Winona State University

Number: 3-7

Responsible Officer: Chief Academic Officer
Responsible Office: Academic Affairs

Policy for the Use of Human Subjects in Research

PURPOSE: Winona State University is responsible for safeguarding the rights and welfare of human subjects participating in research conducted in university facilities or by university faculty, staff, or students on behalf of the university.

This policy provides guidelines and procedures for the protection of human research subjects involved in research in accord with the principles set forth in the Belmont Report, to comply with their application as required by Title 45 Part 46 of the U.S. Code of Federal Regulations – Protection of Human Subjects, and to fulfill the university's Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services.

Winona State will form a federal regulatory board, the Institutional Review Board (IRB), with the authority to approve, require modifications, or disapprove any research activities that fall within its jurisdiction and are conducted under the auspices of the university. All research protocols involving human subjects will be submitted to the IRB for review. The IRB is responsible for determining if has jurisdiction, not investigators or university officials.

Research approved by the IRB may be reviewed and disapproved by university officials; however, university officials my not approve research that has been disapproved by the IRB.

DEFINITIONS:

a) Federalwide Assurance (FWA) – an assurance of compliance with federal regulations for the protection of human subjects in research

b) Human subject – a living individual about whom and investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information

c) Institutional Review Board (IRB) – administrative body established to protect the rights and welfare of human research subjects conducted under the auspices of the institution with which it is affiliated

d) Investigator – an individual performing various human subject research activities, such as obtaining information through intervention or interaction, obtaining identifiable private information, obtaining voluntary informed consent of individuals to participate in research, or studying, interpreting, or analyzing identifiable private information

e) Intervention – includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes

f) Interaction – includes communication or interpersonal contact between investigator and subject

g) Private information – includes information about behavior that occurs in the 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

h) Research – systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

PROCEDURE: See Procedure 3-7a. Procedure is a separate document.

RELATED DOCUMENTS:

a) Belmont Report
b) Title 45 Part 46 of the U.S. Code of Federal Regulations – Protection of Human Subjects

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: