Updated 4/16/2024

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 4/16/2024)

I. STATEMENT OF PRINCIPLES

A. Introduction: 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)

B. **Federal, State, and Local Laws:** 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 HHS 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).

C. **Ethical Principles:** These regulations employ the ethical principles from the Belmont Report as well as other virtues of ethical research in the following ways:

(1) *Respect for Persons:* 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.

a. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

b. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

c. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired

decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(2) *Beneficence:* 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.

a. 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 NWU-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 NWU-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.

b. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

c. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(3) *Justice:* 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, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) *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.

(5) *Openness and Accountability.* While recognizing the need to protect intellectual property rights, Nebraska Wesleyan University 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, NWU 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.

(6) *Professional Guidance.* NWU 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

A. Institutional Responsibility: 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. No retroactive approvals will be granted.

B. Scope of Review Responsibilities: The scope of human subject research activity that is subject to review by the NWU-IRB include the following:

(1) The research is sponsored by Nebraska Wesleyan University (NWU),

(2) The research is conducted by or under the direction of any employee or agent of NWU in connection with his or her institutional responsibilities,

(3) The research is conducted by or under the direction of any employee or agent of NWU using any property or facility of NWU,

(4) The research involves the use of NWU's nonpublic information to identify or contact human research subjects or prospective subjects,

(5) The research is conducted by or under the direction of any employee or agent of NWU and takes place within a foreign country.

C. External Site Research: Research involving II (B)(3)(4) conducted by an entity external to NWU, at minimum, is required to a review by the IRB Chair and Provost or IO. Where appropriate, site permission will be granted pending NWU-IRB review of the submitted application after approval of an external institution IRB review. If NWU is *engaged* in the research, then steps pertaining to cooperative research (VIII. Cooperative Research) must be considered.

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

E. Discretionary NWU-IRB Review: 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

A. 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.

B. Research means a systematic investigation, including research development,

testing and evaluation, designed to develop or contribute to generalizable knowledge. There is no regulatory guidance on the meaning of "generalizability." The essential consideration is whether it was the researcher's *intent* to contribute to a body of knowledge or whether the results were replicable. Activities that 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) This definition was revised in the 2018 Requirements version of the Common Rule to specifically exclude the following activities:

(1) Scholarly and journalistic activities (for example, oral history, journalism, biography, literary criticism, legal research, and historical scholarship)

(2) Public health surveillance activities

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order or criminal investigative purposes

(4) Authorized intelligence, homeland security, defense, or national security mission operational activities.

C. Human Subject is defined as a "living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." (45 CFR 46.102 Protection of Human Subjects 2018)

(1) *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (§46.102)

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

(3) *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). (§46.102)

(4) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (§46.102)

D. Engaged applies to activities that have been determined to be research involving human subjects that are not exempt under HHS regulations at 45 CFR 46.101 (B). NWU is engaged in research when its employees or agents for the purposes of the research project obtain:

(1) data about the subjects of the research through intervention or interaction with them.

(2) identifiable private information about the subjects of the research.

(3) the informed consent of human subjects for the research.

E. 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)

F. 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. **Appendices I-III to this document provide detailed additional requirements found in 45 CFR §46 Subpart B (pregnant women, human fetuses and neonates), 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.]**

G. 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.

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

I. 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

A. Authority of 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. The Provost is responsible for the oversight of the NWU-IRB per the authority of the Institutional President, identified herein as the Institutional Officer (IO). Investigators may need approval from other institutional committees before applying for review by NWU-IRB.

(1) 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.

(2) 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)

B. Authority NWU President and Board of Governors: 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 the research that has not been approved by the NWU-IRB. (§46.112)

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

a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

b. 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 NWU-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 NWU-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 NWU-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, Individuals with impaired decision-making capacity, 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, or appropriately waived 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.

a. The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(8) For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (1) through (7) of this section, and shall make the following determinations:

a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d);

b. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and

c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(9) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, 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.*

(10) NOTE: 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. OFFICE OF HUMAN RESEARCH PROTECTIONS (OHRP) IRB REGISTRATION (APPENDIX IV: SUBPART E)

A. OHRP NWU-IRB Registration: The NWU-IRB must follow registration and reporting requirements of the Office of Human Research Protections (OHRP). The NWU-IRB shall remain aware of any changes to registration or reporting requirements. After initial registration, the NWU-IRB must renew regularly following acceptance by OHRP. Updates to the registration must be made (§46.505):

(a) Within the allotted time frame after changes regarding the contact person who provided the IRB registration information or the IRB chairperson. Updates also include changes to the Provost or IO.

(b) Within the allotted time frame of a change in membership roster of the NWU-IRB.

(c) Within the allotted time frame after permanent cessation of the IRB's review of HHS-conducted or –supported research if the NWU-IRB decides to disband. A written notification must be submitted to OHRP for this matter.

B. Update or Renew an IRB Registration (Appendix IV - Subpart E: Requirements for IRB Registration):

(1) The IRB designated contact will need to know:

a. The IORG number

b. Last name of the IO, as of the most recent registration

c. Last name of the first IRB's Chairperson, as of the most recent registration

(2) Federal Wide Assurance (FWA) registration and any subsequent updates must be approved by OHRP to conduct any research conducted or supported by an U.S. federal department or agency that has adopted the Common Rule,

unless the research is otherwise exempt from the requirements of the Common Rule or a U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance. For FWA, federally-supported means the U.S. Government providing any funding or other support (§46.103).

a. NWU-IRB must renew its FWA regularly per OHRP guidelines, even if no changes have occurred, to maintain an active FWA.

b. NWU-IRB must update its FWA within the time allotted after changes occur regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official.

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

A. NWU-IRB Membership: 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.

(1) *Committee Make-Up:* 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. A list of members must be maintained that contains: Names, experience, earned degrees, type of member, and employment or other relationship with NWU.

(2) *Member Training:* All members of the NWU-IRB shall complete the CITI training for IRB members and will complete any further training as deemed appropriate. The NWU-IRB Chair will also complete the CITI IRB Chair training and must have at least one-year of experience on the NWU-IRB before being elected. Documentation of completion will be

maintained in NWU-IRB records.

(3) *Conflict of Interest:* No member of the NWU-IRB may participate in the initial or continuing review of any project in which the member has a conflict of interest, except to provide information requested by the NWU-IRB.

(4) *Use of External Experts:* 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 with impaired decision making capacity). (§46.107(e))

C. NWU-IRB Chair: The IRB Chair will be appointed by the Provost or IO for a term of 12 months. To be eligible, the Chair must be an IRB member for at least one year. The Chair of the NWU-IRB will complete CITI training for IRB chairs and 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.

D. 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.

(a) *In-Take Supervisor:* 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.

(b) *Initial Screening of Applications:* 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 and may recommend entering into a joint review arrangement, relying on the review of another IRB, or make similar arrangements for avoiding duplication of effort. (§46.114)

(c) *NWU-IRB Meeting Minutes:* The Coordinator will maintain minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. The Coordinator is not a member of the NWU-IRB and has no voting privileges. (§46.115)

(d) *Training and OHRP registration:* The Coordinator shall assist the IRB Chair with maintaining a record of IRB member training certificates and notifying members of training renewal. The Coordinator will update OHRP registration with any changes and complete renewals when applicable.

E. Convened Meetings: The IRB will meet at least biannually in accordance with the academic semester calendar. Minutes must be taken during full board meetings and include the following:

(a) Specific information on the research reviewed (NWU IRB#, type of review) and voted on by the IRB

(b) Reflect the activities and actions of the IRB

(c) A record of those in attendance and the manner of attendance; with a note on absent members. For virtual attendance, members must be in view of their cameras at all times, refrain from outside distractions throughout the meeting, and actively engage through audio capabilities.

(d) An indication that a quorum was established wherein the majority of members were in attendance.

(e) Sufficient information to reflect the arrivals and departures of members, particularly as it pertains to maintaining a quorum throughout the meeting. If a quorum is lost, this is reflected in the minutes and votes cease.

During the biannual meetings or as needed due to research applications, the board will:

(1) complete Full Board Reviews and vote to approve, approve with conditions, disapprove, or table the research for a future discussion with justification

(2) discuss Disapprovals and/or Requests for Reconsideration

(3) annually review NWU-IRB Policy and Procedures and make any necessary revisions. Any revisions to the Policy and Procedures will be reviewed by the Provost or IO before implementation.

VII. RESPONSIBILITIES OF RESEARCH INVESTIGATORS

A. 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.

B. Ethical Considerations Prior to Research: 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 when activities are underway that 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)

C. Submit Application: 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. For any electronic digital signatures, the date must be captured and recorded to verify the information is true and complete. 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 §46.104. Any injury to human subjects or unforeseen problems involving risks must be reported immediately in writing to the Provost and to the NWU-IRB.

D. Changes in Research: 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, the investigator shall cease all research activities and contact the NWU IRB documenting the hazard and the steps taken to eliminate the hazard

E. Notice of completion. To facilitate NWU-IRB record-keeping, research investigators and/or their faculty sponsors must notify the NWU-IRB upon conclusion of an approved project, or when an approved project has been significantly postponed or abandoned. The investigators will provide notification once data collection is complete or upon the approved expiration date of the project, whichever is first. The expiration date will be determined based on reasonableness of the end date relevant to the academic term(s) noted on the application but no more than one year upon approval.

F. 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)

VIII. COOPERATIVE RESEARCH (§46.114)

A. Cooperative Research: Cooperative research projects are non-exempt, not including limited review, projects covered by this policy that involve more than one institution *engaged* in the research. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

B. Reliance Agreement (AKA: Authorization Agreement or Cede Review Agreement): Required for cooperative research wherein the document is signed by all institutions *engaged* in the research §46.114(b)(1). The agreement documents the obligations and responsibilities of the relying institution. A single IRB (reviewing IRB) will be identified as the IRB of record on behalf of one or more institutions with the agreement indicating the level of communication among all engaged institutions and termination circumstances and procedures. The single IRB institution is held responsible for compliance with relevant aspects of 45 CFR Part 46 in a cooperative research project. The relying institutions agree to rely on the single IRB. The agreement may include a single study or multiple. For multiple study agreements, consideration is needed for the extent of the authority. The IO or designee must approve any reliance agreement. The following are points of consideration as noted by the Secretary's Advisory Committee on Human Research Protections (SACHRP) in identifying a single IRB; this is not an exhaustive list:

(1) Expertise and experience of the reviewing (single) IRB

(2) If ceding review is mandatory or optional

(3) Potential risks to participants

(4) Financial implications or funding source

C. The following research is not subject to this provision §46.114(b)(2)**:**

(1) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(2) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(3) For research not involving a Federal department or agency, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

IX. INTERNATIONAL RESEARCH

A. Research engaged with or by faculty, students, or staff of NWU must submit an application for IRB review. Each country poses unique challenges and ethical requirements needing consideration. For any research involving a country outside of the U.S.:

(1) An application must be submitted in sufficient time for review before leaving the U.S. or engaging in research with another country.

(2) The investigator needs to display cultural awareness of the country and population under study. The investigator will relay their familiarity with customs, culture, language, laws, and religious norms. An awareness will relay an understanding of any potential harms and benefits for the participants engaged in the study. The awareness needs to be reflected in all aspects of the study to include recruitment, informed consent, data collection, and data storage. Consideration for the safety of the investigator and efforts to mitigate any risks to them while conducting the research.

(3) The investigator needs to display an understanding and awareness of data storage and maintenance challenges as different countries have norms or laws related to data collection techniques and transporting of data. The research shall clearly relay an understanding of these norms and the challenges associated with maintaining data obtained from or with another country.

