Nebraska Wesleyan University
Institutional Review Board
Policies and Procedures

NEBRASKA
WESLEYAN
UNIVERSITY

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POLICIES AND PROCEDURES
FOR RESEARCH INVOLVING HUMAN SUBJECTS
NEBRASKA WESLEYAN UNIVERSITY
(Updated 10/30/2016)

I. STATEMENT OF PRINCIPLES

Nebraska Wesleyan University is dedicated to the protection of the rights and welfare of all human subjects participating in research sponsored by the University. The University is guided by the ethical principles regarding research involving human subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (the "*Belmont Report,*" http://ohsr.od.nih.gov/guidelines/belmont.html).
(Conforms to §46.103)

All human subjects research will be conducted in accordance with federal, state and local law utilizing the guidelines established in Title 45, Part §46 of the Code of Federal Regulations (referred to as "45 CFR §46"). The main body of this document refers to Subpart A, the Basic Policy for Protection of Human Subjects according to the Department of Health and Human Services. A set of appendices provide additional detail from Subparts B, C and D (vulnerable populations).

Honesty and Integrity. Investigators should be honest in their research and in their responses to the actions of other investigators. This principle applies to all research related activities, including experimental design, generating and analyzing data, publishing results, and acknowledging the direct and indirect contributions of colleagues, collaborators, and others. Investigators shall not engage in plagiarism, piracy, the fabrication of results, or infringement of intellectual property. The commission of any of these acts is regarded as a serious disciplinary offense. Investigators must also declare and manage any real or potential conflicts of interest.

Openness and Accountability. While recognizing the need to protect intellectual property rights, University College encourages all investigators to be as open as possible in discussing their work with others inside and outside the academy. Once results have been published, University College expects investigators to make relevant data and materials available where practical to other investigators, consistent with any third-party consents covering the data and the intellectual property rights of any third parties.

Professional Guidance. University College expects investigators to observe the standards of practice set out in guidelines published by recognized academic, scientific, and professional bodies. All investigators should be aware of the legal requirements affecting their work such as health and safety legislation; legislation regulating the collection, use, and publication of data; and data protection. Academic advisors are responsible for ensuring student investigators have requisite training and information to ensure projects can be carried out safely and ethically.

II. STATEMENT OF INSTITUTIONAL POLICY

Nebraska Wesleyan University bears full responsibility for complying with the federal requirements set forth in Title 45, Part §46 of the *Code of Federal Regulations* (45 CFR §46) as well as any state or local laws as they may relate to research involving human subjects as defined in this policy, without regard to funding source.

In accord with 45 CFR §46, Nebraska Wesleyan has established and will maintain the Nebraska Wesleyan University Institutional Review Board (NWU-IRB), which has the responsibility and authority to review in advance any research activities involving human subjects according to the definitions stated here, and to approve, disapprove, or require changes in such proposed or existing research activities. Approval must be granted by the NWU-IRB before contact is initiated with potential subjects.

The scope of human subjects research activity that is subject to review by the NWU-IRB include the following:

a. the research is sponsored by Nebraska Wesleyan University (NWU),
b. the research is conducted by or under the direction of any employee or agent of NWU in connection with his or her institutional responsibilities,
c. the research is conducted by or under the direction of any employee or agent of NWU using any property or facility of NWU,
d. the research involves the use of NWU's nonpublic information to identify or contact human research subjects or prospective subjects,
e. the research is conducted by or under the direction of any employee or agent of NWU and takes place within a foreign country.

In any case, no research activities involving investigational drugs or devices may be conducted at, by, or in affiliation with Nebraska Wesleyan University.

As a service to the Nebraska Wesleyan University community, the NWU-IRB may on occasion choose to accept requests from faculty or staff to review proposed activities by students which lie outside the definition of research "designed to develop or contribute to generalizable knowledge" as stated below. Examples include projects undertaken for completion of master's degree requirements at NWU, and undergraduate projects which have clear potential for dissemination outside of NWU.

III. DEFINITIONS OF TERMS

Agents of Nebraska Wesleyan University refers to individuals who act on behalf of NWU, exercise institutional authority or responsibility, or perform institutionally designated activities. "Employees and agents" can include faculty, staff, students, volunteers and contractors whether or not the individual is receiving compensation.

Research means 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. (§46.102)

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through *intervention* or *interaction* with the individual or (b) *identifiable private information*. (§46.102)

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. (§46.102)

Interaction includes communication or interpersonal contact between investigator and subject. (§46.102)

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). (§46.102)

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 what is defined as "research involving human subjects."* (§46.102)

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (§46.102)

Vulnerable Populations refers to categories of potential research subjects for which special considerations are required, such as children, prisoners, and pregnant women. This document covers in detail only Subpart A regarding basic rules for general populations, which includes considerations for handicapped or mentally disabled adults who may have legal guardians. **Three appendices to this document provide detailed additional requirements found in 45 CFR §46 Subpart B (pregnant women), Subpart C (prisoners), and Subpart D (children). [Note: For research purposes in Nebraska, individuals under the age of 19 are considered children and the consent of a parent or guardian must be obtained before inviting them to participate in research; the child's assent must also be obtained. This is important because some students are under the age of 19 and cannot participate in research without parent/guardian consent.]**

Additional terms related to conduct of research

Informed consent means the knowing, legally effective consent of an 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.

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as consent.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research procedure(s).

IV. AUTHORITY AND RESPONSIBILITY OF THE NWU-IRB

The NWU-IRB shall have the responsibility to review and the authority to approve, require modification of or disapprove all research activities covered by this policy. As a body the NWU-IRB reports to the Provost.

The NWU-IRB acts on behalf of Nebraska Wesleyan University, but the research activities it has approved may be subject to further review and approval by the President of Nebraska Wesleyan University on behalf of the Board of Governors. However, neither the President nor the Board of Governors may approve research that has not been approved by the NWU-IRB. (§46.112)

The NWU-IRB must be prepared to receive and act on information regarding research underway that is received from a variety of sources, such as human subjects, research investigators, NWU personnel and community collaborators. The NWU-IRB shall have the authority to observe or have a third party observe any research activities. In cases deemed appropriate by the NWU-IRB Chair, information shall be reported to the Provost.

The NWU-IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the NWU-IRB decisions, conditions and requirements or research that has been associated with unexpected serious harm to subjects. Any suspension or termination shall include a statement of the reasons for the NWU-IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and to any federal funders or oversight agencies. (§46.113)

General criteria for NWU-IRB approval of research (§46.111).

(a) In order to approve research covered by this policy the NWU-IRB shall determine that all of the following requirements are satisfied:
  (1) 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.
  (2) 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.
  (3) 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.
  (4) 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 §46.116.
  (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
  (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
  (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects 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 have been included in the study to protect the rights and welfare of these subjects (conforming with federal requirements in 45 CFR Part §46 Subparts B, C, or D). *Researchers who wish to involve vulnerable populations in their projects must have had advanced discussion with the IRB before submitting an application.*

Note that the need for safeguards extends also to the potential effect of subject vs. authority-figure relationships, such as when subjects are students of a faculty member who is also the research investigator, or the subjects are medical patients who may view a health care provider inviting their participation as an authority figure. Subjects in such situations need clear assurance of their right to decline participation without consequences.

V. STRUCTURE OF THE NWU INSTITUTIONAL REVIEW BOARD (§46.107)

The NWU-IRB shall be comprised of a minimum of five members appointed by the Provost for three-year (36-month) terms. The IRB operates 12 months per year with the opening of the academic year in August considered as the first month of a year.

The IRB members will elect a Chair for a term of 12 months. The Chair of the NWU-IRB will remain abreast of policy changes made by federal, state and local agencies so as to ensure compliance with regulatory requirements. Overall the NWU-IRB shall be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds (including consideration of gender, racial, and cultural backgrounds and sensitivity to such issues as community attitudes) to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

As a group, the NWU-IRB shall include NWU faculty in varying academic fields with professional competence to promote complete and adequate review of research activities covered by this policy. The composition of the IRB must include at least one member in a scientific field and at least one member in a non-scientific field. One of the members must be a person not otherwise affiliated with Nebraska Wesleyan University and not part of the immediate family of a person affiliated with Nebraska Wesleyan University. The membership may not consist entirely of men or of women, or entirely of members of one profession.

All members of the NWU-IRB shall complete the same type of training in the protection of human subjects which is required of proposed research investigators who make applications for approval research activities. Documentation of completion will be maintained in NWU-IRB records.

As needed, the NWU-IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond that of the current membership, but these individuals may not vote with the IRB. An example may be the review of research involving a category of vulnerable subjects (e.g., prisoners, children, individuals institutionalized as mentally disabled). (§46.107f)

Role of the Coordinator as administrator of the NWU-IRB

Upon appointment by the Provost, an employee of NWU will serve as Coordinator to provide administrative support to the NWU-IRB, working closely with the NWU-IRB chair to ensure institutional compliance for record-keeping, reporting, and communications with multiple parties as required of NWU by 45 CFR §46.

The Coordinator acts as the intake supervisor for applications, and makes the initial screening of application to ensure that all required elements are included. The Coordinator may communicate directly with applicants and/or their faculty sponsors to address omissions and resubmit. He or she will maintain a log of complete applications eligible for review and forward

completed applications to the NWU-IRB chair.

The Coordinator is authorized to make the initial screening of an application's eligibility for exempt status, and to recommend to the NWU-IRB chair that exempt status be verified and documented. The Coordinator also may screen applications for cooperative projects in which another institution's IRB has already provided primary approval, and recommend to the NWU-IRB chair that approval be awarded based on that documentation.

The Coordinator is not a member of the NWU-IRB and has no voting privileges.

VI. RESPONSIBILITIES OF RESEARCH INVESTIGATORS

Research investigators may be NWU students with a faculty sponsor, faculty members or staff members, or other employees or agents of NWU as defined.

Prior to interacting with potential human subjects in research as defined by this policy, research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that all pertinent laws and regulations are observed. The same responsibilities are in place in when activities are underway which were not initially defined as research and intended to involve human subjects, but now have those characteristics which require approval through the NWU-IRB. (§46.119)

Research investigators are responsible for submitting formal applications for approval of their research plan, containing all required elements and in the format prescribed by the NWU-IRB, including signature of a faculty sponsor if they are students. After approval is granted, researchers are responsible for conducting activities as they were proposed and approved, and for complying with all NWU-IRB decisions, conditions and requirements, including in cases where the research holds exempt status under 45 CFR §46.101. Any injury to human subjects or unforeseen problems involving risks must be reported immediately in writing to the Provost and to the NWU-IRB.

Research investigators must seek approval for proposed changes to activities which affect the involvement of human subjects. Changes may not be implemented without approval of the NWU-IRB except when necessary to eliminate apparent immediate hazards to the subjects. (§46.103b, 4 & 5). In such a case, documentation of the hazard eliminated and the steps taken to eliminate the hazard must be forwarded immediately by the researcher to the NWU-IRB.

Notice of completion. To facilitate NWU-IRB record-keeping, research investigators and/or their faculty sponsors should notify the NWU-IRB upon conclusion of an approved project, or when an approved project has been significantly postponed or abandoned.

Retention of research documents. Research investigators shall retain copies of all consent documents (and assent documents) for a minimum of **three years** after the completion of the

research. If the research investigator is a student, the faculty sponsor is responsible for maintenance of these records for three years. If the research investigator is a faculty member who leaves the institution within this period, all records must be forwarded to the NWU-IRB for retention. (§46.115b)

Researchers in cooperative projects. Research investigators whose projects will be conducted in affiliation or in cooperation with another institution may be allowed to request NWU-IRB approval based on documentation of approval by the other institution's IRB. (§46.114)

VII. DEFINITIONS AND REQUIREMENTS FOR INFORMED CONSENT

General requirements for Informed Consent (§46.116)

In accord with 45 CFR §46.116, no subject may be involved in research which is subject to NWU-IRB oversight (as defined by this policy) without the legally effective informed consent of the subject or the subject's legally authorized representative. Research investigators are responsible for obtaining the subject's informed consent and for insuring that no human subject will be involved in the research prior to the obtaining of the consent. In all cases informed consent shall conform to the following:

a. The information given to the subject, or to the subject's legally authorized representative, must be in a language understandable to the subject or the representative;
b. It must be obtained under circumstances that offer sufficient opportunity for the subject to freely consider whether or not to participate;
c. It must not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the University or its agents from liability for negligence.

Researchers who anticipate projects using subjects who represent Vulnerable Populations (children who are not NWU college students, pregnant women, prisoners,) must meet with the IRB well in advance of the application process for a discussion of additional requirements documented in §46 CFR 45 Subparts B, C, and D.

NOTE: College students in Nebraska who are under age 19 years are minors (i.e. children) according to the State of Nebraska. Researchers planning to use NWU students as subjects must either prevent the participation of students under age 19 or must include procedures to gain and document parent/guardian permission for those students under 19 before they can participate. Once parent/guardian permission is granted, the researcher must also attain the assent of the NWU student who is under 19. (Children are defined in the federal regulations as "persons who have 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." 45 CFR §46.402 a.)

College students of any age as subjects. Special steps must be taken when students in a class are also being asked to participate as subjects in a research project. Students must be assured of their rights to decline participation without consequences, such as through the following means:

a. Participation in the research cannot be a course requirement. Students may be asked to complete the activity as a course requirement or class activity, but they have the right to say they do not want their data utilized within the research, and are thus not participants;
b. If the researcher is also the instructor for the course, a different person needs to explain the research project to the class and obtain the informed consent documents from the students to assure confidentiality and lack of coercion to participate.
c. For projects which are conducted in class, but which are not part of the class requirements, the Informed Consent Form must state that refusal to participate will not affect a student's grade in the class. Further, the form needs to describe the alternative activity that will be made available; and
d. If extra credit is given for participation, alternatives for extra credit must also be provided.

Basic Elements of Informed Consent (§46.116 a)

Unless waived by the NWU-IRB as explained in Section VIII below, research investigators shall provide the following information to each subject:

(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 which may reasonably be expected from the research;
(4) A disclosure of appropriate alternative procedures, 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/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
(7) Identification of the responsible investigator and the investigator's sponsoring institution, and 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;
(8) A statement that participation is voluntary, and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled;
(9) A statement that participants must be at least 19 years of age or older, or have parental permission to participate.
(10) The following statement will be included in ALL written informed consent forms (including

letters): *This research project has been reviewed and approved by the Nebraska Wesleyan University Institutional Review Board. To ask questions about your rights as a research participant, you may contact the NWU-IRB by calling _____, Coordinator, at 402-465-xxxx.*

Additional Elements of Informed Consent (§46.116 b)

In some cases, the research investigator shall also provide one or more of the following additional elements of information to each subject:

(1) A statement that the particular activity may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;
(3) Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
(6) The approximate number of subjects involved in the study;
(7) A description of any photographing, audio taping or videotaping that will occur with specificity;
(8) If information from any records, such as, patient charts, historical documents, etc. will be used in the study, say so clearly. Provide a description of the records as well as a description of the information that will be sought.

Consent for Anonymous Questionnaires

Certain types of survey research use anonymous surveys that are returned by mail or delivered through a means that ensures that the identity of the subject remains individually unknown to the investigator. With prior approval by the NWU-IRB, the researcher may fulfill the requirements of informed consent by providing the subject with a cover letter or set of instructions that includes the following items:

a. An explanation of the research project, its purpose and duration of participation time;
b. An offer to answer questions concerning the project and information on how to contact the investigator;
c. A statement indicating anonymity; and
d. Indication that the return of the questionnaire will constitute the subject's consent to participate. A statement that participation is voluntary must be included.
e. *This research project has been reviewed and approved by the Nebraska Wesleyan University Institutional Review Board. To ask questions about your rights as a research participant, you may contact the NWU-IRB by calling _____, Coordinator, at 402-465-xxxx.*

Situations in which Informed Consent Requirements may be Altered or Waived by the NWU-IRB (§46.116 c & d)

(§46.116 c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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; and
(2) The research could not practicably be carried out without the waiver or alteration.

(§46.116 d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

NOTE: The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective. Furthermore, nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. (§46.116-e-f)

VIII. DOCUMENTATION STANDARDS FOR INFORMED CONSENT (§46.117)

Research investigators shall be responsible for ensuring that each subject's informed consent is documented by the use of a written consent form approved by the NWU-IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the NWU-IRB. A copy of the consent form shall be supplied to each person signing the form.

Two types of consent forms are possible and may be proposed for NWU-IRB approval **(§46.117b)**:

(1) A written consent document that embodies the elements of informed consent required by 45 CFR §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it, or

(2) A "short form" written consent document stating that the elements of informed consent required by 45 CFR §46.116 have been presented orally to the subject or the subject's legally authorized representative. When the "short form" is used, research investigators shall ensure that:
- the written summary of what is to be said to the subject or the representative has received the prior approval of the NWU-IRB;
- a witness is present at the oral presentation and signs both the short form and a copy of the written summary of the oral presentation;
- the short form is signed by the subject or the representative;
- the person obtaining consent signs a copy of the summary; and
- a copy of both the short form and summary is given to the subject or the representative.

