



Interim Administrative Policy

Responsible Official:
Senior Vice President
for Academic Affairs,
Dean of the Faculty

Effective Date: September 1, 2014

Use of Human Subjects in Research - Interim Policy

I. Statement of Purpose

This memorandum contains the policies and procedures that govern:

- activities of the Institutional Review Board (IRB), hereafter referred to as the Board, and;
- all activities, in whole or in part, involving research with humans conducted by faculty, students, and administrative staff of Norwich University.

II. Policies and Basic Requirements

A. Ethical Responsibilities

The University acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects in research. Faculty, students, and administrative staff who conduct research on human subjects shall comply with the policies and procedures established in this memorandum.

B. Specifications of Ethical Authorities

The University is guided by the ethical principles regarding research involving human subjects as set forth in the regulations of the U.S. Department of Health and Human Services, policy on the Protection of Human Subjects (45 Code of Federal Regulations (CFR) 46). The Department of Health and Human Services (hereafter referred to as DHHS) policy shall supersede the policies of individual professional associations, unless otherwise specified in this memorandum. The DHHS policy shall apply to all research conducted on human subjects by University faculty, students, and administrative staff. In instances where the research requires a review, the Board will provide that function for the University. (45 CFR 46.101 specifies research for which an IRB review is required, namely all research funded in whole or part by the DHHS, or one of its agencies, which is non-exempt research.)

C. Definitions and Activities Covered by this Memorandum

The following definitions shall be used in this memorandum and are from 45 CFR 46.102.

Research: A systematic investigation designed to develop or contribute to generalizable knowledge.

Human Subject: A living individual about whom an investigator conducting research obtains a) data through intervention or interaction with the individual, or b) 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 the 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. Private information must be individually identifiable to constitute research involving human subject.

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.

D. Exemptions

It is the policy of the University that all research involving human subjects will be reviewed and approved by the Board before initiation of the research. Research in the following categories is exempt from these regulations:

1. Research involving the use of routine educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
2. Research conducted in established or commonly accepted educational settings, involving normal educational practices and in the confines of a specific academic course. (Note: exempt research would use only subjects and data of subjects who are enrolled in the courses, and the gathered data would not be used outside the classroom. If subjects are recruited from outside the course, or the data are to be presented beyond the confines of the course, the research must be reviewed by the Board.)

The Board will determine whether a specific project shall be exempted under subsections 3-5.

3. Research involving survey or interview procedures, except where any of the following conditions exist:
 - a. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
 - b. The subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.
 - c. The research deals with sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, the use of alcohol, or past traumatic psychological experience.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, 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.
5. Research involving observations (including observation by participants) of public behavior, except where any of the following conditions exist:
 - a. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.
 - b. The observations recorded about the individual, if they became known outside of the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.
 - c. The research deals with sensitive aspects of the subject's own behavior or experiences, such as illegal conduct, drug use, sexual behavior, the use of alcohol, or past traumatic psychological experience.

E. Informed Consent

It is the policy of the University that no research will involve any human being as a subject without first obtaining informed consent, unless informed consent has been specifically waived by the Board. (See section below for specific informed consent requirements.)

F. Confidentiality

It is the policy of the University that all identifying information pertaining to a subject's participation in research remain confidential, except where the subject gives written permission to disclose specific information or identity. Adequate provisions should be taken to protect the privacy of subjects and to maintain the confidentiality of data (45 CFR 46.111.7). The obligation to respect confidentiality also applies to members of the University or research team (assistants, interviews, coders, clerical, staff, etc.) who have access to the information.

G. Risk Policy

It is the policy of the University that risks to subject be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and that risks to subjects be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result (45 CFR 46.111.1-2).

H. Access to Results and Findings

It is the policy of the University that subjects be granted the opportunity to receive feedback from their participation in the research.

I. Responsibilities of the Board

The responsibilities of the Board shall be to:

- Review and amend the policies established in these guidelines when modification is deemed necessary by the Board or broader University community;
- Review all research proposals and act according to these guidelines to either approve new research or ensure the compliance of continuing research;
- Act as a clearinghouse for the ethical guidelines and regulations of various professional associations and appropriate governmental agencies. In order to promote understanding of the policies contained in this memorandum and increase general sensitivity to ethical issues related to human subjects in research, the Board shall disseminate the policies contained in this memorandum;
- Hold hearings to respond to complaints from the University community regarding issues related to research with human subjects;
- Recommend sanctions to the Senior Vice President of Academic Affairs and Dean of the Faculty (SVPAA) regarding violations of these guidelines;
- Maintain records of Board activity as required by 45 CFR 46.115, which include copies of all research proposals reviewed, minutes of meetings, and copies of correspondence between the Board and investigators.