(4) The investigator will review the ethical guidelines of the host country as it relates to human subjects research. This understanding will be relayed clearly in the research elements aligned with relevant ethical standards. Investigators are encouraged to review the OHRP International Compilation of Human Research Standards for guidance on regulations and norms of the listed countries.

(5) Researchers must maintain communication with the NWU IRB per approval guidelines. Any sites in the country engaged in research will need appropriate permissions. An approval letter from a local IRB or ethics review committee in that country may be required.

B. The researchers shall disclose the funding source for any international research. If any element of the research or program under research is funded by a U.S. government agency or affiliate, additional approvals must be obtained.

X. DEFINITIONS AND REQUIREMENTS FOR INFORMED CONSENT

A. General Requirements for Informed Consent (§46.116a): General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth below:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language or format understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with the policy set forth below:

a. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

b. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that

does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

B. Vulnerable Populations: Researchers who anticipate projects using subjects who represent Vulnerable Populations (children who are not NWU college students, individuals with impaired decision-making capacity, 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.

(1) *Nebraska Age of Consent:* **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.) Hence, if research is occurring in a jurisdiction other than the state of Nebraska, then the local laws governing age of consent will apply.

(2) *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 that are conducted in class, but 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 or course credit is given for participation, alternatives for credit must also be provided. A description must be provided as to the number of credits and the process by which credits will be awarded.

C. Basic Elements of Informed Consent (§46.116b): Unless waived by the NWU-IRB as explained in Section VIII below, research investigators shall provide the following information to each subject or their legally authorized representative.

(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.

a. Monetary or nonmonetary compensation or reimbursement is not considered a benefit to participants to include course credit or gift cards. Compensation must be clearly communicated in the recruitment materials and informed consent to include the amount, an indication that any compensation or reimbursement is equitable among all participants and respectful of their time, and if prorate, the process is explained in a manner that is not offensive to participant time and effort in completing the study while considering the level of participation and withdrawal at any point;

(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 (if the study is conducted in the state of Nebraska. If the study occurs outside Nebraska, then the age of consent in that jurisdiction should be inserted).

(10) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(11) The following statement will be included in ALL informed consent forms

(including electronic and 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 at irb@nebrwesleyan.edu.*

D. Additional Elements of Informed Consent (§46.116c): Except in cases of broad consent or waivers of consent, the research investigator shall, in some cases, also provide one or more of the following additional elements of informed consent to each subject or the legally authorized representative.

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's or the legally authorized representative'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 statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline

or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

E. Elements of Broad Consent (§46.116d): Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements set forth above. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The following information must be included in all broad consent documents:

a. A description of any reasonably foreseeable risks or discomforts to the subject.

b. A description of any benefits to the subject or to others which may reasonably be expected from the research;

c. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

d. 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;

(2) When appropriate, the following information should also be provided to each subject or the legally authorized representative:

a. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

b. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(3) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description

must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(4) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(5) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(6) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(7) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(8) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of research-related harm.

F. 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:

(1) An explanation of the research project, its purpose and duration of participation time;

(2) An offer to answer questions concerning the project and information on how to contact the investigator;

(3) A statement indicating anonymity; and

(4) Indication that the return of the questionnaire will constitute the subject's consent to participate. A statement that participation is voluntary must be included.

(5) If the survey or questionnaire is conducted electronically through email or a social media platform, then a statement indicating that no information that can be used to identify an applicant, such as an IP address, will be collected.

(6) *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 at irb@nebrwesleyan.edu.*

G. Situations in which Informed Consent Requirements may be Altered or Waived by the NWU-IRB (§46.116 e-f): 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. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements set forth above, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(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 (§46.116 e (3) i A-D):

a. public benefit or service programs;

b. procedures for obtaining benefits or services under those programs;

c. possible changes in or alternatives to those programs or procedures; or

d. possible changes in methods or levels of payment for benefits or services under those programs; and

e. The research could not practicably be carried out without the waiver or alteration (§46.116 e (3) ii)

