



Winona State University

## **Policies and Procedures for the Use of Human Subjects in Research**

**(Mandated by Federal Regulations)**

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### I. STATEMENT OF PRINCIPLES

Winona State University is responsible for safeguarding the rights and welfare of human subjects participating in research which is affiliated with the university in any way. This policy is not intended to infringe on the academic freedom of researchers, nor is it intended to supplant existing professional codes of ethics. It simply establishes the procedures necessary to protect the rights of human subjects involved in research in accord with the ethical principles of respect for persons, beneficence and justice as set forth in [The Belmont Report](#), to comply with the application of those principles as required by [Title 45 Part 46 of the U.S. Code of Federal Regulations – Protection of Human Subjects](#), and to fulfill the terms of WSU's Federalwide Assurance (FWA) on file with the U.S. Department of Health and Human Services.

The regulations define research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The regulations define a human subject as “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.” (For additional definitions, see Background Materials.) Questions as to whether or not activities constitute human subjects research may be directed to the Human Protections Administrator or any faculty member of the Institutional Review Board.

Special note: If your research project will involve any of the following, before completing the Protocol Request, contact the Human Protections Administrator to receive information on additional special requirements which must be met in these cases: children (minors), prisoners, pregnant women, fetuses or human in vitro fertilization.

In the case of any discrepancy between this WSU policy and current federal rules and regulations, the federal regulations take precedence.

### II. DESIGNATION OF THE INSTITUTIONAL REVIEW BOARD (IRB).

- A. WSU will further these above principles by forming a federal regulatory board whose responsibilities shall be to:
1. develop WSU policies, procedures, and guidelines to protect human subjects.
  2. serve as a resource for researchers on issues concerning the treatment of human subjects
  3. Review, approve, require modifications in, or disapprove all research activities involving human participants. This review (45 CFR 46.111) shall determine if:

## Regulation 3-7

- a. risks to subjects are minimized
  - b. 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.
  - c. selection of subjects is equitable
  - d. informed consent will be sought from each prospective subject or the subject's legally authorized representatives
  - e. informed consent will be appropriately documented
  - f. the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
  - g. there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.
  - h. when some or all of the subjects may require special protection or are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards are included in the study to protect the rights and welfare of these subjects.
  - i. possible conflict of financial interests exists
  - j. successful completion of an IRB-approved education program on the protection of human subjects has been documented.
4. maintain written records of the following (45 CFR 46.115):
- a. list of IRB members and their vitas.
  - b. written procedures for the IRB.
  - c. minutes of IRB meetings, including attendance, votes, actions taken, the basis for requiring changes in or disapproving research, the basis for approving waivers in the informed consent process (45 CFR 46.117), special review steps taken in instances where the research involves children (45 CFR 46.404-407), prisoners (45 CFR 46.305-306), or pregnant women (45 CFR 46.204-207) and a summary of discussions.
  - d. copies of all research protocols reviewed, including scientific evaluations, if any.
  - e. sample informed consent documents.
  - f. statements of significant new findings provided to subjects.
  - g. reports of any injuries to human subjects.
  - h. progress reports submitted by investigators.
  - i. records of continuing review activities.
  - j. copies of all correspondence between the IRB and the investigators.

## Regulation 3-7

- k. IRB records shall be kept three (3) years and records related to research conducted shall be kept three (3) years after the completion of research.
  5. conduct continuing review of research at least once a year.
  6. respond to complaints that researchers have failed to obtain needed approval or mistreated, coerced, or deceived subjects.
  7. withhold, suspend or terminate approval of research that is not being conducted in accordance with requirements, or that has been associated with serious harm to subjects, and notify appropriate institutional officials of any such actions.
- B. Title: The Institutional Review Board will be known as the WSU IRB.
- C. Members shall (45 CFR 46.107):
1. have the professional competence necessary to review specific research.
  2. be appointed with due consideration given to race, gender and cultural background and sensitivity to such issues as community attitudes and not consist entirely of one profession.
  3. include one member whose primary concerns are scientific and one whose primary interests are non-scientific (e.g., lawyer, clergy, ethicist, etc.).
  4. include one community member not otherwise affiliated with the institution nor part of the immediate family of a person affiliated with the institution
  5. not have a conflicting interest.
  6. successfully complete an IRB-approved education program in the protection of human subjects.
  7. include, at the IRB's discretion, individuals with competence in special areas to assist in the review of issues which require expertise beyond that available on the IRB.
- D. Membership (45 CFR 46.107):
1. The IRB shall consist of at least five members, including: 4 IFO, 1 community member (by invitation of the IRB), and the Grants & Sponsored Projects Director (as a non-voting member), who shall serve as human protections administrator. When reviewing protocol requests involving prisoners as human subjects, a prisoner or prisoner representative will be appointed to the IRB for the purpose of reviewing that protocol (45 CFR 46.304), except in cases where the protocol will also be reviewed by another IRB that already includes a prisoner or prisoner representative.
  2. Recommendations for IFO appointments will be made to the Committee on Committees by departments with faculty conducting research involving human participants. These departments include communication studies, health and human performance, psychology and nursing. Additional departments may be asked to recommend additional

## Regulation 3-7

appointments based upon the level of research activities conducted by their department faculty and/or students. Each spring, the IRB will notify the Faculty Senate if any additional departments' faculty and/or students have submitted IRB Requests for Approval of Protocol forms in the past three consecutive academic years. Those Departments will be invited to make recommendations to the Committee on Committees for IRB appointments. Similarly, the Faculty Senate will be notified if any department currently represented on the IRB has not had faculty and/or students submit IRB Request for Approval of Protocol forms in the past three consecutive academic years. Those departments will no longer be invited to make recommendations to the Committee on Committees.

3. Selection: As with other federal regulatory boards, members will be appointed by the Faculty Association Senate and serve with approval of the WSU President.

### E. Term of membership:

1. Terms commence with fall semester and may be unlimited.

### F. Officers shall include:

#### 1. The Chair, who shall:

- a. be selected by majority vote of the IRB.
- b. complete any education programs required by WSU's Federalwide Assurance (FWA) on file with the U.S. Department of Health and Human Services.
- c. call meetings of the full IRB as needed.
- d. respond to any complaints received.
- e. relay decisions of the IRB on protocol requests requiring full committee review.

#### 2. The Human Protections Administrator, identified in WSU's Federalwide Assurance (FWA) on file with the U.S. Department of Health and Human Services, shall:

- a. call the first meeting of the academic year and other meetings as needed in the absence of the Chair.
- b. keep minutes.
- c. keep records of all protocols and related correspondence.
- d. provide the IRB with lists of approved expedited and exempt requests at each monthly meeting and at the end of the year..
- e. serve as a non-voting, advisory member of the IRB.
- f. maintain a list of all current members, their vitae and documentation of their completion of an IRB approved education program in the protection of human subjects.
- g. submit updates and reports as required by WSU's Federalwide Assurance.

### G. Meetings:

1. shall follow Robert's Rules of Order.
2. must be attended by a majority of the membership, including one non-scientist.

## Regulation 3-7

3. shall be convened to review all proposed research, except when an expedited review procedure is used and the protocol has been approved or a protocol requesting exemption is considered and has been approved. IRB actions require a majority vote of the quorum.
4. shall require members with conflicting interests in a protocol under review be absent when any vote is taken regarding that protocol.
5. may be conducted via a conference call, provided all necessary documentation has been distributed to all members in advance.

### III. INITIAL REVIEW PROCESS:

Faculty, students and other researchers must submit an IRB Request for Approval of Protocol Form for research projects requiring full review, for projects requiring expedited review and for projects that fall under the exempt category. In instances when an instructor assigns course research projects that will be similar in nature and will all fall under the expedited and/or exempt categories, s/he may choose to have students follow the standard review procedures or s/he may use the Course Protocol Review process described in Section E.