Documentation of informed consent regarding protected health information

If research requires use or disclosure of protected health information for which a subject's authorization or a waiver is required under the Health Information Portability and Accountability Act (HIPAA), the research investigator must submit an appropriate form for NWU-IRB approval as part of application materials. Investigator requests for waivers or alterations of the patient authorization requirements under HIPAA will be reviewed by the NWU-IRB using these procedures, as modified to reflect the applicable HIPAA regulations.

Situations where documentation of Informed Consent may be waived by the NWU-IRB (§46.117c)

§46.117c An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) 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.

IX. DEFINITIONS OF TYPES OF REVIEW

All recommendations and determinations made by the NWU-IRB are based in the Criteria (§46.111) found in Section IV "Authority and Responsibility of the NWU-IRB." The content of proposed research plans will determine what extent of review must take place:

Type #1: Exempt from formal review

Type #2: Eligible for Expedited Review

Type #3: Requires "Full Review"

Type #1: Exempt status

Exempt status is not a review but is a determination of status made by the NWU-IRB chair and/or an agent of the NWU-IRB (the Coordinator) that a proposed project is exempt from the formal review process. Such projects pose minimal risk, meaning that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Projects which involve "vulnerable populations" (children, pregnant women, prisoners) are never given exempt status.

For general populations of participants, identified categories which are considered exempt include the following, but the research investigator is responsible for providing proposed plans in enough detail that the eligibility for Exempt status is clear.

Identified categories of projects which are Exempt: (§46.101b)

(1) 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.

(2) 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 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.

(3) 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 paragraph (b)(2) of this section, 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.

(4) 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.

(5) 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.

(6) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service

Type #2: Expedited Review

Expedited review may be used by the NWU-IRB when the research activities present no more than minimal risk and involve only the following procedures which are named in the Federal Register: 63 FR 60364-60367, November 9, 1998: (http://www.hhs.gov/ohrp/news/federal-register-notices/federal-register-11-09-1998-vol-63-no-216/index.html#)

Categories of research that may be reviewed through an expedited review procedure:

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR §46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver alteration, or exception) apply regardless of the type of review utilized, whether expedited review or full review.

(F) Categories one (1) through seven (7) pertain to both initial review and continuing IRB review.

Research Categories
(http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html)

(NWU DOES NOT SUPPORT RESEARCH PROJECTS IN CATEGORY 1)

1. [NOT PERMITTED AT NWU] Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   a. [NOT PERMITTED AT NWU] Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b. [NOT PERMITTED AT NWU] Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a. 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

   b. from other adults and children, considering the age, weight, and health 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.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) 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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. 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. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR §46.101(b)(4).This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. 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. (NOTE: Some research in this category may be exempt from the HHS

regulations for the protection of human subjects. 45 CFR §46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Type #3: Full formal review

Full formal review will be used by the NWU-IRB when the research activities proposed do not allow for expedited review and are not exempt from review.

X. PROCEDURES FOR RESEARCH INVESTIGATORS

Application Process [this process is a to-do list which can be revised]

1) Researchers must provide proof of training about the rights and welfare of human participants in research. This training can be obtained through one of the following:
    - The National Institutes of Health (NIH) on-line training module "Protecting Human Research Participants" located at http://phrp.nihtraining.com. This training module is free and will take 2 to 3 hours to complete.
    - The Collaborative Institutional Training Initiative (CITI) on-line training module located at https://www.citiprogram.org/index.cfm?pageID=88. NWU is not a subscribing organization for CITI so there is a charge for this training module unless the researcher has other organizational affiliations that are subscribers.

2) Create research plan (protocol) for the project.

3) Create all applicable supporting documents (site permission letter, data collection tools, informed consent documents, invitations to participate, etc.)

4) Determine whether or not protocol meets exempt and/or expedited review status.

5) If applicable, secure letters of permission from authors of data collection tools; letters of cooperation from community partners; signed confidentiality agreements.

6) Complete application and all attachments.

7) Review all documents with for accuracy and completeness. Students must work through this process with a faculty advisor.