(2) 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. An IRB may not omit or alter any of the requirements described in the General Elements of Informed Consent set forth above. If a broad consent procedure is used, an IRB may not omit or alter any of the requirements above (§46.116 f)

a. The research involves no more than minimal risk to the subjects;

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

c. The research could not practicably be carried out without the waiver or alteration;

d. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

H. Informed Consent, Federal, State and Local Law, and Emergency Care: 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 h (3) ii)

XI. DOCUMENTATION STANDARDS FOR INFORMED CONSENT (§46.117)

A. Documentation: 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 authorized (physical signature or electronic

confirmation) by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the NWU-IRB. For electronic digital signatures, the date must be captured and recorded to verify authorization. When applicable, the investigators will provide a version in a language or format understandable to the subject or the legally authorized representative. A copy of the consent form shall be supplied to each person signing the form (§46.117a).

B. Two Types of Consent 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 this form may be read to the subject or the subject's legally authorized representative (§46.117b (1)):

(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 and that the key information required by (§46.116(a) (5)) was presented first to the subject, before other information, if any, was provided: When the "short form" is used, research investigators shall ensure that:

a. the written summary of what is to be said to the subject or the subjects legally authorized representative has received the prior approval of the NWU-IRB;

b. 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;

c. the short form is signed by the subject or the subject's legally authorized representative;

d. the person obtaining consent signs a copy of the summary; and

e. a copy of both the short form and summary is given to the subject or the subject's legally authorized representative.

C. Documentation of informed consent regarding protected information:

a. *Health Information Portability and Accountability Act (HIPAA):* 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 their 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.

b. *Federal Educational Rights and Privacy Act (FERPA):* Research requiring the use of grades (points, percentages, scales, etc.) or disclosure of educational records must obtain consent or assent specifically identifying the information requested. The investigator will communicate efforts to minimize risk and maintain confidentiality of the information.

D. Documentation of informed consent involving Artificial Intelligence (A.I.) or Third-Party software:

a. *Artificial Intelligence (A.I.) or Machine Learning (M.L.)*: As noted by the Secretary's Advisory Committee on Human Research Protections (SACHRP), A.I. research may be compliant but not necessarily adequate in protecting the rights and welfare of participants. If A.I. or a M.L. tool is used to interact with, analyze, or gather data from participants, then an NWU-IRB review is required. The extent of A.I. or M.L. shall be explained in the informed consent and any risks associated with such use. The informed consent will reflect efforts to minimize risks and maintain confidentiality.

b. *Third-party software*: Any research involving third-party companies (Qualtrics, SurveyMonkey, Otter, etc.) must be reviewed by the NWU-IRB. The application will clearly explain the intended use of the software and reflect the investigator's understanding of confidentiality when using the software and the data security/protection and privacy policies for the company relevant to the software. The extent of use, to include data collection and maintenance, will be described in the informed consent and reflect any risks associated with using the software. Risks include default collection of identifiable data or storage of data for future third-party use. The informed consent will include efforts to minimize the risks and

maintain confidentiality.

E. Situations where documentation of Informed Consent may be waived by the NWU-IRB An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either (§46.117c (1)):

(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.

(3) If the subject or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(4) 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.

XII. DEFINITIONS OF TYPES OF REVIEW

A. Three Types of NWU-IRB 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" of these policies. Each of three review types will be discussed in turn below. These types are: Exempt from formal review, Expedited Review, and Full Board Review

B. 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.

(1) *Exemption and Vulnerable Populations***:** Use of the exemption categories with respect to "vulnerable populations" for research subject to the requirements of subparts B (Pregnant Woman), C (Prisoners), and D (Children): Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) Subpart B (Pregnant Women): Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) Subpart C (Prisoners). The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) Subpart D (Children). The exemption categories (1), (4), (5), (6), (7), and (8) below may be applied to research subject to subpart D if the conditions of the exemption are met. Exempt categories (2)(i) and (ii) only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exempt category (2)(iii) below may NOT be applied to research subject to subpart D.

(2) *General Populations*: 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.

