Winona State University

Number: 3-7a

Responsible Officer: Chief Academic Officer
Responsible Office: Academic Affairs

Procedure for the Use of Human Subjects in Research

PURPOSE: To establish guidelines, procedures, and responsibilities for the protection of human subjects involved in research conducted in university facilities or by university faculty, staff, or students on behalf of the university.

DEFINITIONS:

a) Office for Human Research Protections (OHRP) – part of the U.S. Department of Health and Human Services which provides regulatory oversight and guidance in the protection of rights, welfare, and well-being of human subjects involved in research

DESIGNATION OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The university will designate a federal regulatory board according to the criteria of 45 CFR 46.107 and consistent with the policies of the university.

1. Membership
   a) The IRB will consist of at least five members with varying backgrounds, including at least four and up to nine IFO members; one community member; and the Grants & Sponsored Projects Director (non-voting) who will serve as Human Protections Administrator

   b) Recommendations for IFO appointments will made to the Committee on Committees by departments with faculty members conducting human subjects research

   c) The Human Protections Administrator will notify Faculty Senate as to which ten departments have submitted the greatest number of protocols for IRB review in the past three consecutive years; those departments will recommend up to two candidates for IRB appointment

   d) If there are more than nine candidates, the Committee on Committees will select nine for recommendation to Faculty Senate

   e) Members will be appointed by the Faculty Association Senate and serve with the approval of the Winona State President

   f) Terms commence on October 15 and will extend for a minimum of three years and may be unlimited

2. Members
Members will:
   a) Have the professional competence necessary to review specific research, be appointed with due consideration to diversity of its members and to sensitivity to community attitudes

   b) Include one whose primary concerns are scientific

   c) Include one whose primary interests are non-scientific

   d) Include one community member not otherwise affiliated with the institution nor part of the immediate family of a person affiliated with the university

   e) Not have conflicting interests, which include participation in or supervision of a study under review, financial interest in a study, a personal relationship with a PI, a fiduciary relationship with a sponsor, non-financial interests that may be conflicting, or other reasons that could be believed as conflicting

   f) Successfully complete an IRB approved education program in the protection of human subjects participating in research

   g) Include, in the IRB's discretion, individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB

   Officers will include a chair, selected by majority vote of the IRB, and the Human Protections Administrator, identified in Winona State's FWA.

3. Meetings
Meetings will be convened to review all proposed research except when the expedited review procedure is used or a protocol requesting exemption is considered. Meetings may be conducted in person or via teleconference or an electronic submission system through consultation between the IRB chair and HPA.

   IRB actions require a majority vote of the quorum, with a quorum defined as half of the total number of board members plus one member. Members with a conflicting interest in a protocol under review must be absent when any vote regarding the protocol is taken.

RESPONSIBILITIES:

1. Institutional Review Board (IRB)
The IRB is charged with the following responsibilities:
   a) Develop policies, procedures, and guidelines to protect human subjects

   b) Review and approve, require modifications, or disapprove any research activities involving human subjects following the criteria of 45 CFR 46.111

   c) Notify investigators and, when appropriate, institutional officials of its decision to approve, require modifications, or disapprove the proposed research activity

   d) Conduct continuing review of research at intervals appropriate to the degree of risk, and at least once per year for full board reviews

e) Maintain written documentation of IRB activities following 45 CFR 46.115; records required by this policy will be retained for three years and records relating to research conducted will be retained for three years after completion of the research

f) Respond to reports of research conducted without needed approval or of mistreatment, coercion, or deception of subjects

g) Withhold, suspend, or terminate approval of research that is not being conducted in accordance with requirements or associated with harm to subjects, and notify appropriate institutional officials and OHRP of such conduct

2. Human Protections Administrator
The Human Protections Administrator (HPA) is identified in the university's Federalwide Assurance (FWA) on file with the U.S. Department of Health and Human Services with the following responsibilities:
a) Serve as a non-voting, advisory member

b) Maintain a list of all current members, their vita, and documentation of their completion of an approved education program in the protection of human subjects

c) Call and organize meetings in the absence of the IRB chair

d) Maintain meeting minutes, records of protocols, and related correspondence in accordance with 45 CFR 46.115

e) Submit reports as required by the university's FWA

3. Chief Academic Officer
The Chief Academic Officer may review and disapprove research that has been approved by the IRB. However, the officer may not approve human subjects research if it has been disapproved by the IRB.

4. Principal Investigator
Primary responsibility for any one study rests with the principal investigator or with the supervising faculty or staff member for studies conducted by students. The PI is responsible for seeking IRB review and approval as appropriate, and for the protection of human subjects for the duration of any one study.

PROCEDURES:

1. Human Subjects in Research Education
The PI and any co-investigators must complete the "Human Subject Education Module" or an equivalent course and submit certification documenting completion to the IRB. Current certification must be on file before a protocol will be considered for review.

2. Categories of Review
a) Research supported by external agencies will be reviewed in accord with the appropriate agency guidelines

b) Research not supported by external agencies but subject to regulation will be subject to either expedited or full review by the IRB

c) Research that involves no more than minimal risk may be reviewed through an expedited review procedure by the chair or one or more experienced reviewers designated by the chair following the criteria of 45 CFR 46.110

d) Research specifically exempt from full IRB review, as defined in 45 CFR 46. 104, is still subject to review by the chair or a designee to confirm exemption and compliance with federal regulations

3. Initial Review

Investigators involved in human subjects research activities must submit the Protocol Request package for studies requiring full and expedited review and for those that fall under the exempt category.

a) Requests for initial and continuing review will be submitted to the HPA via an approved submission system

b) The package must include the Protocol Request Form, which will include a description of the study, its scientific rationale, subject selection and recruitment procedures, anticipated risks and benefits, consent procedures, safeguards for vulnerable populations where appropriate, and identification of possible conflicts of financial interests

c) All packages must provide for obtaining documented informed consent of all subjects or subjects' legally authorized representatives according to 45 CFR 46.116; obtaining consent may be waived only by the IRB under specific circumstances

d) The IRB may also request the inclusion of additional documentation in the package, such as subject recruitment messages, data collection instruments, etc.; the HPA will provide a checklist of these elements to assist investigators

e) The PI and all co-investigators must sign the package, certifying that information provided is correct and agreeing to abide by the decisions of the IRB

f) Complete packages requiring full review will be forwarded to all IRB members and a meeting will be convened; investigators may be invited to participate

g) Complete packages requiring expedited review and involving no more than minimal risk, or previously approved projects involving minor changes, will be forwarded to an individual IRB member on a rotating basis; whenever possible, members will not be asked to review packages from investigators from their own departments

h) Complete packages in the exempt category will be forwarded to an individual IRB member on a rotating basis; whenever possible, members will not be asked to review packages from investigators from their own departments

i) The HPA will notify the investigators of the review decision within five duty days of receipt of the complete package, whenever possible

j) An individual reviewer has the full authority to approve or declare exempt a request, but may not disapprove a request without the full vote of the IRB

k) Disapproved studies may not be conducted at or in association with Winona State; this does not preclude investigators from modifying the protocol package for future review by the IRB

4. Review Criteria
   The review will determine that:
   a) Risks to subjects are minimized
   b) Risks are reasonable in relation to anticipated benefits
   c) Subject selection is equitable
   d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative
   e) Informed consent will be appropriately documented
   f) The research plan makes adequate provision for monitoring data to ensure safety of subjects
   g) There are adequate provisions to protect the privacy of subjects and maintain confidentiality of data
   h) Additional safeguards are included to protect the rights and welfare of subjects who may be vulnerable to coercion or undue influence
   i) Possible conflict of financial interests may or may not exist

5. Continuing Review
   a) For minimal risk studies approved through expedited review, approval remains in effect for the duration of the study; however, the IRB may determine to review non-exempt research at intervals appropriate to the level of risk

   b) Studies approved through full IRB review that are not completed in less than one year will minimally be required to file yearly continuing review progress reports; however, the IRB may require reports or review at intervals appropriate to the level of risk

   c) Monitoring procedures other than annual reporting will be documented by the IRB at the time of initial review or upon review of a continuing review report; monitoring actions may include discussions with investigators, discussions with subjects, site visits, and solicitation of further documentation on methodologies involving human subjects

6. Modifications, Amendments, Reporting
   Proposed changes in research activities will be reported to the HPA using the approved submission system for IRB review and approving prior to initiating the change, except when a change is necessary to eliminate an immediate hazard to subjects.

   Proposed changes to expedited and exempt studies will be reviewed by the original reviewer or the chair. Proposed changes to full review studies will be reviewed by the full IRB. Substantial changes that may impinge on human subjects may be subject to further review or monitoring at the discretion of the IRB.

7. Unanticipated Problems, Adverse Events
   Unanticipated problems and significant adverse events involving risks to subjects will be reported to the HPA using the approved submission system full IRB review. The IRB will require either the problem be remediated, or the research be discontinued. Notification of the IRB decision will be forwarded to the investigators and to appropriate institutional officials. Institutional officials may take disciplinary action in accord with language in the appropriate bargaining agreement.

   The HPA, in accord with 45 CFR 46, will notify appropriate federal agencies as required by the FWA.

8. Complaints

If a person believes that the rights or welfare of any human participant are being violated in university related research, that the research presents unacceptable risks to subjects or others, or that the research is being conducted in serious or continuing noncompliance with federal regulations or university policy, that person may notify the HPA or IRB chair of the concern. The chair or a designee will investigate the concern as follows:

a) Conduct an inquiry to determine if the complaint is valid

b) If valid, contact the investigators to determine if the problem can be resolved

c) If, in the majority opinion of the IRB the resolution is acceptable, notification will be forwarded of the agreed resolution to the investigators and their immediate supervisors

d) If, in the majority opinion of the IRB the resolution is not acceptable, approval of the research will be withheld, suspended, or terminated; the investigators and appropriate institutional officials will be notified of the decision

e) Institutional officials may take disciplinary action in accord with language in the appropriate bargaining agreement

f) The HPA will notify appropriate federal agencies as required by the FWA

RELATED DOCUMENTS:

45 CFR 46
45 CFR 46.107
45 CFR 46.110
45 CFR 46.111
45 CFR 46.115

SIGNATURE, TITLE AND DATE OF APPROVAL:

This policy needs to be signed by the approval officer (listed below) before it is considered approved.

Approved: _____
President

Date: 1-18-19

Policy History:
Date of Adoption:
Date of Implementation:
Date & Subject of Revisions: