North South University

Office of Research

Human Subjects Research Protection Program (HSRPP)—Policy Statement 2019

Preamble

The Directorate General of Health Services, Ministry of Health and Family Welfare, with technical assistance from the World Health Organization and the Bangladesh Medical Research Council, published its ***National Health Research Strategy*** in January 2009, Section 3.8, "Ethical Research," of which stipulates: "Maintaining ethical standard shall be mandatory in conducting all research involving human subjects by following Ethical Guidelines for Biomedical Research."

The Bangladesh Medical Research Council has published its ***Ethical Guidelines for Conducting Research Studies Involving Human Subjects (2013)***, including interventional studies, epidemiological studies, tissue transplantation research, and human genetic and genomic research.

Similarly, the Directorate General of Drug Administration, Ministry of Health and Family Welfare, issues its ***Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products***, with a view to "protecting the right of human subjects participating in clinical trial" while "clinical trial would be conducted in Bangladesh to get global recognition." Chapter 3 of the Guidelines concerns operation of an Institutional Review Board or Independent Ethics Committee.

Accordingly, North South University (NSU) faculty, staff, and students involved in human subjects research falling within the scope of this national mandate and ethical guidelines shall comply with the above noted pertinent national guidelines as well as international standards governing responsible conduct of research involving human subjects.

All investigators are expected to commit fully to their *professional duty* to safeguard the safety, rights, and welfare of human participants in biomedical and/or behavioral research. As a matter of ethical practice, this means that (1) all investigators must understand their principal duty of *non-maleficence*—to "do no harm" to human subjects—even as researchers are motivated by *beneficence*—to "do good" according to their professional ability; that (2) all investigators must *impartially* and *fairly* evaluate *benefit* and *risk* to human participants when conducting either biomedical or behavioral research; and (3) all investigators must defer to the *autonomy* of human participants in such research and, therefore, satisfy due process requirements involved in *prior, explicit, informed consent* of all research subjects recruited as participants.

As the BMRC ethical guidelines stipulate in Section 1.2, the "objectives" of ethical approval are multiple:

a. To safeguarding the dignity, rights, safety and well being of all potential research participants.
b. To protect the rights of a researcher to carry out legitimate investigation, as well as the reputation of the institution.
c. To minimize potential for claims of negligence made against the researchers, the institution concerned and any collaborating individual or organization.

d. To require evidence of ethical approval in refereed journals.
e. To influence the research design with ethical consideration.
f. To avoid potential problems [later] on, by [trial] to ensure that the main ethical issues are address[ed] before the research starts

To this end, the **Office of Research at NSU (OR-NSU)** has formulated requisite policy and procedures governing human subjects research protection (Human Subjects Research Protection Program—HSRPP), including establishment of a university-wide **Institutional Review Board/Ethics Review Committee (IRB/ERC).** NSU's IRB/ERC has the authority to review, approve, or disapprove research protocol submitted by NSU researchers, following standard review for scientific merit as evaluated by the **Scientific Review Committee (SRC)** of the respective School (School of Health and Life Sciences—SHLS; School of Engineering and Physical Sciences—SEPS; School of Business and Economics—SBE; and School of Humanities and Social Sciences—SHSS) within which the faculty member has his/her primary faculty appointment. Faculty research projects having a human subjects research component are expected to consult with the chairperson of the school SRC as appropriate and the chairperson of the NSU IRB/ERC to determine whether the proposed research is subject to IRB/ERC review.

For purpose of NSU's HSRPP, and consistent with best international practices, OR-NSU designates an **"Institutional Official" (IO)** to have charge of the relevant operational functions of HSRPP. The Institutional Official at NSU shall be the Vice Chancellor or his nominee.

The IO is charged to assure faculty, staff, and student researchers comply with university policies and procedures governing human subjects research. The IO is expected to be knowledgeable of the local social, cultural, and legal context of biomedical and behavioral research conducted in Bangladesh so as to have proper oversight of NSU research activities in coordination with the university's Director of OR-NSU. The IO (a) promotes and enhances responsible conduct of research (RCR) at NSU; (b) assures, subject to the authority of the Vice Chancellor, fair allocation of appropriate physical, financial, and human resources to facilitate university-wide compliance; and (c) implements, in coordination with OR-NSU, continuing RCR education and training of faculty, staff, and students essential for a sustainable culture of research integrity at NSU. Further, any allegation of research misconduct committed by NSU faculty, staff, or students is to be submitted to the IO for preliminary evaluation and disposition. As stipulated by NSU research misconduct policy, the IO will refer allegations of research misconduct to the Director OR-NSU for proper investigation and resolution.

As mandated by standards of human subjects research protection, NSU establishes an IRB/ERC, with membership as identified and approved in the membership list following. Membership is subject to change as recommended by the Director, Office of Research-NSU, and as approved by the Institutional Official.

NSU Institutional Review Board/Ethics Review Committee (IRB/ERC)

Membership List

Name	Degrees	Specialty	Full/Part-time NSU Faculty	Status
Dipak Kumar Mitra	Ph.D., MPH	Public Health	Full-time	Chair
Kazi Nadim Hasan	Ph.D., M.Phil., M.Sc.	Internal Medicine, Human Molecular Genetics	Full-time	Vice Chair
Md. Mahbubur Rahman	Ph.D., MS	Pharmacology, Physiology	Full-time	Member
Md. Maqsud Hossain	Ph.D., M.Sc.	Veterinary Science & Medicine; Bioinformatics, Computational Biology	Full-time	Member
Ahmed Hossain	Ph.D., M.Sc.	Biostatistics	Full-time	Member
Nur Newaz Khan	M.CHM	Medical Anthropology	Full-time	Member
Md. Rizwanul Islam	Ph.D., LLM	Law; Intellectual Property Law	Full-time	Member
Cynthia McKinney	Ph.D., MALD	Political Science, Law & Diplomacy	Full-time	Member
Shama E. Haque	Ph.D.	Environmental Science & Engineering	Full-time	Member
Rossen Roussev	Ph.D., MA	Applied Ethics	Full-time	Member
TBA	NA	Non-scientific/Community	NA	Member

Alternate Members:

1. Mahbubur Rahman (Ph.D., *Political Science*; full-time NSU faculty)
2. Dr. Hasan Mahmud Reza (Ph.D., *Molecular & Developmental Biology*; full-time NSU faculty)
3. Non-scientific/Community Member (TBA)

Term of appointment: Three years (01 January 2019 - 31 December 2021)

Appointed by Joint Coordinating Authority:

_____ Date _____
Designated Institutional Official (IO)

_____ Date _____
Director, Office of Research-NSU

As Approved by:

_____Date _____
Vice Chancellor

This policy statement is effective from the date of authorized signatures entered above.

IRB/ERC Functions and Authority

Since its founding as the first private university in Bangladesh, NSU operates on an American model of higher education and pursues its research mission consistent with national mandate and international standards of research integrity. Accordingly, NSU's Office of Research has adapted in the following policy the relevant regulatory standards published in the American Code of Federal Regulations (Title 21, 1.1.56 ff.) to guide IRB/ERC standard operating procedure at NSU, while also accounting for the ethical guidelines provided by the offices of the Directorate General of Health Services of the Ministry of Health and Family Welfare, the Directorate General of Drug Administration of the Ministry of Health and Family Welfare, and the Bangladesh Biomedical Research Council.

NSU faculty, staff, and students engaged in human subjects research are strongly recommended to adhere to ethical guidance from national agencies as noted in the preamble, as well as adhering to reputed international standards as published by the World Health Organization (WHO), the Council for International Organizations of Medical Sciences (CIOMS), the World Medical Association (WMA), the Nuffield Council on Bioethics (NCB), and others as appropriate to specific research protocol. Questions concerning interventional studies, epidemiological studies, genomic research, and tissue transplantation research can be answered reasonably by consulting the BMRC ethical guidelines in addition to the following general guidance.

Sections Following:

A. Definitions

(a) *Adverse event* means any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

(b) *Clinical investigation* means any experiment that involves a test article and one or more human subjects. Specifically, a clinical trial is any investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety

and/or efficacy. The terms *research*, *clinical research, clinical study, clinical trial*, and *clinical investigation* are deemed to be synonymous.