#### A. Submissions

1. Requests for initial and continuing review shall be submitted to the Human Protections Administrator (HPA).
2. The HPA shall assign identifying protocol numbers and review each request for completeness. If required information is missing (e.g., project title; project dates; investigator, co-investigator or faculty sponsor names and signatures; documentation of completion of the required Human Subjects Education Module; etc.) or if the form is substantially incomplete, the HPA shall notify the investigator as to what additional information is required before the request can be considered complete and forwarded for IRB review.
3. Complete requests requiring full IRB review shall be forwarded to all IRB members for consideration at the next scheduled meeting. Complete requests in the expedited or exempt categories shall be forwarded for review to individual faculty members of the IRB on a rotating basis. Whenever possible, IRB faculty members shall not be asked to review requests from faculty and/or students in their own departments. (If IRB faculty members are not available, as may be the case during the summer months, the HPA may review requests in the exempt category.)
4. Individual reviewers of requests in the expedited or exempt categories may correspond directly with investigators if they have any questions or require additional materials to complete the review process.
5. Upon approval of requests in the exempt or expedited categories, the individual reviewer shall send a Certification Form to the Investigator. A copy of the Certification Form and all other correspondence and documentation related to the review shall be sent to the HPA.

#### B. Full Review – Review by Full IRB Required

## Regulation 3-7

1. Investigators seeking approval of all research supported by external agencies, and any other nonexempt research not eligible for expedited review, must complete the IRB Request for Approval of Protocol Form for full IRB Review (see attachments) In order for the IRB to evaluate the protocol, the form requests information with regard to:
  - a. a description of the project.
  - b. the scientific rationale for the project.
  - c. the risks to subjects.
  - d. all procedures that are experimental.
  - e. the anticipated benefits to subjects, if any.
  - f. the subject selection, recruitment procedures (including any inducements offered), and the anticipated number of subjects.
  - g. the proposed consent document and process to be used.
  - h. additional safeguards to be used if potentially vulnerable subjects (the elderly, prisoners, children, cognitively impaired people, or people who are economically or educationally disadvantaged) are to be enrolled.
  - i. methods used for monitoring the data collected to insure the privacy of the subjects and the confidentiality of data.
  - j. identification of any possible conflict of financial interests.
  - k. documentation of successful completion of an IRB-approved education program on the protection of human subjects.
2. The IRB considers the Request for Approval at a full meeting. Investigators may be invited to participate, if it is deemed necessary.
3. Through the IRB Chair, the IRB will issue a written certification (see attachments) within 10 duty days of receipt of the complete request by the HPA.
  - a. If any modifications are required and agreed upon by the investigators, they will be indicated on the notice.
  - b. Approval by the IRB will remain in effect for the duration of the project with minimally a yearly review. More frequent reviews may be required if the IRB believes this would be in the best interests of the subjects involved.
  - c. In the case of disapproval, a rationale for such a decision will be provided. This notice will be forwarded to the investigators and any appropriate agencies and/or university personnel (e.g. president, dean, department head, etc.).
  - d. Projects that have been disapproved may not be conducted at or in association with WSU. This does not preclude investigators from appropriately modifying their protocol for future reconsideration by the IRB.

### C. Expedited Reviews – Review by Chair or IRB Faculty Member

1. The Secretary of the U.S. Department of Health and Human Services publishes categories of research that may be reviewed by the IRB through an expedited review procedure. This process may be used for:
  - a. Projects involving research in those categories identified by the federal government, and published in the *Federal Register* (45 CFR 46.110), as involving no more than minimal risk. (See Background Materials.) Minimal risk means "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of

## Regulation 3-7

themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (45 CFR 46.102)

- b. Projects involving minor changes in previously approved research during the period (of one year or less) for which approval was authorized.

If investigators believe their research falls into one of the expedited categories (see Background Materials), they must complete the IRB Request for Approval of Protocol Form (see attachments). In such cases, the Chair of the IRB or an experienced, designated faculty member of the IRB shall provide the review of the IRB Request for Approval of Protocol Form. The individual reviewer shall have the full authority of the IRB to provide the needed approval, but may not disapprove a request without a vote of the full IRB. The principles and procedures for evaluating and approving requests requiring full IRB review apply to the review of requests in the expedited category. Expedited written certifications (see attachments) shall be issued by the individual reviewer within 5 duty days of receipt of the complete request by the HPA.