(3) *Identified categories of projects which are Exempt (§46.104d)*: NOTE: This list of exempt categories below is taken directly from the aforementioned federal regulation and, therefore, the list does not follow the format commonly used in these policies but follows the format of the regulation itself.

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special

education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3) (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal

or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(1) (i) The identifiable private information or identifiable biospecimens are publicly available;

(2) (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when

that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health

(3) activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected

(4) subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be

published on this list prior to commencing the research involving human subjects.

(6) Taste and food quality evaluation and consumer acceptance studies:

(1) (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

(2) of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d) (See Section VIII of these Policies);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not

prevent an investigator from abiding by any legal requirements to return individual research results.

B. **Expedited Review (CFR §46.110b-d):** An IRB may use the expedited review procedure to review the following:

(1) Some or all of the research appearing on the list described in this section below, **unless the reviewer determines that the study involves more than minimal risk**;

(2) Minor changes in previously approved research during the period for which approval is authorized;

(3) Research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

C. Expedited IRB Processing: Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. The NWU-IRB typically has at least two members review expedited applications. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in §46.108(b).

(1) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

(2) The federal department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

D. **Applicability of NWU-IRB's Expedited Review Process**:

(1) Research activities that present no more than minimal risk to human subjects, and 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.

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

(3) 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.

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

(5) 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.

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

E. Expedited Research Categories: Categories for expedited review are listed below. They are not formatted as commonly found in these policies but are formatted as they are found at the following federal websites: **(http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html)** 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#

(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.

F. Full Board 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 either because the proposed study does not satisfy any of the categories for exempt status or expedited review, or if the proposed study is determined to be more than minimal risk.

XIII. PROCEDURES FOR RESEARCH INVESTIGATORS

A. Researcher Training: IRB applications require a copy of a certificate demonstrating the completion of "protection of human subjects training" for all project personnel, including students and faculty sponsors, through the Collaborative Institutional Training Initiative (CITI). Accepting certificates from other training providers will be at the discretion of the NWU-IRB Chair such as those from Protecting Human Research Participants. NWU provides access to CITI for campus members free of charge. Please see the IRB webpage on the NWU website for links and instructions to the specific training certifications. Training must be renewed every three years.

B. Application: All projects subject to NWU-IRB review must complete the application form and include all relevant supporting material as found on the checklist on the final page of the application. Faculty sponsoring student research are responsible for ensuring the accuracy, consistency, and overall quality of the

NWU-IRB application. Please complete the application in accordance with the instructions below. Please save all documents as a single pdf and submit the completed application to irb@nebrwesleyan.edu.

(1) *Cover Page:* Please be sure to fill in all of the information for your study on this page. This is a reference page with important information for identifying your study and for our records. It is also important that all investigators – principal investigator, co-investigators, and faculty sponsors – sign the application. Faculty sponsors are required for research involving an NWU student principal investigator. Electronic digital signatures must capture and record the date the information is verified as true and complete.

(2) *Background:* Please provide a brief summary of your research project, including review of relevant academic studies, rationale, objectives/purposes, and/or major hypothesis(es). Please include a list of academic references as an attachment. NOTE: Please try to keep your description to 1-2 single-spaced pages. Also please write it with the layperson in mind. This is of particular importance when the research concerns medical or other natural scientific projects. It should also be consistent with the description provided in the informed consent document.

(3) *Sample Studied – Sample Selection Process***:** Describe the population to be studied and information on selecting of your sample. Explain how participants will be recruited into your study. Include copies of any recruitment emails, letters, etc. as an appendix.

(4) *Procedures for Data Collection***:** Provide information on the nature of the participants' involvement, their time commitment, etc., include a copy of your data collection instrument(s) as an appendix.

(5) *Site Permission:* If you are collecting data at a place of business/organization, you must also include a signed and dated site permission letter indicating that you are allowed to conduct research at/with members of that business/organization. This does not include informal meetings with research participants in public places such as coffee shops, etc. The faculty sponsor or investigator is unable to grant site permission. If the department chair is the faculty sponsor or investigator, then the division chair will review and authorize the site permission.

