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IRB Review of Research with Human Subjects

Purpose

Northern Illinois University (NIU) has the responsibility for protecting the rights and welfare of human subjects used in research projects conducted at this institution or under the direction of any employee or agent of this institution, whether funded or not, and regardless of the source of funding. In compliance with the Department of Health and Human Services (DHHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended), and the Food and Drug Administration (FDA) regulations (21CFR 56), NIU has established one or more duly constituted Institutional Review Board(s) to review all research involving the use of human subjects and to set forth institutional policy regarding such research. These Institutional Review Boards report directly to the Vice President for Research and Innovation Partnerships.

Policy Narrative

This institution is guided by the ethical principles regarding all research involving humans as 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). These principles include:

1. **Respect for persons** (individuals should be treated as autonomous agents, subjects should enter into the research voluntarily and with adequate information, persons with diminished autonomy are entitled to protection);
2. **Beneficence** (maximize possible benefits of the research to the participants and to society while taking steps to minimize potential harm);
3. **Justice** (equitable distribution of the burdens and benefits of research).

IRB oversight ensures that the rights and welfare of human participants are protected and that the research, or FDA-regulated activity, meets institutional and regulatory requirements:

1. The Public Health Service Act (PHS) and its amendments compiled in the “Final Rule”,

45 CFR 46, Subpart A

   a. 45 CFR 46 subpart B-pregnant women, fetuses, and neonates

   b. 45 CFR 46 subpart C-prisoners

   c. 45 CFR 46 subpart D-children.

2. The Food and Drug Administration (FDA)

   a. 21 CFR 50-human subjects protections

b. 21 CFR 56-institutional review boards

c. 21 CFR 312-investigational drugs and biologics

d. 21 CFR 812-investigational devices

The IRB encourages and promotes constructive communication among the research administrators, department chairs/directors, research investigators, clinical care staff, and institutional officials, as well as the human subjects, in order to maintain a high level of awareness regarding the safeguarding of the rights and welfare of the subjects. Correspondence concerning human subjects research and requests for additional information should be directed to the IRB, in care of the Office of Research Compliance, Integrity and Safety (ORCIS), Division of Research and Innovation Partnerships.

University personnel involved in human subjects research are required to submit research protocols for review and approval to the IRB. The research may not begin without prior approval by the IRB.

I. DEFINITIONS

A. *RESEARCH*:
45 CRF 46.102(l) Common Rule- Subpart A "A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

21 CFR 50.3(g) and 21CFR 56.102(e) Food & Drug Administration "Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this regulation, regarding non-clinical laboratory studies

B. *HUMAN SUBJECT*:
45 CRF 46.102(e) Common Rule- Subpart A "A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens."

21 CFR 50.3(g) and 21CFR 56.102(e) Food & Drug Administration "An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient."

Note that the terms “human subject” and “human participant” are used interchangeably in IRB policies and procedures.

C. ***INTERVENTION***: includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

D. ***IDENTIFIABLE PRIVATE INFORMATION:*** Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

E. ***IDENTIFIABLE BIOSPECIMEN:*** A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimens.

F. ***INTERACTION*****:** includes communication or interpersonal contact between investigator and subject.

This includes online surveys.

G. ***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 identifiable information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record) as well as information provided specifically in response to data collection.

H. ***GENERALIZABLE KNOWLEDGE****:* new information that has relevance beyond the population or program from which it was collected and is intended for dissemination in any format. Knowledge that can be generalized is collected under systematic procedures that reduce bias, allowing the knowledge to be applied to populations and settings different from the ones from which it was collected.

I. ***MINIMAL RISK***: means that 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.

J. ***ASSENT***: a minor's **explicit** affirmative agreement, oral or written, to participate in research. Failure to object cannot be construed as assent.

K. ***LEGALLY AUTHORIZED REPRESENTATIVE***: "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 procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research." (45 CFR 46.102(i)).

L.*.MINOR CHANGE:* changes in the research plan which do not substantively affect the risk or benefit of the research. Minor changes may include, for example, changes in research personnel, small changes to wording of questionnaires which do not change the nature of the questions to be asked, insignificant variations to the amount of blood being drawn for a research sample, changes in presentation of materials such as interview to questionnaire format, changes which reduce the risks to participants, adding new advertisements, increasing the duration of the study.

M. *PROGRAM EVALUATION:* when the purpose of data collection is to evaluate the success of a program in achieving its objectives, and the information gained from the evaluation will be used to provide feedback to that program, the evaluation is non-research. In the non-research scenario, the evaluation is used as a management tool to monitor and improve the program. The evaluation activity is often a component of the regular, ongoing program. Information learned from the evaluation has immediate benefit for the program and/or the clients receiving the services or interventions. The information is not intended to be generalizable beyond the individual program.

N. *ANONYMITY:* pertains to data or information having no known source or having no name or identity associated with it. For research data to truly be considered anonymous, it must be impossible to trace them back to their source (the individual who provided them). Substitution of a code number, initials, pseudonym, etc. for the subject's name does not automatically anonymize the data if a mechanism exists whereby the data can be linked to the individual subject (e.g., a master list or decoding pattern). Investigators should also be aware of situations in which there is a possibility of deductive identification of otherwise anonymous subjects on the basis of separate elements of data (e.g., birthdate, occupation, and zip code). In these situations, subjects and information can only be protected by confidentiality not anonymity.

O. *CONFIDENTIALITY*: pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that his/her participation and/or information will not be divulged to others without permission in ways that are inconsistent with the understanding of the original consent. The measures taken by an investigator to protect confidentiality should be commensurate with the potential risk to research subjects that could result from a breach of confidentiality.

P. *CLINICAL INVESTIGATION (*21CFR 50.3(a)25c): for studies subject to FDA regulations, any experiment that involves a test article and one or more human subjects and that either 1) is subject to requirements for prior submission to the FDA under section 505(i) (Abbreviated New Drug Applications) or 502(g) (device exemptions) of the Food Drug and Cosmetic Act or 2) Is not subject to the requirements for prior submission but the results of the experiment are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Q. ***CLINICAL TRIAL:*** a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

II. RESEARCH SUBJECT TO IRB REVIEW

The IRBs are responsible for the review of all research or clinical investigations meeting the definition of research with human subjects (as defined in section II), regardless of funding source, in which the University is considered to be engaged in the research or clinical investigation. The University is considered to be engaged in the research project when one or more of the following apply:

1. The research is sponsored by the University

2. The research is conducted, in whole or in part, by members of the University faculty, staff or students acting in their University capacity regardless of the location of the activity, either at NIU or elsewhere in the world.

3. The University receives a direct federal award to conduct human subject research, even where all activities involving human participants are carried out by a subcontractor or collaborator.

This includes research conducted for thesis or dissertation projects that meet the definition of research with human subjects or clinical investigations. However, student projects conducted as a part of a course requirement, and which will not be used or presented outside of the classroom or department, may not require IRB review as they are unlikely to produce generalizable knowledge. However, the IRB may review student projects upon request.

The IRB is also involved in the oversight of any Investigational New Drug (IND) and Investigational Device Exemption (IDE) clinical trials conducted by University faculty, staff, and students.

Projects where Northern Illinois University faculty, staff, and students are not engaged in the research or clinical investigation, but where members of the University community are targeted as participants, and projects conducted by an agent of another institution using any of the University's property or facilities, may not be required to obtain approval by the Northern Illinois University IRB, but must obtain appropriate approvals, if applicable, from those responsible for the relevant subject population or resource.

For further information on determining when the University is engaged in research see the OHRP guidance document "Engagement of Institutions in Human Subject Research (2008.)" http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

The Northern Illinois University IRBs will ensure review of research which the University is engaged in either by conducting the review or by initiating a formal agreement to allow another IRB from an institution with a Federalwide Assurance to serve as the designated IRB of record for the research.

Northern Illinois University may also serve as the designated IRB of record for collaborative research with other Assured institutions.

Faculty, staff, retired faculty or staff, and students who are under the oversight of a faculty or staff advisor who is also listed on the protocol may submit an application to the IRB. This individual must be the point of contact. Exceptions may be made with the approval of the review board, please contact ORCIS for additional information. The IRB will evaluate whether the primary investigator for the protocol has sufficient experience and expertise to conduct the research safely and responsibly. Exceptions require the approval of the IRB.

All faculty, staff, or students who are engaged in human subjects research must complete appropriate human subjects protection training prior to conducting the research. Northern Illinois University requires the CITI online training module "Social and Behavioral Research-Basic/Refresher, Basic Course" or documented proof of equivalent training.

III. EXEMPTION FROM IRB APPROVAL CRITERIA

Certain human subjects research activities may be eligible for a determination of exempt status. In order to be considered for a determination of exempt status, the research must be covered in one or more of the categories listed below. These exemptions do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

1. Research (not regulated by the FDA) 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 (not regulated by the FDA) that only includes 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) information obtained is recorded in such a manner that human subjects cannot be readily 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.

(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 following determinations:

a. there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

b. participants are not vulnerable to coercion or undue influence to participate

c. where the subject of the survey or interview questions is potentially emotionally distressing, such as sexual assault or trauma, the consent adequately discloses the nature of the survey and/or interview questions

NOTE: **Research involving children may only be considered exempt under this category when the project is limited to normal education tests or observation of public behavior and the investigator does not participate in the activities being observed. Such research may not include prisoners as participants under the exemption.**

3. Research (not regulated by the FDA) 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:

(i) information obtained is recorded in such a manner that human subjects cannot be readily 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.

(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 following determinations:

a. there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

b. participants are not vulnerable to coercion or undue influence to participate.

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.

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 purpose of the research.

4. Secondary research (not regulated by the FDA) 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:

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

(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 HIPAA (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 45CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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 subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects (not regulated by the FDA) that are conducted or supported by a Federal department or agency, 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.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service 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 the IRB conducts a limited IRB review and makes the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements for broad

consent (see the NIU "Informed Consent for Human Research" policy for the required elements of broad consent).

(ii) Broad consent is appropriately documented, or a waiver of documentation is appropriate and approved by the IRB

(iii) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

8. Secondary research use of identifiable private information or identifiable biospecimens 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

(ii) Documentation of broad consent or waiver of documentation of consent was obtained

(iii) The IRB conducts a limited IRB review and makes the determination that (a) there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data and (b) the research to be conducted is within the scope of the types of secondary research described in the broad consent obtained when the private information or biospecimens were stored

(iv) The investigator does not include returning individual research results to the subjects as part of the study plan unless there are any legal requirements to do so.

Researchers conducting projects they believe may qualify for an exempt determination must complete an IRB application and obtain written notification from the Office of Research Compliance, Integrity, and Safety (ORCIS) before proceeding with the research. The IRB application for projects which may qualify for an exemption will be reviewed by one or more qualified reviewers who may or may not be a member of the IRB. In no case may a project be reviewed by an individual with a real or perceived conflict of interest in the research. The reviewer will determine whether or not the project meets one or more of the exemption categories defined in this policy. The exempt determination should not be made by the researcher. A copy of the IRB application and the exempt determination will be maintained in the IRB records, and members of the relevant IRB will be notified of the study's exempt status.

If a research project has been determined to be exempt, the IRB need not apply the requirements for approval described under section V. Requirements for IRB approval. Exemptions 2 (iii), 3 (iii), 7, and 8 do require limited IRB review, and the limited review requirements are specified in the exempt category descriptions above. There is no requirement for continuing review. However, if the researcher wishes to make changes to the research protocol which do not meet the definition of minor changes (see section II of this policy), or which might change the protocol in such a way that it might no longer be eligible for the exempt determination (for example, changing data collection so that data which was anonymous is now identifiable), the researcher must submit an amendment application to ORCIS. The IRB administrator will determine if further review is required.