### D. Exempt Research – Review by Chair or IRB Member

1. If investigators believe their research falls into one of the exempt categories set forth in 45 CFR 46.101 (see Background Materials.), they must complete the IRB Request for Approval of Protocol Form (see attachments) to confirm the exemption. The Chair or a designated member of the IRB will then review the protocol to confirm that it does have exempt status and that appropriate documentation of the informed consent process is on file. A denial of exemption or disapproval of exempt research must be an IRB decision. The written certification (see attachments) will be issued by the individual reviewer within 5 duty days of receipt of the complete request by the HPA.

### E. Course Protocol Review – Review by Chair or Designee Required

1. Instructors assigning course research projects to students that will be similar in nature, and that will involve activities that fall under the expedited or exempt categories, may require students to follow the standard submission procedures described above, or may use the following Course Protocol Review procedures.
  - a. The instructor submits a Faculty Request for Pre-Approval of Course Protocols form (see attachments) to the HPA. The HPA Office processes the requests according to the standard procedures described in Section A.
  - b. Upon receiving confirmation of Pre-Approval, each student in the course completes an individual Student Request for Approval of Individual Projects for Pre-Approved Course Protocols form (see attachments). The instructor should collect the student requests and submit them to the HPA in a single package. The HPA Office processes the requests according to the standard procedures described in Section A.

## IV. CONTINUING REVIEW:

## Regulation 3-7

The IRB shall maintain an ongoing review of nonexempt human research with respect to subjects' rights. Nonexempt projects that are not completed in less than one year will minimally be required to file a yearly Project Status Report with the HPA before the anniversary date of the IRB's most recent approval (see attachments). The HPA will forward the report and any additional documentation required for review as follows: Copies of reports on expedited projects will be reviewed by the original reviewer or the IRB Chair. Copies of reports on projects that originally required full IRB review will be reviewed by the full IRB.

Monitoring procedures other than annual reporting shall be established by the IRB at the time of the initial review or upon review of a Project Status Report on a case-by-case basis. One or more of the following actions may be employed as part of the monitoring procedure:

1. Discussions with the investigators.
2. Discussions with subjects who participated in the research.
3. Discussions with other persons involved in the research (e.g. assistants).
4. Site visits.
5. Solicitation of further documentation on research methodology impinging on human subjects.

### V. REVIEW OF PROTOCOL CHANGES

Proposed changes in a research activity must be reported in writing to the HPA for IRB review and approval prior to initiating the change, except when changes are necessary to eliminate immediate hazards to the subjects. The HPA will forward the appropriate documentation as follows: Proposed changes on expedited projects will be reviewed by the original reviewer or the IRB Chair. Proposed changes on projects that originally required full IRB review will be reviewed by the full IRB. Investigators who report substantial changes that may impinge on human subjects may be subject to further review or monitoring by the IRB. Such a review shall occur at the discretion of the IRB.

### VI. UNANTICIPATED PROBLEMS/SIGNIFICANT ADVERSE EVENTS

Unanticipated problems involving risks to subjects and significant adverse events must be reported in writing to the HPA for full IRB review. The IRB shall require either (1) the problem be remedied or (2) the research be discontinued. Notification of such a decision will be forwarded by the IRB Chair to the investigators and/or university personnel (e.g., president, vice president, dean, etc.) The HPA will notify appropriate federal agencies as required by the FWA in consultation with the responsible institutional official (the President). Institutional officials, in accord with language in the appropriate collective bargaining agreement, may take disciplinary action.

### VII. COMPLAINTS:

Anyone who believes that the rights of any human participant involved in a WSU related research project are being violated, that research is being conducted that presents unacceptable risks to the subjects or others, or that research is being conducted in serious or continuing noncompliance with federal regulations or this policy, is encouraged to inform the HPA or IRB Chair of their concern. The IRB Chair or his/her designees will then:

1. conduct a fact-finding inquiry to determine if the complaint is valid..