J. Implementation

1. Research Approval Form

The principal research investigator shall complete and submit a “Proposed Research Approval Form” (hereafter referred to as the Proposal) to the Board. Proposals should conform to the format in Appendix A of this memorandum and should be professionally prepared. Proposals submitted by undergraduate and graduate students must be sponsored by a member of the faculty. The faculty sponsor shall submit a “statement of approval,” which describes the nature of the project, faculty member’s relationship to the project (e.g. instructor, thesis chair), and procedures for monitoring student work on the project.

2. Proposal Review Process

a. Meeting Schedule and Submission Deadline

The Board shall meet at least once per month while the University is in regular session to review proposals; a schedule of meeting dates and deadlines will be publicly disseminated before the second week of each semester. The Board will be convened during the summer months at the discretion of the Board Chairperson as need dictates. Proposals shall be submitted to the Chairperson of the Board not less than eight working days (Monday-Friday) before the published meeting dates of the Board.

b. Review Process and Outcomes

The Chairperson of the Board shall distribute proposals to each member for full Board review. Meetings at which the proposal is reviewed require that a majority of the Board members be present. The Board shall reach the following approval decisions:

Unconditional Approval: At least two-thirds majority of present voting members find the proposal acceptable and in compliance with the policies of this memorandum within changes or modifications.

Conditional Approval: At least a two-thirds majority of present voting members approve some elements of the proposed project and require that modifications or corrections be made in other elements to bring it into compliance with specific policies. A project that is conditionally approved may begin its approved elements; the remainder of the project may continue when full approval is granted by the Board.

Exemption: A two-thirds majority of present voting members may determine that the proposed research is exempt from further review consistent with the exemption policies in section II.D of this memorandum.

Rejection: A proposal that is not unconditionally approved, conditionally approved, or exempted will be rejected. A specification of the reasons for rejection will be included with this outcome.

A researcher may testify and present other evidence in support of their proposal at the Board review. The Chairperson should be notified in writing at the time of submission if the researcher wishes to appear before the Board.

The Board shall inform the principal researcher in writing of the action taken within one week of the review date.

c. Appeals

A researcher may appeal a Board decision and appear before the Board for a second hearing for reconsideration. A modified proposal may be submitted for the reconsideration hearing. If the initial decision of the Board is not changed in the second hearing, the researcher may appeal to the SVPAA. The Chairperson shall act as the Board representative in any further proceedings, and will submit a report to the SVPAA that will include a history of the case, decisions of the Board and reasons for denial or modification. The SVPAA will review the procedures used to reach the decision and confer with the Board for reconsideration. Note that 45 CFR 46.112 states that further review by officials of the University may not result in approval of research if it has not been approved by the Board.

d. Review Criteria

In order to approve research covered by these regulations the Board shall determine that all of the following requirements are satisfied:

1) Risks

The proposed research must demonstrate that it complies with the risk policy described in section II.G above. Estimates of risk to human subject should be articulated and substantiated where possible, and must rise above mere speculation and conjecture. Assessments of risk should also be confirmed to actual “human subjects” as defined in section II.C.2 above.

2) Informed Consent

The proposed research must demonstrate that the requirements for informed consent detailed below have been met for all elements of the research that require informed consent.

(a) Elements: The following basic elements of informed consent shall be communicated to each subject, and shall be in language understandable to the subject (45 CFR 46.116[a]):

(1) A statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject’s participation, a description of the procedures to be followed, 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 that may reasonable be expected from the research.
 - (4) A disclosure of 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 medical (or psychological) 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 subject's rights, and whom to contact in the event of a research related injury to the subject.
 - (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 (during the research) without penalty or loss to benefits to which the subject is otherwise entitled.
- (b) Procedures: The informed consent procedure used in the proposed research must be approved by the Board and shall consist of any of the following:
- (1) A written consent document that embodies the elements of informed consent, and which is read and signed by each subject;
or
 - (2) A "short form" written consent document stating that the elements of informed consent have been presented orally to each subject. "Short Form" consent must be signed by subject.
 - (3) An alternative informed consent procedure provided that the research adequately documents that the research could not be carried out without the alteration. Alternative informed consent may include a waiver if the following conditions apply:
 - i) the research involves no more than minimal risk to the subjects, and;
 - ii) the waiver or alternation will not adversely affect the rights and welfare of the subjects, and;

iii) the research could not practically be carried out without the waiver or alteration, and;

iv) whenever possible, the subjects will be provided with additional pertinent information after participation.

e. Confidentiality Requirements

The proposed research must make adequate provisions to maintain the confidentiality of data and to ensure the privacy of individual subjects.

f. Researcher Feedback

The proposed research must make an adequate and meaningful attempt to allow subjects access to information about the project and their participation. Feedback shall be in the form of a written summary outlining the subject's participation in the research for projects that require a signed informed consent form. Research that does not require a signed informed consent form should make a reasonable effort to inform subjects of mechanisms by which they may learn more about the research if they so request.