Studies which are determined to be exempt by the IRB are still required to adhere to basic ethical principles regarding the rights and welfare of participants. Risks to participants should be minimized and investigators should obtain informed, voluntary consent from their participants. Any promises of

confidentiality that the researcher makes in the consent process should be adhered to. Exemption status also does not excuse the researcher from any other legal requirements, such as FERPA, HIPAA, PPRA, or state-mandated reporting requirements.

V. REQUIREMENTS FOR IRB APPROVAL

Projects which involve research with human subjects and do not qualify for an exempt determination will be reviewed by the IRB either through expedited review or by the convened IRB. Review will be conducted by IRB members and consultants, as needed, who have appropriate scientific or scholarly expertise for adequate review of the proposed research. Research projects must satisfy all of the following criteria to be approved:

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 knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB shall not consider long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB shall take into account the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited. The IRB will be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, 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 45 CFR 46.116 and *The Belmont Report*.

5. Informed consent will be appropriately documented in accordance with and to the extent required by 45 CFR 46.116 and 46.117.

6. Where appropriate, the research plan makes adequate provision for monitoring the data collection to ensure the safety of subjects.

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

8. Additional safeguards have been included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, persons with impaired decision-making capacity, or economically or educationally disadvantaged persons.

In addition to the eight criteria listed above, the following additional determinations will be made:

9. Projects which are receiving external funding must be congruent with the funding application(s). Any additional funding agency requirements for review must be met.

10. Any investigator or institutional conflicts of interest must be disclosed and considered de minimis, eliminated, or where found to be of significant financial interest, managed. Researchers may contact the Research Integrity Officer in the Office of Research Compliance, Integrity and Safety for guidance on conflict of interest.

11. All persons on the research team must be qualified to perform the research and have completed the required training in human subjects research protection.

12. In addition to the requirements of the Northern Illinois University IRB policy and the regulations cited in section I of this policy, research projects are required to comply with any additional applicable local, state, and/or federal laws or regulations, including HIPAA and FERPA.

VI. IRB REVIEW ACTIONS

The IRB may make the following determinations about a research protocol submission:

1. May approve the protocol as submitted

2. May conditionally approve the protocol, pending receipt of specific revisions or clarifications – the IRB may designate the IRB chair (and other members with appropriate expertise) to review the responses and determine that the conditions have been satisfied

3. May defer (table) a decision on the protocol for further review when the IRB has significant questions and/or concerns that must be addressed before a determination is made – the IRB will request revisions and clarifications which must be reviewed by the convened IRB at a future date

4. May disapprove the protocol

5. May suspend the research project or suspend the Principal Investigator's permission to conduct the research – suspension may involve all activities of the research or only certain activities

6. May terminate the protocol, ending all activities related to the research project or the permission of the Principal Investigator to conduct the human subject research

Appeals of IRB decisions should be made in writing to the IRB, via the Office of Research Compliance, Integrity and Safety. The IRB will review the appeal at the next regularly convened meeting. Should a researcher wish, the appeal may be made in person.

In addition, the IRB has the authority to:

1. Appoint one or more individuals (other than the researcher) to observe the consent process or the research procedures and report back to the IRB with any findings. The IRB may appoint such an individual whenever the IRB determines, based on information available such as unanticipated problem reports, complaints, potential conflicts of interest, deficiencies noted in IRB files, or media or scholarly reports of research activity, that monitoring is in the best interests of the human participants.

2. The IRB may appoint one or more individuals (other than the researcher) to audit protocol activities either at random or when deemed necessary to determine that no material changes have occurred since the previous IRB review.

These actions of the IRB may be in response to an initial application, an application for continuation, or an application for an amendment to a previously approved protocol.

