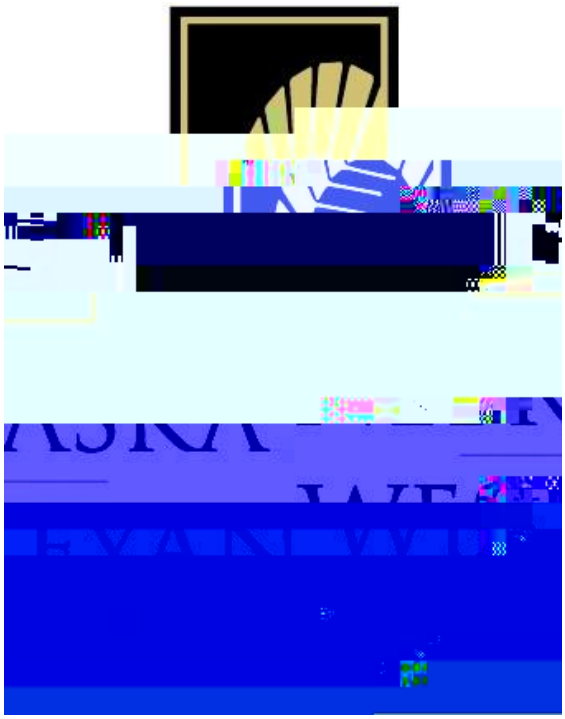
Updated 4/16/2024

Nebraska Wesleyan University
Institutional Review Board
Policies and Procedures



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 Reh Reh

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 th e 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

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(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: Researchinvolving II (B)(3)(4) conducted by an entity external to NWU, at minimum, is required to a review by the IRB Chair and

and

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*

or the individual's legally authorized representative. Such consent can be

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

(6)

unless the research is otherwise exempt from the requirements of the

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:*

(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 neededdue to research applications, the board will :

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.

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.

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.

B. The researchers shall disclose the funding source for any international research. If any element of the researchor 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.

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).

collection of identifiable private information or identifiable biospecimens:

a. A statement that identifiers might be removed from the identifiable

(including electronic and letters): *This research project*

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

(3) A statement indicating anonymity; and

(4)

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. (§46.116h (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 receivedthe prior approval of the NWU -IRB;

b. a witness is present at the oral presentationand 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 re quested. The investigator will communicate efforts to minimize risk and maintain confidentiality of the information.

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 (§46.117ɑ(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 linkin g 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.

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

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

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, r eputation, 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 HHSt

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

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*:

(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)

(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 convenedmeeting. 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. F ith an amendment

not required for research beyond the expiration date unless changes are made to the approvedapplication . Upon completion of the research, aResearch 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 renewedprior 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 studyor 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 2 7

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(1) *Meeting Minutes:* The Coordinator will take minutes of the meeting which documents the attendance, actions, actual votes by each membepresent, 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 ef the

accompany the proposals, approved sample consent documents, progress reports submitted by research investntestntestntest

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

(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

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 mini mal 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)

(a)

(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.

(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 in45 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.

(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

(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.

(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

(1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or

(2) the following:

§§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

§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