8) Sign and date the application – signature(s) of researcher(s) and from faculty advisor, if student. Combine all pieces of the application into a single pdf.

9) The faculty advisor (not student researcher) is authorized to submit the single pdf to the NWU-IRB Coordinator via e-mail to complete the application process.

Proposed changes to approved research

Any changes to an approved research protocol must be approved by the NWU-IRB. The PI should submit an Amendment application to the Coordinator prior to making any changes to the protocol. This includes, but is not limited to any changes in personnel, research methods or procedures, research subjects, data collection instruments, and/or informed consent forms.

Requests for Reconsideration

When a research investigator chooses to question a decision made by the NWU-IRB, the investigator shall submit a written request for reconsideration to the Coordinator with justification. The research investigator shall have the right to be present at a meeting convened for the reconsideration of his/her proposal.

XI. PROCEDURES FOR NWU-IRB CONSIDERATION OF APPLICATIONS

Nebraska Wesleyan will ensure that the NWU-IRB has a sufficient roster of qualified members, meeting space, and sufficient staff support through actions of the Provost.

The Coordinator will record and screen all incoming applications, and forward the complete applications to the IRB Chair.

The following procedures relate to applications for research limited to general populations as required by the Federal Code of Regulations, 45 CFR §46, subpart A. The NWU-IRB's review of applications for research involving Vulnerable Populations (children, pregnant women,

prisoners) will be subject to additional requirements as included in the Federal Code of Regulations, 45 CFR §46 sub-parts B, C, and D. *Research investigators and their faculty sponsors must have thoroughly reviewed Subparts B, C, and/or D and held prior discussion with the NWU-IRB prior to preparing and submitting applications which involve Vulnerable Populations.*

In all cases of consideration and review, the NWU-IRB will determine whether a project that is approved will require continuing review more often than annually, as appropriate to the degree of risk.

For consideration of projects with Exempt status

In cases of Exempt, the Chair will determine/confirm this status and instruct the Coordinator to communicate this status to the research investigator. If the Chair has a potential conflict of interest, the Chair shall designate another NWU-IRB member to determine/confirm the exempt status.

For consideration of projects eligible for Expedited Review

In cases eligible for Expedited Review, the Chair will review the application and engage one other IRB member to also review. No member may take part in review of a project in which they have a potential conflict of interest. The Chair will determine whether consensus has been reached regarding approval or to request changes. The Chair will inform the Coordinator what members provided review and to communicate findings to the research investigator. Approval is awarded for a maximum of 12 months unless the Chair determines more frequent review is required based on the degree of risk.

If approval is not awarded through Expedited Review, the Chair will advance the application to the level of Full Review.

For consideration of projects requiring Full Review

For conduct of a Full Review, the Chair will convene a meeting of all NWU-IRB members and must ensure that a majority of the members are in attendance including a member with non-scientific background. No member may take part in review of a project in which they have a potential conflict of interest. Members will be provided all materials in advance of the meeting.

The Coordinator will take minutes of the meeting which documents the attendance, actions, actual votes by each member present, the basis for any required changes or a disapproval, and a summary of any discussion of controversial elements and the group's resolution of them.

During Full Review, an approval may be awarded by a majority of the members present. On behalf of the NWU-IRB, the Coordinator will issue a letter of approval to the research investigator (and faculty sponsor).

If a Full Review results in modifications being required to gain approval, the Coordinator will issue a letter to the research investigator on behalf of the NWU-IRB, outlining these requirements and indicating how the researcher may resubmit the application.

If a Full Review results in disapproval, the Coordinator will issue a letter to the research investigator on behalf of the NWU-IRB, which includes the reasons for disapproval and offers the opportunity for the researcher to respond in writing or in person during a subsequent meeting of the NWU-IRB which may be convened by the Chair for that purpose.

Procedure for Continuing Review of ongoing approved projects

A continuing review of ongoing research shall be conducted as a Full Review at a convened meeting, regardless of whether the original approval had resulted from an Expedited or Full Review.

As part of a continuing review, the IRB Chair will determine whether a project needs verification from sources other than the research investigator that no material changes have occurred since prior review. No NWU-IRB member may participate in continuing review of a project in which the member has a conflict of interest. A continuing review shall be conducted at convened meetings and at timely intervals.