In addition, the Institutional Official or designee has the authority to review and approve part or all of a research protocol in an ad hoc fashion if the study is not federally funded and the project pertains to an ongoing public health concern.

VII. EXPEDITED REVIEW

Certain research protocols may not require review by a fully convened IRB and may be reviewed by one or more experienced IRB members (typically the IRB chair or vice chair and additional members as needed) through an expedited review process. Investigators submitting research proposals that they believe may qualify for expedited review must complete the same application and provide the same information as that required for convened IRB review. All of the requirements in section V. of this policy

must be met. The expedited reviewer(s) may make any of the determinations described in section VI. with the exception that a study cannot be disapproved through the expedited review process. The expedited reviewer may ask for consultation from other IRB members or from consultants or may refer the protocol for convened review if in his/her opinion the expertise of the full board would provide a more comprehensive review.

The following categories of research submissions may be considered for expedited review:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   (a) 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) 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 children1[1], 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.

1[1]Children are defined in the HHS 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 46.401(a).

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

Examples: (a) hair and nail clippings in a non-disfiguring 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 gum-base 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.)

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (This rule applies if the data are not anonymous)

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.

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.

10. Minor changes proposed for previously approved research during the period (one year or less) for which approval is authorized. Changes which significantly increase risk or decrease benefit are not minor changes.

11. Research reviewed by the convened IRB which has been conditionally approved pending one or more specific minor revisions, and the review is to confirm that the requested changes were implemented

or an IRB-determined acceptable justification for not implementing the change(s) has been provided by the Principal Investigator.

When the Subcommittee Review procedure is used, all members of the IRB shall be advised of research proposals which have been approved under this procedure by listing these proposals on the next agenda of the convened IRB meeting. At a convened IRB meeting, any member may request that an activity that has been approved under the Subcommittee Review procedure be reviewed by the IRB in accordance with Full Board Review procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. The determination of the IRB will be conveyed to the researcher and the department following the meeting.

XIII. FULL BOARD REVIEW

When the IRB chair has received a research proposal involving more than minimal risk to the subjects or that does not fall within the exempt or expedited review categories, the proposal is referred for review by the IRB at a convened meeting.

Research protocols scheduled for review shall be distributed by ORCIS staff to all members of the IRB approximately one week prior to the meeting. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.

A majority of the voting membership of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the IRB can conduct its review of research. For a research protocol to be approved it must receive the approval of a majority of those voting members present at the convened meeting. No IRB member may participate in the IRB's initial or continuing review or vote on any project in which the member has an interest, except to provide information requested by the IRB. The determination of the IRB will be conveyed, in writing, to the researcher and the department following the meeting.

Research protocols are typically approved for a period not to exceed 365 days from the original date of review. In some cases, such as projects that are especially complex or present high-risk to subjects or projects that are proposed by researchers with a history of repeated noncompliance, the IRB may elect to approve the project for a period of less than 365 days.

In cases where research activities were initially approved under Subcommittee Review procedures and subsequently reviewed by Full Review procedures, the decisions reached at the convened meeting shall supersede any decisions made through the Subcommittee Review.

IX. CONTINUING REVIEW

The IRB will conduct continuing review of research requiring review by the convened IRB (Full Board Review) or by expedited IRB review at intervals appropriate to the degree of risk, not less than once per year. Unless the IRB determines otherwise, continuing review of research is **not** required in the following circumstances:

1. The research was determined to be exempt or exempt with limited IRB review.

2. The research has progressed to the point that it involves only analysis of de-identified information or biospecimens.

For those projects requiring continuing review, researchers should submit an application for continuation of approval in a timely manner to avoid interruption of their data collection. ORCIS will send the necessary form to the investigator a minimum of one month prior to the expiration date. Data collection must stop at the conclusion of the approval period until continuation of approval is granted by the IRB. If IRB approval lapses for longer than 30 days without response from the principal investigator, IRB approval of the protocol will be administratively terminated. Reactivation of the protocol may require the submission of a new IRB application.