(6) *Risks to Research Participants:* Provide information on any physical, social, or psychological risks that could be experienced by the research participants in this study. Describe any special arrangements to protect their safety, including protecting their privacy and confidentiality.

(7) *Storage and Protection of Data***:** Specify where and how both physical/paper and electronic data will be stored and protected so as to ensure participants' privacy and confidentiality. NWU policy requires that all data be kept in a secure location for a minimum of three years after study completion.

(8) *Describe Benefits to Participants***:** Provide information on any direct benefits, such as payments, gift cards, reimbursement for travel, etc., and any indirect benefits that may result from participating in the study. This does not include benefits to the larger research community, outside agencies, etc. This question is in regard to benefits to the participant. The process and specific benefits must be clearly explained to the participant.

(9) *Informed Consent Procedures***:** Describe how informed consent is to be obtained and documented. If your research takes place in the state of Nebraska, then prospective participants must be 19 years of age or older to provide informed consent. If prospective participants are 18 years of age or younger, then parental consent and youth assent forms must be used. However, if the research is being conducted outside Nebraska, then the local laws governing age of consent will apply. You should follow the instructions found on the Informed Consent template on the NWU-IRB webpage and the criteria listed in these policies.

(10) *Funding:* Disclose the funding source for any aspect of the research requiring such. For any research funded by a grant, detail the grant and elements approved by the grant funds. Any research funded by a U.S. government agency or affiliate shall obtain appropriate approvals before applying to the NWU IRB for review.

C. Amending a Study: Sometimes studies take an unexpected turn such that the research protocol, e.g. sample selection, data collection, and/or informed consent processes, need to change in order for the project to continue. In this case, the NWU-IRB must be notified of the change and an Application Amendment form must be submitted for IRB review at: irb@nebrwesleyan.edu. The project cannot continue until the amendment(s) receive NWU-IRB approval. 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. Any change to the approved research timeline to include postponement or abandonment, must be authorized by the NWU-IRB prior to the approved project expiration date. Retroactive approval of amendments will not be granted as a new application must be submitted.

D. **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.

E. **Project Completion:** Once a study is complete, the principle investigator and faculty sponsor (when applicable) must complete a Research Completion Notification form by the assigned end date and submit it to the NWU-IRB coordinator at irb@nebrwesleyan.edu.

XIV. PROCEDURES FOR NWU-IRB CONSIDERATION OF APPLICATIONS

A. **Introduction:** 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 following procedures relate to applications for research limited to general populations as required by the Federal Code of Regulations, 45 CFR §46. 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.

B. **Application Review Process:** Applications will be reviewed in the order received and with consideration to the type of review (exempt, expedited, full-board). Applicants must plan sufficient time for the review process, approximately one month, from initial submission to final NWU-IRB approval, excluding academic breaks. All NWU-IRB applications will be reviewed through the following process:

(1) *Complete Application:* Complete the application described above. Be sure that the principal investigator, all co-investigators, and all faculty sponsors sign the form. Also make sure that the application is accompanied by all required appendices, and that the application and the materials in the appendices are consistent. Please submit your application via email to irb@nebrwesleyan.edu.

(2) *IRB Coordinator Review***:** The IRB Coordinator will review your application for completeness. If the application is found to be incomplete, it will be sent back to the applicant with a list of what still needs to be included. Once the application is complete, the IRB Coordinator will assign an NWU IRB reference number. The number will be included in all communications relevant to the project and a record of communication will be maintained. The Coordinator will process the application and pass it on to the IRB Chair for review.

(3) *IRB Review:* Applications are submitted under one of three categories: Exempt, Expedited, and Full Board Review. Exempt applications are reviewed by the IRB Chair. Other NWU-IRB members may review Exempt applications at the discretion of the chair. Expedited applications are reviewed by two IRB members. The Chair, however, is ultimately responsible for confirming the findings of other IRB members for exempt and expedited review. Applications requiring full board review will be reviewed by all IRB members at a convened meeting. In this case, the decision is based on a majority vote. Please see below for further explanation of full board review procedures.