XII. RECORD-KEEPING REQUIREMENTS AND PROCEDURES

The Chair of the NWU-IRB shall ensure the maintenance of adequate documentation of NWU-IRB activities, normally with the assistance of the Coordinator.

Records relating to a specific research activity shall be maintained for at least 3 years after termination of the last NWU-IRB approval period for the activity. These records include:

a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by research investigators and reports of injuries to subjects.

b. Copies of all correspondence between the NWU-IRB and the research investigators.

c. Records of continuing review activities.

d. Any statements of significant new findings provided to subjects, as required by 45 CFR §46.116 (b) (5).

Additional records shall be maintained in detail as follows:

a. Written procedures for the NWU-IRB as required by 45 CFR §46.103 (b)(4) and (b)(5).

b. A list of NWU-IRB members as required by 45 CFR §46.103 (b)(3).

c. Minutes of NWU-IRB meetings. Minutes shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the NWU-IRB; the vote of these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports with opinions. If a member in attendance has a conflicting interest regarding any project and therefore did not participate in a review, minutes shall show that this member did not participate in the review, except to provide information requested by the NWU-IRB. These records shall be maintained for a period of at least 3 years after termination of an NWU-IRB approval period for a research activity discussed in the minutes.

NWU-IRB records of research funded by federal agencies or departments shall be accessible for inspection and copying by authorized federal representatives at reasonable times and in a reasonable manner, or shall be copied and forwarded to the appropriate federal agency or department when requested by authorized representatives.

APPENDICES

APPENDIX I – Research Involving Pregnant Women, Human Fetuses, and Neonates

Subpart B: Additional Protection for Pregnant Women, Human fetuses and Neonates
CFR Title 45, Part §46, Subpart B

The Nebraska Wesleyan University Institutional Review Board (NWU-IRB) will abide by these regulations in considering applications for human subjects review involving subjects as described in CFR Title 45, Part §46, Subpart B

§46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at §46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of §46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in §46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.202 Definitions.

The definitions in §46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.
(c) Fetus means the product of conception from implantation until delivery.
(d) Neonate means a newborn.
(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.
(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
(c) Any risk is the least possible for achieving the objectives of the research;
(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.205 Research involving neonates.

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
  (1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
  (2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
  (3) Individuals engaged in the research will have no part in determining the viability of a neonate.
  (4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:
  (1) The IRB determines that:
    (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
    (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
  (2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:
  (1) Vital functions of the neonate will not be artificially maintained;
  (2) The research will not terminate the heartbeat or respiration of the neonate;
  (3) There will be no added risk to the neonate resulting from the research;
  (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §46.204 or §46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and
(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:
    (1) That the research in fact satisfies the conditions of §46.204, as applicable; or
    (2) The following:
        (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
        (ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

APPENDIX II – Subpart C: Research Involving Prisoners

Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
CFR Title 45, Part §46, Subpart C

The Nebraska Wesleyan University Institutional Review Board (NWU-IRB) will abide by these regulations in considering applications for human subjects review involving subjects as described in CFR Title 45, Part §46, Subpart C.

§46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.
(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.
(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.

As used in this subpart:
(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
(b) *DHHS* means the Department of Health and Human Services.
(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at §46 FR 8366, Jan. 26, 1981]

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:
    (1) The research under review represents one of the categories of research permissible under §46.306(a)(2);
    (2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
    (3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
    (4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
    (5) The information is presented in language which is understandable to the subject population;
    (6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
    (7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.
(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:
  (1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and
  (2) In the judgment of the Secretary the proposed research involves solely the following:
    (i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    (ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
    (iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
    (iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

APPENDIX III – Subpart D: Research Involving Children

Subpart D: Additional Protections Pertaining to Children Involved as Subjects in Research CFR Title 45, Part §46, Subpart D

The Nebraska Wesleyan University Institutional Review Board (NWU-IRB) will abide by these regulations in considering applications for human subjects review involving subjects as described in CFR Title 45, Part §46, Subpart D.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.
   (1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.
   (2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of §46.101 of subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of subpart A are applicable to this subpart.

[48 FR 9818, Mar.8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991.]

§46.402 Definitions.

The definitions in §46.102 of subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are persons who have 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.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;
(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;
(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
    (1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or
    (2) the following:
        (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
        (ii) the research will be conducted in accordance with sound ethical principles;
        (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.
(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may

find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and §46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:
(1) Related to their status as wards; or
(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.