As part of the continuing review process, the investigator is expected to provide a progress report to the IRB. This information is requested as part of the "Continuation of Approval" form. The progress report should include the following information:

1. number of subjects accrued;

2. unanticipated problems and adverse events*;

3. withdrawals and dropouts*;

4. subject complaints*;

5. summary of recent literature relevant to the research published since the last progress report that might impact subject risk;

6. request for amendments, if any, prior to their implementation;

7. changes in sponsor or study personnel including verification of training of new personnel;

8. any other information the investigator believes to be relevant.

* The number of subjects affected as well as an explanation should be provided if this event has occurred.

The IRB may also request verification from sources in addition to the investigator that no material changes have occurred since previous IRB review if the project is especially complex or presents high-risk to subjects or if the project is conducted by a researcher with a history of repeated noncompliance.

Applications for continuation will be reviewed by the appropriate review method, either administrative, expedited, or full board review. Continuing review for projects which do not require review by the convened IRB AND which do not have any federal funding may be reviewed administratively by ORCIS staff with appropriate training and experience.

X. REVIEW OF AMENDMENTS

Proposed changes (amendments) to an approved research project must be promptly reported to the IRB. Approval by the IRB must be obtained before the change to the research protocol is implemented. Examples of amendments that may be made include changes in questionnaires or interview questions, alterations to recruitment materials or consent forms, changes in research procedures or their duration or frequency, changes in study sites or populations recruited, or study personnel.

Minor changes may be approved by the IRB via expedited or administrative review. If a study was initially approved by expedited review, amendments which do not affect the risk/benefit assessment may also be approved by expedited review in most cases. If the amendment involves the addition of research participants or the addition or removal of co-investigators, approval will occur through administrative review. Other changes must be reviewed and approved at a convened meeting of the IRB before changes can be implemented. In the rare circumstance where a change must be made prior to IRB review to eliminate apparent immediate hazards to the research participants, the Principal Investigator must notify the IRB chair as soon as the change is made and promptly submit a written amendment for IRB review and post-facto approval.

Amendments to a research protocol may be submitted at any time during the approval period for the protocol or may be submitted in conjunction with an application for continuation.

XI. PROJECTS WITH EXTERNAL FUNDING

I. PROCEDURES FOR REVIEW OF EXTERNALLY FUNDED PROJECTS

Researchers should be aware that some agencies require institutional approval of Human Subjects research at the submission stage of a grant proposal and should allow enough time for the Institutional Review Board (IRB) to review and approve their protocol before the grant submission deadline. More often, federal, and private agencies require IRB approval before awarding a grant. The IRB application should include the Sponsored Programs Administration number assigned to the grant.

NIU may be required to certify to the funding agency, for research involving human subjects, that the institution is operating under an approved Assurance and provide certification that an appropriate Institutional Review Board has, within 12 months of the budget period start date, reviewed, and approved the proposed activity in accordance with the regulatory requirements consistent with 45 CFR Part 46. The Chair of the IRB will provide a letter of certification for submission to the funding agency at the request of Sponsored Programs Administration (SPA).

During the course of a research project, subsequent supplement certification to the agency may be required when:

1. involvement of human subjects in a project is proposed and the activity previously had only indefinite plans or no plans for the involvement of human subjects, or

2. the researcher(s) propose to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

Certain types of applications for grants, cooperative agreements, or contracts are submitted with the knowledge that human subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving human subjects remain to be selected, and projects in which human subjects' involvement will depend upon completion of instruments or other preparatory activities. These applications need not be reviewed by an IRB in order to receive a grant account. However, no research activities involving human subjects may occur until the project has been reviewed and approved by the IRB or determined to be exempt."

Agency approval may be required to change the originally approved involvement of human subjects on a project. In these instances, confirmation of agency approval is also required before the change can occur. Investigators must work with SPA to discuss prior agency approval requirements.