(4) *IRB Decision***:** Upon review, applications will receive a memo indicating one of the following decisions: approval/certification as exempt, conditional approval, revise and resubmit, or disapproval. NOTE: Projects must receive IRB certification as exempt or approved (as defined below) before they may begin. The NWU-IRB does not issue retroactive approvals.

(a) *Certification as Exempt/Approval***:**

(1) *Exempt:* Applications that have been certified as exempt do not require IRB continuing review. Applicants will receive a memo to this effect and will include the NWU-IRB reference number. If the study is projected to exceed the expiration date, then update the NWU IRB with an amendment. Full-board continuing reviews are

not required for research beyond the expiration date unless changes are made to the approved application. Upon completion of the research, a Research Completion Notification form must be submitted.

(2) *Expedited or Full Board:* All approvals for those studies processed through expedited or full board review require IRB continuing review and are approved for no more than one year. If a study exceeds one year, then the approval must be renewed prior to the approved expiration date. All renewals require full board review. Finally, all approved projects are subject to NWU-IRB audit at the chair's discretion. Applicants should keep their certification/approval memo for their records and use their NWU-IRB reference number in further correspondence with the NWU-IRB. The NWU-IRB will also keep a copy of the memo in its files.

(b) *Conditional Approval:* An application is conditionally approved when there are minor changes necessary to approve the study or certify it as exempt. The changes are not considered significant ethical concerns but rather may be areas requiring clarification or deemed inessential. Once the changes are made, the application will be approved and a memo with the NWU-IRB reference number will be issued.

(c) *Revise and Resubmit:* An application will be sent back for revision when it needs significant changes. Once the changes are made, the application may be resubmitted for further review.

(d) *Disapproval:* A study that is found not to meet ethical standards for research and cannot be modified to do so will not receive approval. It is important to bear in mind, however, that disapproval of a study must result from a full board review.

C. Full Board 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.

(1) *Meeting Minutes:* 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.

(2) *Majority Vote:* 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 project is conditionally approved, revise and resubmit, or disapproved, the Coordinator will issue a letter to this effect with the NWU-IRB's rationale for its decision.

D. Communication: The NWU-IRB will issue memos communicating its decisions and requirements for modification. These memos will serve as documentation and will be kept in the project's file on the NWU-IRB's SharePoint site. Applicants are also encouraged to keep these memos and all other IRB communication for future reference. Please see below for further NWU-IRB record keeping requirements.

E. 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.

XV. RECORD-KEEPING REQUIREMENTS AND PROCEDURES

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

B. Documentation of Research Activity (CFR §46.115): 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:

(1) 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.

(2) Rationale for IRB decisions pertaining to exempt, expedited, or full board review

(3) Copies of all correspondence between the NWU-IRB and the research investigators.

(4) Records of continuing review activities.

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

C. Additional Records: Additional records shall be maintained in detail as follows:

(3) Written procedures for the NWU-IRB as required by 45 CFR §46.108 (a) (3)-(4)

(4) A complete and current list of NWU-IRB members.

(5) 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.

F. Federal Agencies and Departments: 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 – Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, 45 CFR part 46

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 45 CFR 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: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, 45 CFR part 46

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 45 CFR 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: Additional Protections for Children Involved as Subjects in Research, 45 CFR part 46

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 45 CFR 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

(3) 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.

APPENDIX IV – Subpart E: Registration of Institutional Review Boards, 45 CFR part 46

The Nebraska Wesleyan University Institutional Review Board (NWU-IRB) will comply with the registration requirements for research involving human subjects as described in 45 CFR part 46, Subpart E.

§46.501 What IRBs must be registered?

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§46.502 What information must be provided when registering an IRB?

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e) (1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an ``active protocol'' is any protocol for which the

IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under §46.103(a).

IRB registration becomes effective when reviewed and accepted by OHRP.

The registration will be effective for 3 years.

§46.504 How must an IRB be registered?

Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with §46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.