## Regulation 3-7

2. If the complaint is valid, the IRB Chair or designee shall contact the investigator(s) to determine if the problem can be resolved.
3. If, in the IRB's majority opinion, the resolution is acceptable, notification of the agreed upon resolution will be forwarded by the IRB Chair to the investigator(s) and his/her immediate supervisor.
4. If, in the IRB's majority opinion, the resolution is unacceptable, the IRB will withhold, terminate, suspend or terminate approval of the research. Notification of such an action will be forwarded by the IRB Chair to the investigator(s) and/or appropriate institutional officials (e.g., president, vice president, dean, etc.).
5. Institutional officials, in accord with language in the appropriate collective bargaining agreement, may take disciplinary action.

When the IRB responds to a complaint, the HPA will notify appropriate federal agencies as required by the FWA in consultation with the responsible institutional official identified in the FWA (the President).

### VIII. BACKGROUND MATERIALS

#### A. Definition of Human Research (45 CFR 46.102).

1. Research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
2. Human subject means "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."
3. Intervention means "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."
4. Interaction includes "communication or interpersonal contact between investigator and subject."
5. Private information means "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."

#### B. Categories of Human Research (45 CFR 46.101)

1. Research supported by external agencies ; e.g., DHHS. Such research will be reviewed by the IRB in accord with the appropriate agencies guidelines.
2. Research not supported by external agencies, but subject to regulation. Such research shall be subject to either an expedited or full review by the IRB (see Section III) and must conform to the principles outlined in Section I.
3. Research eligible for expedited review. Categories of research eligible for expedited review as published in the Federal Register (63 FR 60364) on November 9, 1998, are:

## Regulation 3-7

- a. Clinical studies of drugs and medical devices only when one of the following conditions is met: (i) research on drugs for which an investigational new drug application is not required; or (ii) research on medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (I) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (ii) from other adults and children, considering the age, weight, and height of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
- c. Prospective collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings in a nondisfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat), uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of the rupture of the membrane prior to or during labor; supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and sputum collected after saline mist nebulization.
- d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples include physical sensors that are applied to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow and echocardiography; and moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- e. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- f. Collection of data from voice, video, digital, or image recordings made for research purposes.

## Regulation 3-7

- g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
  - h. Continuing review of research previously approved by the convened IRB (under certain circumstances).
4. Exempt research. Specifically exempt from full IRB review, but still subject to review by the Chair or designee to confirm exemption and compliance with federal regulations, are:
- a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
  - b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.
  - c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under "b." above, if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
  - d. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
  - e. Research and demonstration projects, which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
  - f. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the

## Regulation 3-7

Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- D. **INFORMED CONSENT:** Research procedures must provide for obtaining the written informed consent of all subjects or subjects' legally authorized representatives. The requirement of obtaining a signed consent form may be waived only by the IRB under special circumstances. The basic elements of informed consent (45 CFR 46.116) are designed to ensure subjects understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The elements are:
1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, 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.

When appropriate, the following additional elements of informed consent must be included:

9. 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;
10. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

## Regulation 3-7

11. Any additional costs to the subject that may result from participation in the research;
12. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;
13. 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
14. the approximate number of subjects involved in the study.

This WSU Regulation supersedes WSU Policy 3-7, July 1, 2001

AUTHENTICATED BY:

Darrell W. Krueger  
Darrell W. Krueger  
President

March 24, 2003  
Date of Adoption

Authoritative References:  
President

[45 CFR 46 – Protection of Human Subjects, HHS](#)  
[21 CFR 50 – Protection of Human Subjects, FDA](#)  
[21 CFR 56 –Institutional Review Boards, FDA](#)

Date of Adoption:

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### LIST OF ATTACHMENTS

[Request for Approval of Protocol Form \(including Guidelines for Written Consent Forms and Sample Forms\)](#)

[Faculty Request for Pre-Approval of Course Protocols Form \(including Guidelines for Written Consent Forms and Sample Forms\)](#)

[Student Request for Approval of Individual Projects for Pre-Approved Course Protocols Form \(including Guidelines for Written Consent Forms and Sample Forms\)](#)

[Guidelines for Written Consent Form and Sample Forms](#)

[Project Status Report Form](#)

[Certification Form](#)