is available from the Research Compliance Office or on the internet at www.ogrd.wsu.edu/Forms.asp. Any questions regarding IRB review or the content of the manual should be directed to the IRB coordinator at the Research Compliance Office.

The IRB coordinator communicates with researchers regarding IRB decisions and requests for additional information.

f. Adverse reactions reporting

Any unanticipated, serious or continuing problems encountered that pose actual or potential risks to subjects must be reported to the IRB immediately but not later than 10 days following the event. Such events should be reported in writing to the Research Compliance Office. The IRB coordinator or the Research Compliance Officer will report in writing within 10 working days to the IRB Chairperson, Vice Provost for Research, relevant Department or Agency Head (sponsor), any applicable regulatory body and OHRP, any report of adverse events as mandated in the Federal Regulations.

g. Records of continuing review

The IRB is required to continue to reevaluate research projects at intervals appropriate to the degree of risk, but not less than once a year. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. The approval letter from the IRB will indicate the expiration date. A continuing review form will be sent to the Primary Investigator several weeks prior to the expiration date.

A “Continuing Review Request Form” can be accessed online at our website (http://www.ogrd.wsu.edu/page.asp?id=9).

XI. Investigator responsibilities

a. Education requirements

All researchers must attend human subjects education prior to (or concurrent with) a human subject protocol submission to the WSU IRB. In addition, refresher education will be required every five
years. The researcher may submit a letter or certificate indicating completion of human subjects education along with their protocol application. The researcher is responsible to maintain records of their human subject education and provide copies with their protocol submissions. Researchers include (but are not limited to) faculty, staff, and graduate students. Undergraduate students will not be required to complete human subjects education but should receive training from their faculty advisor or course instructor and should be encouraged to complete human subjects education.

The WSU IRB will accept a certificate from any approved human subjects education to satisfy these requirements. The WSU IRB Coordinator provides human subjects education each semester and also is available to provide education as requested by departments or classes. The WSU IRB website has a resources section with links to some education available on-line ([http://www.irb.wsu.edu/IRBResources.asp](http://www.irb.wsu.edu/IRBResources.asp)). In addition many other human subjects education opportunities are available from various sources. Please contact the WSU IRB Coordinator prior to completing human subjects education not provided by or listed on the resources page of the WSU IRB website.

b. **Study protocol**

Researchers applying for review need to submit a completed Human Subjects Form regardless of review category. Information regarding the number of copies required is included in the instructions for completing IRB applications. In order for the application to be processed, it must be signed by a dean, director or chair and all requested supplemental materials such as consent documentation and survey instruments must be included.

If a researcher plans to use human tissue samples in their research, they need to submit a completed Human Tissue Use Form.

c. **Informed consent document**

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. The procedures used in obtaining informed consent should be designed to educate the subject in terms that they can understand. Hence, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The
written presentation of information is used to document the basis for consent and for the subjects' future reference. Therefore when a written form is used the subject must always receive a copy for their records.

- 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.

- Describe the overall experience that will be encountered. What exactly will the subjects be asked to do?

- Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.

- Describe the benefits that subjects may reasonably expect to encounter. There may be none other than a sense of helping the public at large.

- Describe any alternatives to participating in the research project.

- Federal regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence. For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release.
(e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects. The word “anonymous” should not be used to describe what is actually confidential.

- If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[g]), an explanation must be given of whatever voluntary compensation and treatment will be provided. Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation. The regulations prohibit waiving or appearing to waive any legal rights of subjects.

- The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation. Furthermore, a single person is not likely to be appropriate to answer questions in all areas because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the IRB. Therefore, each consent document can be expected to have at least two names with telephone numbers for contacts to answer questions in these specified areas.

- The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations (45 CFR 46.116[a][8]). It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of either not participating or withdrawing at any time.

The IRB may approve procedures for documentation of informed consent that involves either (I) a written consent form signed by the subject; (II) verbal consent script; or (III) in limited circumstances, waiver of signed written consent form.
Written Consent Form Signed By Subject or Legally Authorized Representative
In most circumstances, the IRB will require that informed consent be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative. This consent form must embody the required elements of informed consent. This form may be read to the subject or the subject's legally authorized representative. However, the investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed. A copy of the document must be given to the person signing the form. The written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with an informed consent document written in a language understandable to them.

Verbal Consent
As an alternative to standard written informed consent documents, verbal consent may be used if approved by the IRB. In general, the subject must also be provided with a written summary of the information that is presented orally.

Waiver of Written Consent or Implied Consent
The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

A. Risk of Potential Harm
   That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or

B. No More Than Minimal Risk
   That the research presents no more than minimal risk of harm to subjects 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 subjects with a written statement regarding the research.

   • Telephone Surveys

   The informed consent process may be altered from the written standard in some cases where a telephone survey
methodology is used. Where research is considered to be minimal risk, often consent may be obtained via telephone.

The following items minimally must be included in the consent script:

- The purpose of the research
- The researcher’s name and his/her association with WSU
- How confidentiality of their responses will be maintained
- Participation is voluntary (and non-participation will not result in penalty), the participant can refuse to answer any questions or terminate their participation at anytime.
- Additional items may be required based on the subject matter and risks to subjects.

d. **Assent document and parental consent**

Under 45 CFR 46 Subpart D, assent is defined as a child’s affirmative agreement to participate in research. A child is defined as a person who has 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.

The IRB shall determine that adequate provisions have been made for soliciting the assent of children. The IRB will take into consideration the ages, maturity and psychological state of the children involved.

The IRB shall determine, in accordance with and to the extent that consent is required by 45 CFR 46.116 of Subpart A, that adequate provisions are made for obtaining consent from each child’s parents or guardian.

As a general rule, children ages 3 to 6 should be assented verbally and the researcher shall provide a verbal assent script along with their IRB application for review. Children ages 7 to 17 should be assented with a written assent form. The researcher shall provide a copy of the written assent form along with their IRB application for review. When a researcher provides assent documentation to the IRB for review, they shall also provide a copy of the parental consent form that will be used. Assent form templates are available on the Research Compliance Office website.

The WSU IRB usually prefers to have separate parental consent and child assent forms. However, whether the forms are
combined or separate both the parental consent and the child assent should include information indicating that the child may refuse to assent (participate in the research) even if the parent/guardian has provided consent. In this way the child is treated as an autonomous agent.

e. **Requests for modification in study after initiation**

   All modifications to currently approved research are required to have IRB review and approval prior to implementation. Minor changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved protocols that may affect the risk to subjects may be forwarded to the full IRB for review. A Request for Modification Form, and any modified items such as consent forms, protocols, investigator brochures, study instruments, recruitment tools, etc., need to be submitted with the application.

   A modification may require full IRB review if the modification is significant and impacts the risks and benefits to subjects in the research. Changes in the risks or benefits to subjects may require modifications to the consent form and re-consenting of subjects. The IRB may only approve modifications submitted during a current approval year to the end of that period. For example, if the new, renewal, or continuing approval is issued on January 1, 2004 it will have an expiration date of December 31, 2004. If a modification is approved during this time, the approval still lasts only until December 31, 2004. Please incorporate all modifications into the continuation application, protocol, and when applicable the informed consent forms for IRB consideration during the annual review.

f. **Reports of unexpected adverse events**

   All adverse events should be reported to the IRB in writing as well as any actions taken on the part of the researcher as a response to the adverse event.

g. **Progress reports**

   Two months prior to the expiration of an approved protocol the principal investigator will receive a renewal form. Investigators desiring to continue their research are responsible for completing the renewal form and returning it to the IRB office in time for review before the expiration date. The timeline for review is the same as for initial review. Investigators should allow 10 working days for exempt and expedited projects. Renewals requiring full board review must be received at least ten calendar days prior to the next meeting.
h. Graduate student research
Student initiated research involving human subjects, whether dissertation, thesis, or other research projects, should be supervised by a faculty advisor and submitted to the IRB for review. IRB review and final approval should take place during the proposal stage of the dissertation or thesis. 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 WSU IRB that a graduate student has not obtained IRB approval prior to initiating their research involving human subjects, the IRB will refer the student researcher/advisor(s) to the Graduate School.

i. Undergraduate student activities
Undergraduate students may frequently be involved with classroom activities or other projects involving human subjects (i.e. surveys, observing behavior, etc.). The WSU IRB requires that all activities involving human subjects be submitted to the IRB. Individual students or groups of students may submit WSU Human Subject applications for review. The WSU IRB Coordinator is available to help and assist students and faculty/instructors. The WSU IRB Coordinator is also available to present full or abbreviated human subject education to undergraduate classes.