XII. COOPERATIVE RESEARCH AND THE USE OF IRB AUTHORIZATION AGREEMENTS AND INDIVIDUAL INVESTIGATOR AGREEMENTS

If two or more federally assured institutions collaborate on non-exempt human subject's research or on research which is exempt with limited review, the institutions may rely on a single IRB (an "IRB of record") for review and continuing oversight of the research, in order to avoid having the same project be reviewed by two or more IRBs. In order to do this, an Institutional

Authorization Agreement (IAA) must be put in place between the IRB of record and the IRBs of those institutions who will rely on it for review.

Research that is exempt and does not require limited IRB review

Collaborative research which qualifies for one of the exempt categories which does not require limited review does not require an IAA agreement. The NIU researcher may either rely on the NIU IRB office to make the exempt determination or may submit a copy of the exempt determination letter and the exempt application from the IRB of a collaborating researcher that has made the exempt determination to ORCIS and this office will verify that the exempt determination is acceptable. No further action is then required. If ORCIS does not concur that the research qualifies for one of the exemptions listed above, the application will be submitted to the NIU IRB Chair for a second opinion. If the Chair concurs that the exemption does not apply, the NIU researcher must submit a complete IRB application to the NIU IRB.

Research where NIU Personnel are the Primary Investigator which requires either limited IRB review or expedited or full board IRB review

If the primary or lead investigator for cooperative research is from NIU, the NIU IRB will generally review the project. The IRBs of the collaborating researchers' institutions have the option of initiating an IRB authorization agreement (IAA) with NIU, allowing the NIU IRB to be the IRB of record, or they may choose to have the project reviewed by their own IRB. All institutions whose personnel are engaged in the cooperative research must either have an IAA in place or have review by their own IRBs.

In some cases, even when the primary investigator is affiliated with NIU, there may be justification for NIU to rely on one of the other cooperative institution's IRB. Examples of such an instance are projects where the subject population will be drawn from the persons affiliated with the other institution, or where the other institution's IRB has expertise better suited to the research.

Research where NIU personnel are not the Primary Investigator which requires either limited IRB review or expedited or full board IRB review

If NIU faculty, students, or staff are involved in cooperative research with researchers from another institution but are not the lead investigator, NIU may initiate an IAA with the lead

investigator's IRB, allowing that IRB to provide oversight for the project. A copy of the IRB approval letter and IRB application from the IRB of record will be provided to NIU's IRB chair, who will make a determination about whether the proposed IAA is appropriate.

Cooperative Externally Funded Research

If the cooperative research is externally funded, the researcher must be sure to discuss the sponsor's IRB requirements with Sponsored Programs Administration to ensure that all sponsor IRB requirements are met.

Cooperative Research with Unaffiliated Investigators which requires either limited IRB review or expedited or full board IRB review

Unaffiliated investigators are persons who wish to collaborate with NIU faculty, students, or staff but are not affiliated with NIU or with any other institution with a FederalWide Assurance (that is, they do not have their own IRB). In order for unaffiliated investigators to collaborate on research projects with NIU faculty, students, or staff, such persons must complete an Individual Investigator Agreement (IIA), which will be provided by ORCIS.

The NIU investigator's IRB application must include the information that an unaffiliated investigator will be collaborating on the research project and should provide a summary of that person's qualifications to serve as a co-investigator on the project. Unaffiliated investigators must complete the required CITI human subjects protection training module or provide documentation of equivalent training.

As stipulated in the Individual Investigator Agreement, the unaffiliated investigator must also verify the following:

(1) The Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and

welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by the IRB.

(9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

The IIA must be completed before the project can receive IRB approval. No IIA is required for unaffiliated investigators for projects which do not require limited IRB review, expedited review, or full board review.

Procedural History of the Policy

Approved by the convened Institutional Review Board and the VP for Research in January 2021.