



National University of Health Sciences General Policies

Title: **Protection of Human Subjects
from Research Risks**

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President

Date

01-07-19

POLICY STATEMENT

National University of Health Sciences (NUHS) recognizes its responsibility to provide measures to reasonably protect individuals as subjects of research conducted under the auspices of NUHS.

Procedures

All research projects involving human subjects must be reviewed and approved by the duly constituted Institutional Review Board (IRB), except as those categorized as exempt in 45 CFR 46.104.

NUHS entrusts the investigator with primary responsibility for the protection of individuals participating in studies as human subjects. NUHS assumes its responsibility for meeting the conditions for the protection of human subjects as required by the National Research Act and implemented by the Federal Policy for Protection of Human Subjects, also known as the common rule. The common rule applies to federal departments and agencies listed below and are based on and replace subpart A of the 1981 Department of Health and Human Services regulations for the protection of human subjects. The federal agencies and departments to which the common rule applies are: Office of Science and Technology Policy, Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency and Agency for International Development, Department of Housing and Urban Development, Department of Veteran Affairs, Environmental Protection Agency, Department of Health and Human Services, Food and Drug Administration, National Science Foundation, and Department of Transportation. NUHS assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the common rule, the University will comply with the terms of the "Federal-wide Assurance for Institutions within the United States" unless the research is otherwise exempt from the requirements of the common rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance

In assuming its responsibility, NUHS intends to encourage the conduct of research, which will benefit the human condition and, at the same time, protect the rights and welfare of human subjects participating in the research, the investigators doing the research and NUHS. NUHS faculty, staff and students conducting human subject research under this policy are responsible for compliance with all federal regulations and any additional regulations required by NUHS or state and local laws or regulations that provide additional protections for human subjects.

Administration

Executive functions to be performed by NUHS include the development of policy; the continuing education of personnel with respect to policy; the modification of this policy to maintain its conformity with laws and regulations; and provision of appropriate administrative support and legal assistance for the IRB. NUHS officials

responsible for carrying out or delegating these functions are the Dean of Research, the Vice President for Academic Services and the President.

Applicability

This policy is applicable to all research involving human subjects, which is conducted under the auspices of NUHS, unless the only involvement of human subjects will be in one or more of the categories described in 45 CFR 46.104, which are exempt from this policy.

Definitions of Terms and Phrases

- A. Human Subject means a living individual (whether a member of the public, an employee of NUHS, or a student) about whom an investigator conducting research (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- B. Intervention includes both physical procedures by which data or biospecimens are gathered (for example venipuncture) and manipulations of the subject or the subjects' environment that are performed for research purposes.
- C. Interaction includes communication or interpersonal contact between investigator and subject.
- D. Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect not to be made public (for example, a medical record).
- E. Identifiable private information is private information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.
- F. Identifiable biospecimen is biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.
- G. Legally Authorized Representative means an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by NUHS as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.
- H. 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.
- I. Research means a systematic investigation including research, development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- J. Research Involving Human Subjects Under the Auspices of NUHS means the research is (i) supported externally by way of a grant, contract, or similar agreement between the sponsor (public or private) and NUHS; (ii) the research is supported internally by NUHS; (iii) the research is conducted upon assignment by NUHS; or (iv) the research is actively assisted by the use of NUHS facilities, resources, supplies, equipment or personnel.
- K. IRB means an institutional review board established in accord with and for the purposes expressed in this policy. The IRB is responsible for the review and approval of modifications for approval or disapproval of all research subject to this policy.

- L. IRB Approval means the determination of the IRB that the research has been reviewed and may be conducted under the auspices of NUHS within the constraints set forth by the IRB and by other NUHS, state, local and federal requirements.
- M. IRB Certification means the official notification by NUHS to the sponsor (public or private) that a research project or activity involving human subjects has been reviewed and approved by the IRB in accordance with an approved assurance
- N. Clinical trial means 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 the interventions on biomedical or behavioral health-related outcomes.
- O. Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.
- P. Common Rule is the Health and Human Services regulations 45 CFR part 46 subpart A "Basic HHS Policy for the Protection of Human Research Subjects"

Implementation

Determination of human research involvement shall be made by the Dean of Research and the investigator in consultation with the Chair of the IRB. This determination shall be made during the preparation of the research protocol as outlined in NUHS' "The Guide for Preparation and Processing of Human Research." The determination of exemption eligibility will be made by the Chair of the IRB, except as may be provided by other applicable state, federal or local laws. An investigator who believes his/her research is exempt under one or more of the stated exempt categories shall submit his/her written protocol to the IRB together with a statement that he/she believes it to be exempt and the reasons for such belief. The Chair of the IRB shall make a determination of exempt status under the provisions for exempt review as provided elsewhere in this policy and a written statement from the Chair of the IRB of exempt status shall be attached to the protocol and maintained in the office of the Dean of Research.

Upon determining that a proposed research project involves human subjects and that the research is not exempt from IRB review as defined in this policy, the investigator shall submit a written protocol to the IRB, which is based on the proposal for the research. The format for the protocol will be supplied by the IRB and is available in the office of the Dean of Research.

Institutional Review Board

- A. The IRB shall be composed of seven individuals including the Chair. The membership shall include NUHS faculty or professional personnel, one student and at least one member who is not otherwise affiliated with NUHS and is not part of the immediate family of a person affiliated with NUHS. The IRB shall include at least one member whose primary concerns are in a nonscientific area. All members are appointed by the President of NUHS. Faculty and public members are usually appointed for a term of three years and a member may fill succeeding terms at the pleasure of the President. The student member is appointed for a term of at least one year.

Members shall have varying backgrounds to promote complete review of research activities commonly conducted under the auspices of NUHS. The IRB shall be sufficiently qualified through the experience and expertise of its members and diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel and safeguard the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations and standards of professional conduct and practice. The IRB shall therefore either include persons knowledgeable in these areas or shall consult with appropriate NUHS administrators (President, Vice Presidents, Deans, Dean of Clinics) and the Research Committee to obtain the needed information. If

the IRB finds that it regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, considerations shall be given to including among the IRB's membership one or more individuals who are knowledgeable about and experienced in working with these subjects.

Every effort will be made to be nondiscriminatory and to ensure that the IRB does not consist entirely of men or entirely of women, including the University's consideration of qualified persons of both sexes, so long as no selection is made to the IRB solely based on gender. The IRB shall not consist entirely of members of one profession.

No member who has a conflicting interest in particular research may participate in the IRB's initial or continuing review except to provide information requested by the IRB.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond, or in addition to, that available on the IRB. These individuals may not vote with the IRB if the individual is not an employee of NUHS, such invitation may be extended only with the approval of the President or his/her designee.

B. Responsibilities, Functions, and Operation of the IRB

1. The IRB shall develop and follow written procedures for (i) conducting its initial review and for reporting its findings and actions to the investigator and NUHS, (ii) determining which projects require review more often than investigators that no material changes have occurred since the previous review; and (iii) ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.
2. The IRB shall develop and follow written procedures for ensuring prompt reporting to the IRB, appropriate NUHS officials and the sponsor of the research of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.
3. Except when an expedited review procedure is used (see F of this policy), the IRB shall review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it shall receive the approval of a majority of those members present at the meeting.
4. The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. The IRB is therefore responsible for the full, expedited or exempt review of proposed research protocols involving human subjects.
5. The IRB shall require that information given to subjects as part of informed consent is in accordance with the Common Rule.
6. The IRB shall submit minutes of all meetings to the Vice President for Administrative Services, to be forwarded to the President.

C. General Requirements for Informed Consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The

information that is given to the subject or representative shall be in language understandable to the subject or representative. No informed consent may include any exculpatory language through which the subject or the representative is made to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, NUHS or its agents from liability for negligence. The following information shall be provided to each subject will be in accordance with 45 CFR 46.116.

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.

D. Criteria for IRB Approval of Research

To approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized by (i) using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB 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 participation in research). The IRB shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment, the IRB shall take into account the purposes of the research and the setting in which the research will be conducted, and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by this policy. 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.
4. Informed consent will be documented, in accordance with, and to the extent required by this policy.
5. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

E. Expedited Review

The eligibility of some research for review through the expedited review procedure is in no way intended to negate or modify the policies of NUHS or the other requirements of the federal common rule for the protection of human research subjects.

The IRB may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Expedited review shall be conducted by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited review procedure. When the expedited review procedure is utilized, all

IRB members shall be informed in writing by the Chair of proposals, which have been approved under the procedure.

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 subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasions of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review, expedited or convened, utilized by the IRB.

Categories of research that may be reviewed by IRB through expedited review procedure will be those established by the US Secretary of Health and Human Services and published as a Notice in the Federal Register.

F. Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects

Certain types of applications for grants, cooperative agreements, or contracts are submitted to external funding sources (public or private) with the knowledge that 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 institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects' remains to be selected; and projects in which human subjects' involvement will depend on completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by the IRB before the application or proposal is submitted. However, except for research exempted under 45 CFR 46.104 or waived under Section E of this policy, no human subjects may be involved in any project that is subsequently supported by these applications until the project has been reviewed and approved by the IRB.

G. Research Undertaken without the Intention of Involving Human Subjects

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed by the IRB, as provided in this policy.

H. Review by NUHS

Research covered by this policy that has been approved by the IRB is subject to further appropriate review and approval or disapproval by officials of NUHS. However, institutional officials may not approve the research if it has not been approved by the IRB.

I. Suspension or Termination of IRB Approved Research

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected or serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate NUHS officials and the sponsoring agency.

J. Cooperative Research

Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, NUHS, as well as the other institution(s) is/are responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the sponsoring agency, when an investigator employed by NUHS is participating in a cooperative project, there may be either (i) a joint review arrangement or (ii) NUHS may rely on the review of the qualified IRB from the cooperating institution.

K. IRB Records

The office of the Dean of Research shall prepare and maintain adequate documentation of IRB activities including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. 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 controverted issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and investigators.
5. A list of IRB members in the same details as described in Section A of this policy.
6. Written procedures for the IRB in the same detail as described in Section B of this policy.
7. Statements from investigators of significant new findings provided to subjects.

The records required by this policy shall be retained as described in the NUHS policy "Institutional Review Board Records". All records shall be accessible for inspection and copying by authorized representatives of the sponsoring agency at reasonable times and in a reasonable manner.

Research Committee of NUHS

A. Function

The Research Committee is a standing committee of NUHS and serves as a resource to NUHS, to the Dean of Research and to the IRB in all matters concerning research activity conducted under the auspices of NUHS. Activities of the Research Committee include, but are not limited to:

1. Advice to the IRB regarding institutional commitments, regulations and standards of professional conduct.
2. Review of research proposals of new investigators, and proposals that establish a new line of research, to determine that the specific aims and objectives of the research are consistent with the mission and goals of NUHS. This includes:
 - a. Review of the time commitment to the project by individuals participating in the project.
 - b. Review of the proposed budget in terms of institutional priorities and available resources.
 - c. When requested by the principal investigator of a project or the Dean of Research, the Research Committee may review the project for scientific merit. In this instance, review by independent reviewers will be waived.

B. Membership

Six faculty members of NUHS serve on the Research Committee. Members are appointed by the President. Senior faculties are appointed for a term of five years, junior faculty for a term of three years. The Dean of Research is the Chair of the Research Committee.