Certain undergraduate classes may be facilitated by seeking a “blanket approval” from the WSU IRB. The WSU IRB may provide such approval when the course instructor provides a completed WSU Human Subjects application, clearly describes the type of activities, and templates for Informed Consent. Further, such “blanket approval” requires that the activities will not involve any topics or subjects that would require expedited or full board review. The WSU IRB Coordinator is available to discuss and assist faculty and instructors in obtaining “blanket approval”. “Blanket approvals” must be renewed at least annually.

XII. Health Insurance Portability and Accountability Act (HIPAA)

The Privacy Rule regulates the way covered entities under the Rule, handle individually identifiable health information known as protected health information (PHI). 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.
WSU Human Subjects Applications must include the HIPAA Checklist and, when the study will be accessing PHI (Protected Health Information), an Authorization.

XIII. Discussion of special topics and activities

a. Recording (photographs, audio, video)
The regulations (45 CFR Part 46) require that whenever voice, video, digital, or image recordings are made the protocol 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 considered on the informed consent. In this case a research participant could choose to participate in the study but choose to accept or decline the recording of their participation.

b. “Blanket” classroom approval
Certain classes may be facilitated by seeking a “blanket approval” from the WSU IRB. The WSU IRB may provide such approval when the course instructor provides a completed WSU Human Subjects application, clearly describes the type of activities, and templates for Informed Consent. Further, such “blanket approval” requires that the activities will not involve any topics or subjects that would require expedited or full board review. The WSU IRB Coordinator is available to discuss and assist faculty and instructors in obtaining “blanket approval”. “Blanket approvals” must be renewed at least annually.

The WSU IRB Coordinator is available to help and assist students and faculty/instructors. The WSU IRB Coordinator is also available to present full or abbreviated human subject education to classes.

c. Research involving children
WSU adheres to Subpart D of the DHHS regulations (Additional protections for Children Involved as Subjects in Research). Children are persons who have not attained legal age (18 years old in Washington). The WSU IRB will require that children approximately 3
years old and older provide their assent to participate in research activities. Children from approximately 3 to 6 years old should be assented verbally (a verbal assent script should be submitted to the IRB) and children from 7 through 17 years old should be assented with a written assent form.

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.

d. Research conducted in other facilities
Whenever WSU researchers, staff, or students will be conducting human subjects research in other facilities (such as hospitals, clinics, schools, school districts, American Indian reservations, factories, offices, etc...) the WSU IRB will generally require a letter from a facility manager or other authorized individual. The letter must indicate that the facility representative is aware that the research is taking place in their facility and that they agree to allow the proposed research activities to proceed.

e. Research involving Native Americans
The WSU IRB reviews all proposed research activities that involve Native Americans at the full board review level. The WSU IRB will have a Native American or an experienced Native American advocate assist in the review. All research that is proposed to take place on an American Indian reservation will require a letter indicating that the Tribe is aware of and approves of the proposed research activity.

XIV. Frequently Asked Questions

What is human subjects research?
“Human subjects research” is defined as a systematic investigation designed to develop to generalizable knowledge, which involves the collection of data from or about living human beings.

Why must it be reviewed?
Federal and university policies require that all projects conducted by faculty, staff and students using human subjects must be reviewed. The overall intent of the policy is to ensure that human subjects are treated physically, psychologically and socially in such a way as to minimize embarrassment and stress, and to avoid harm or other negative effects.
* “All projects” includes undergraduate and graduate class projects, senior theses, high school senior projects in addition to graduate level research course projects, pilot studies, theses and dissertations.

**Who reviews it?**
The University has authorized the Institutional Review Board (IRB) to review and approve human subjects research. The IRB is a campus-wide committee made up of faculty, administrators, student representatives and community members. Certain categories of research may be eligible for less intensive review procedures than review by the full Board.

Protocols should be reviewed by department level committees prior to being submitted to the IRB for either an exempt review, expedited, or full board review.

**How is it submitted?**
Human subjects research projects are submitted via a completed IRB application. The form is available on our website at http://www.ogrd.wsu.edu/HSANBIO/human/PDF/HSForm.pdf.

**When does it have to be submitted?**
When submitting projects, sufficient time should be allowed for adequate review. The IRB meets once a month during the academic year except for August. For projects requiring full review, proposals must be submitted 10 calendar days prior to a scheduled meeting in order to be placed on the agenda of that meeting. Projects will be placed on the meeting agenda in the order they are received by the IRB. If there are too many reviews for any given month, the proposal review may be postponed to the next meeting.

Projects eligible for less intensive review procedures may be submitted at any time and will generally be reviewed within 10 working days. Please contact the Research Compliance Office or consult the IRB website for IRB meeting information.

**How will it be reviewed?**
The review of human subjects research is confined solely to procedures affecting the rights and welfare of human subjects. The review focuses on such issues as risk to subjects, voluntary participation, informed consent, and confidentiality. Reviewers may contact principle investigators if they have questions about the study as described in the Human Subjects Application Form. Dialogue between reviewers and investigators is especially important for protocols that will be reviewed at a full board meeting. Investigators can often clarify the protocol and/or consent procedures for the reviewers so that the review can proceed much more efficiently at the actual IRB meeting. Primary investigators (and faculty advisors if student investigator) are encouraged to attend the full board meetings during the review of their study.
Where can you get assistance?
The IRB coordinator and Research Compliance staff are available to answer questions that may arise during the submission process and even after approval. Contact information for these individuals can be found on the IRB website.

What happens if you fail to comply with University policy and Federal regulations regarding use of human subjects in research?
If non-compliance is alleged, an investigation will be initiated by the IRB. The researcher will be informed of the allegations and given ample time to respond. The IRB will then review the relevant information and make a determination regarding non-compliance. Non-compliance is not taken lightly and can have serious consequences for the researcher, advisor (if the researcher is a student), the sponsor and the University. The project may be terminated and the University could lose Federal funding related to research activities. If non-compliance is found, the IRB is required to report the issues to the Vice Provost for Research. If the IRB determines the non-compliance to be either serious or continuing, it must be reported to Office for Human Research Protection (OHRP) and if funded, the funding agency. The review of human subjects research at the University is a collaborative process intended to result in mutually acceptable research procedures which accomplish the investigator’s scientific objectives while protecting the rights and welfare of the subjects. The IRB tries to be as flexible as possible and reviews each project as a separate case rather than imposing rigid requirements. Every attempt is made to take into account all factors in determining the outcome of the review.

It is especially important that students who use data gathered from human subjects for theses and dissertations be fully aware of university policies. Failure to comply with university review procedures may make it impossible for the Graduate School to accept theses or dissertations.

NOTE: APPROVAL OF A PROJECT BY THE IRB SIGNIFIES ONLY THAT THE PROCEDURES ARE IN PLACE TO ADEQUATELY PROTECT THE RIGHTS AND WELFARE OF THE SUBJECTS AND SHOULD NOT BE TAKEN TO INDICATE UNIVERSITY APPROVAL TO CONDUCT THE RESEARCH

Is your project considered to be “research” under the Federal regulations?
Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities [45 CFR 46.102(d)].

Does your project involve “human subjects”?
Human Subject – a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) data through intervention or interaction with the individual, or (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects [45 CFR 46.102(f)].

**If you are using existing/archival data, do you still need to obtain IRB approval?**

Yes, if the study meets the definitions of both “human subjects” and “research” discussed above. Such data is eligible for exempt review if no identifiers exist in the data set (defined above). This requirement for review also applies to identifiable records you may have access to in your daily duties either at work or school (i.e. a teacher has access to student grades but cannot use those records for research without IRB approval.) IRB approval must be obtained BEFORE obtaining the data set.

**Your project meets both of the criteria (research” and “human subjects”) listed above. Now what?**

The IRB has developed a Human Subjects Application Form. The form must be typed, and illegible forms will be returned to investigators without being reviewed. The assurance form located at the end of the application must be signed by the Primary Investigator, the faculty advisor (if PI is a student), and by the chair, director or dean of the department.

**Additional Materials**

The following items, where appropriate, must be included with the Human Subjects Application Form:

- Copy of consent and if applicable, assent forms (or script if verbal consent procedures will be used)
- Copies of all questionnaires/surveys/interview questions
- Recruitment materials (i.e. anything you will use to recruit subjects including press releases and flyers)
- Description of methodology
- School district/organization permission to conduct research
Application forms are available online at our website.

**How do you know if you have the most recent application form?**
Check the IRB website at [http://www.ogrd.wsu.edu/forms.asp](http://www.ogrd.wsu.edu/forms.asp) or contact the Research Compliance Office to make sure you are completing the most recent version of any given form. The forms are reviewed and updated as often as is deemed necessary by the IRB. As requirements change, forms are updated to reflect those changes. Therefore, completing the most recent form is necessary for an accurate and thorough review in accordance with applicable guidelines and policies.

**Has the risk related to this project been clearly assessed and discussed in the application**
When answering the question on the application, consider the following types of risk or discomfort:

- **Physical Risk:** Physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research.

- **Psychological Risk:** May be experienced during the research situation and/or later, as a result of participating. This includes anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, and altered behavior.

- **Social/Economic Risk:** Alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling with negative consequences, or diminishing the subject’s opportunities and status in relation to others. Economic risks include payment by subjects for procedures, loss of wages or income, and damage to employability.

- **Legal Risk:** Risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally liable.

- **Loss of Confidentiality:** Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks include invasion of privacy, as well as the social, economic and legal risks outlined above.

**Where do you send the completed application and attachments?**
Your application and all attachments should be sent or delivered to:

Research Compliance Office
IRB Coordinator
Neill Hall 423
PO Box 643140
Forms with original signatures must be delivered to the Research Compliance Office before approval will be granted.

**Where can you receive training on Human Subject Research?**
Currently a Human Subject Certification Class is offered by the Research Compliance Office twice a semester. You can sign up for these classes on our website at [http://www.ogrd.wsu.edu/workshops.asp](http://www.ogrd.wsu.edu/workshops.asp) or by calling 335-9661.

If you are a faculty member and would like to have a human subject research presentation given to one of your classes in a more simplified format, please contact the IRB coordinator for more information.

**How will your application be reviewed and how long will the process take?**
Three (3) levels of review are utilized to review applications for human subject use: exempt, expedited and full board. Applications are reviewed by the IRB coordinator, IRB Chair or other primary reviewer designed by the IRB Coordinator. After the initial review, the reviewer determines the appropriate level of review.

Projects eligible for **exempt** review may be reviewed and approved by the primary reviewer.

Projects eligible for **expedited** review must be reviewed and approved by the primary reviewer and one other IRB member.

**Full Board Review** is review of proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in non-scientific areas. Those projects slated for Full Board review will be assigned to a primary and secondary reviewer. These reviewers will review the protocol and contact the PI for any additional information or needed revisions. The primary or secondary reviewer (or third/alternate when applicable) will then present the application and their review to the Board. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

Criteria for each level of review are discussed in a later section of this Handbook.

**NOTE: The reviewers have discretion concerning the level of review. Any expedited reviewer may request that the protocol be reviewed by the full board.**

If applications are complete and no additional information must be requested to complete the review, the following estimates apply:
Exempt Review 10 working days  
Expedited Review 10 working days  
Full Board Review 14 days – one month (must be submitted at least 10 calendar days prior to the next scheduled meeting)

What does the IRB look for when deciding whether or not your project will be approved?

IRB may only approve an application when its decision is based on consideration of the following:

Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal regulation. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal regulation.

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

How will you know when your application has been approved?

The Principal Investigator will be notified in writing of IRB approval. The approval documents will contain the approval date, the expiration date and the IRB protocol number.
Conditions of Approval
Approval of a project by the IRB only signifies that the procedures adequately protect the rights and welfare of the subjects and should not be taken to indicate University approval to conduct research. Approval of a project by the IRB applies only to the procedures submitted in the application. The investigator must secure prior approval from the IRB for any changes in the procedures that will affect human subjects, including recruitment procedures. The investigator must also report to the IRB any problems that arise in connection with human subjects participation. If an approval is granted with contingencies, those contingencies must be satisfied (reviewed and approved) prior to beginning the project. Approval for projects is valid only until the expiration date. Multi-year projects must be reviewed no less than annually. (See below for the procedures for obtaining a continuation of approval.)

IRB approval will expire before you finish your project. What do you need to do to maintain IRB approval?
The IRB is required to continue to reevaluate research projects at intervals appropriate to the degree of risk, but not less than once a year. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. The approval letter from the IRB will indicate the expiration date.

A “Continuing Review Request Form” can be accessed online at our website (http://www.ogrd.wsu.edu/page.asp?id=9). Reminders will be sent to the Primary Investigator several weeks prior to the expiration date.

NOTE: If approval for the project lapses, conducting the research beyond the expiration date is a violation of University policy as well as federal regulations. In addition, a new application must be filed in order to gain continued approval for a project.

You want to change something in your project. Do you have to resubmit everything to the IRB?
All changes in the project that deviate from the original submission must be approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subjects.

This approval is gained by submitting a completed Request for Modification form to the IRB for review and approval. The forms are available online at http://www.ogrd.wsu.edu/page.asp?id=9.

If someone participating in your study has an unexpected or negative reaction, what do you do?
Any unanticipated, serious or continuing problems encountered that pose actual or potential risks to subjects must be reported immediately but not later than 10 days following the event. Such events should be reported to the Research Compliance Office. The IRB Coordinator or the Research Compliance Officer will report in writing within 10 working days to the IRB Chairperson, Vice Provost for Research, relevant Department or Agency Head (sponsor), any applicable regulatory body and OHRP, any report of adverse events as mandated in the Federal Regulations.

XV. Definitions

Assent
§ 46.402 Definitions: “Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

“Children” are persons who have not attained the legal age for consent to treatment or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

From Informed Consent A Guide to the Risks and Benefits of Volunteering for Clinical Trials (Kenneth Getz & Deborah Borfitz, 2002): p. 130, “Children aren’t expected to give their consent, but they’re often asked to give their assent.” “IRBs consider parental permission sufficient if the research is going to be done on young children (vaguely defined as somewhere under the age of seven to 11) who lack the intellectual and emotional ability to understand what they’re agreeing to.”

Belmont Report
A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979.

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. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

Any research project 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 a Certificate.

For more information: http://grants.nih.gov/grants/policy/coc/index.htm
Confidentiality
The manner of treating private information, which has been disclosed by the individual subject to a particular person or persons for a specific purpose, such that further disclosure of the information will not be allowed to occur without authorization.

Continual Review
Research that has been approved will undergo review until the completion or termination of the research, including scheduled continual reviews of research that will occur at least annually.

Data
Refers to information that is collected for analysis or used to reason or make a decision.

Exempt
The Common Rule codified in 45 CFR 46.101(b) specifies that research activities may be classified as exempt in the policy if human subjects involvement is limited to one of the listed scenarios, including studies involving the collection or study of existing data when those data either are publicly available or are not personally identifiable. One member of the IRB reviews exempt protocols. Usually that member is the IRB Coordinator. Exempt reviews take about 10 working days.

Expedited
The Common Rule codified in 45 CFR 46.110 specifies that research activities may be eligible for expedited review if the protocol involves only minimal risk or a previously reviewed protocol is receiving modifications that are only minor. Expedited review is carried out by two IRB Members. Such expedited reviews have the force of full reviews, except that if the protocol is found not acceptable, then it must receive review by the full committee; the chair or designee alone cannot reject a proposal. These reviews take about 10 working days.

Human Subject
"A human subject is a living individual about whom an investigator (professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information."
(45 CFR 46.102(f))

HIPAA
Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information. The Privacy Rule was issued to protect the privacy of health information that identifies individuals who are living or deceased.

Informed Consent
The knowing, legally effective consent of any individual or the individual's legally authorized representative; such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

**Institutional Review Board (IRB)**
A committee formed to facilitate the protection of human subjects in research.

**IRB Approval**
The determination by the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.

**Minimal risk**
The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Personally Identifiable Health Information**
Health or medical data or information that can be linked manifestly or inferentially to an individual.

**Principal Investigator**
The individual with primary responsibility for the design and conduct of a research project.

**Prisoners**
A prisoner is defined by federal regulations as any individual involuntarily confined or detained in a penal institution and/or individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to incarceration.

**Private Information**
Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

**Protocol**
The formal design or plan of an experiment or research activity.

**Research**
"Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that
is considered research for other purposes. For example, some demonstration and service programs may include research activities."

(45 CFR 46.102(d))