3. *Compliance*

a. Binding Nature of Board Decisions: The research investigator shall comply with all Board decisions, conditions, and requirements.

b. Changes and Modifications: It is the responsibility of the researcher to report in writing any changes in research that might occur after approval has been granted. The researcher must report changes in a timely fashion and comply with all monitoring requirements imposed by the Board when the proposal was approved.

c. Complaints about Violations: Complaints from the general community about violations of these policies or a particular project may be submitted to the Board for investigation. If allegations are substantiated, the Board shall proceed with following:

- 1) Hold a hearing to reconsider the proposal if the complaints concern an approved project; all affected research activities must be halted until the matter is resolved. The researcher must be present at this hearing; if the researcher refuses to participate, the case will be referred to the Associate Vice President for Research.
- 2) Conduct a hearing to determine further action for those projects that have not been reviewed or approved by the Board. The researcher must be present at this hearing; if the researcher refuses to participate, the case will be referred to the Associate Vice President for Research.

- 3) In all cases, notify the researcher in writing to discontinue the research, and notify in writing the researcher's Department Chair and College Dean, the Associate Vice President for Research, and the SVPAA that an order to cease research has been issued.

d. Sanction Procedures: Violation of any policies and requirements of this memorandum shall first be heard before the Board. In cases where Board action is not effective or appropriate, the researcher or Board may appeal to the Senior Vice President of Academic Affairs and Dean of the Faculty. If no satisfactory resolution results, the researcher or Board may appeal to the President of the University.

Board Membership Requirements

Membership in the Board shall conform to the rules for membership in Institutional Research Boards established by 45 CFR 46.107, as summarized below:

1. The Board shall be composed of two representatives from each undergraduate College, and shall have no fewer than five members. The Board shall be sufficiently qualified through the experience and expertise of its members, the diversity of the members' backgrounds, and sensitivity of members to such issues as community attitudes and respect for the rights and welfare of human subjects.
2. The Board shall be composed of members who have sufficient professional competence necessary to review specific research activities. The Board must also have members able to ascertain the acceptability of proposed research in terms of institutional commitments, applicable law, and standards of professional conduct and practice.
3. If the Board reviews projects involving a category of vulnerable subjects, it may invite one or more individuals who have primary concern for the welfare of these subject to assist with the review, if at least two members of the Board request such representation. These individuals may not vote with the Board.
4. The Board shall include both male and female members representing a variety of professions. At least one member whose primary expertise is in a non-scientific area shall be included.
5. Board members who have a conflict of interest regarding a specific project may not participate in the review of said project.
6. The Board may, upon the request of at least two members, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available to the Board. These individuals may not vote with the Board.

Appendix A Research Proposal Format

All proposals submitted to the Institutional Review Board for review shall be professionally prepared and conform to the following format:

1. Names(s), title(s), address(es), and telephone number(s) of investigator(s).
2. Project title.
3. Proposed starting and ending dates of the research.
4. Purpose of the research.
5. Statement of the research problem.
6. Detailed description of the research design (e.g. survey, experiment, observation, etc.) Attach copies of any instrument(s) to be used.
7. Description of the study population, sampling methodology, and criteria for selection of subjects.
8. Your assessment of the risks and potential benefits to human subjects. Refer to section *Definitions* above for definition of “minimal risk” and “human subject.”
9. Informed consent procedure. Refer to section above on **Review Criteria** for informed consent requirements and format. (Attach copy of form if applicable.)
10. Describe procedures for insuring the confidentiality of data and anonymity of subjects.
11. Feedback sheet or explanation of procedures for subject feedback. (Attach feedback sheet if applicable.)
12. Other documentation that the researcher feels would help the Board better evaluate the proposal.
13. Statement of compliance. The following statement of compliance must appear on all proposals submitted for review:

To the best of my knowledge, the plan of conduct for this research conforms with the policies and procedures for the use of human subjects at Norwich University.

Signature of the Researcher(s)

Date

14. Faculty sponsor statement of approval. Faculty sponsors of student research must submit an approval statement that describes the nature of the project, the faculty member's relationship to the project (e.g. instructor, thesis chair), and procedures for monitoring student work on the project. The faculty sponsor must also include the following statement of compliance in their approval:

To the best of my knowledge, the plan of conduct for this research conforms with the policies and procedures for the use of human subjects at Norwich University

Signature of the Researcher(s)

Date

Department(s)

All proposals must be submitted to the Chairperson of the Institutional Review Board not less than eight working days (Monday-Friday) before the published meeting dates of the Board.

September 1, 2014