Clinical trials are generally classified into Phase I to Phase IV: Phase I to "establish a preliminary evaluation of safety;" Phase II to "demonstrate therapeutic activity and to assess short-term safety of the active ingredient;" Phase III to determine "the short- and long-term safety/efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value;" Phase IV is "performed after marketing of the pharmaceutical product," and "normally in the form of postmarketing surveillance, or assessment of therapeutic value or treatment strategies."

(c) *Confidentiality* means prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a participant's identity.

(d) *Contract* means a written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

(e) *Contract research organization* means a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial related duties and functions.

(f) *Directorate General OF Drug Administration (DGDA)* means the DGDA supervises and implements all prevailing Drug Regulations in the country and regulates all activities related to import, procurement of raw and packing materials, production and import of finished drugs, export, sales, pricing, etc.

(g) *Good Clinical Practice (GCP)* means a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

(h) *Human subject* means an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy individual or a patient.

(i) *Impartial Witness* means a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the participant.

(j) *Independent Data-Monitoring Committee (IDMC)/Data and Safety Monitoring Board (DSMB)* means independent data-monitoring committees that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

(k) *Informed consent* means a process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.[*]

(l) *Inspection* means the act by a regulatory authority (ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical trial that may be located at the site of the trial, at the sponsor's and/or contract research organizations (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority (ies).

(m) *Institutional Review Board (IRB),* also known as *Ethics Review Committee (ERC),* means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical and/or behavioral research

[*] BMRC requires the Informed Consent Form to include the following information: aim and method of the research; criteria for selection of the participant; duration of participation; expected benefits from the research; risks/discomfort involved during participation; measures to be taken to minimize risks; confidentiality of records; medical services to be provided by the investigators; provision for compensation for injury, disability or death of subjects; statements mentioning that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled. Address of contact person in case of queries be provided.

involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of human subjects recruited as participants in research.

(n) *Interim Clinical Trial/Study Report* means a report of intermediate results and their evaluation based on analyses performed during the course of a trial.

(o) *Investigational Product* means a pharmaceutical form of an active ingredient including plant/animal-derived medicinal products or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication (off-label use), or when used to gain further information about an approved use.

(p) *Investigator* means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject), or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(q) *IRB approval* means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and governmental requirements.

(r) *Legally acceptable representative* means an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective participant, to the participant's participation in the clinical trial.

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

(t) *Monitoring Report* means a written report from the monitor to the sponsor after each site visit and/or other trial-related communication according to the sponsor's SOPs.

(u) *Participant/Trial Participant* means an individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

(v) *Participant Identification Code* means a unique identifier assigned by the investigator to each trial participant to protect the participant's identity and used in lieu of the participant's name when the investigator reports adverse events and/or other trial related data.

(w) *Protocol* means a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline the term protocol refers to protocol and protocol amendments.

(x) *Protocol amendment* means a written description of a change(s) to or formal clarification of a protocol.

(y) *Quality assurance* means all those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported incompliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

(z) *Quality Control (QC)* means the operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

(aa) *Randomization* means the process of assigning trial participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

(bb) *Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)* means any untoward medical occurrence that at any dose:

(1) results in death,
(2) is life-threatening,
(3) requires inpatient hospitalization or prolongation of existing hospitalization,
(4) Results in persistent or significant disability/incapacity, or
(5) is a congenital anomaly/birth defect

(cc) *Source Data* means all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

(dd) *Source Documents* means original documents, data, and records (e.g. hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).

(ee) *Sponsor* means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than the individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(ff) *Sponsor-investigator* means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(gg) *Test article* means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation.

(hh) *Trial Site* means the location(s) where trial-related activities are actually conducted.

(ii) *Unexpected Adverse Drug Reaction* means an adverse reaction, the nature or severity of which is not consistent with the applicable product information

(jj) *Vulnerable Participants* means individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable participants include patients with incurable diseases, persons in nursing homes, unemployed, illiterate or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

(kk) *Well-being* means both physical and mental integrity of the human participant in research.

B. Circumstances in which IRB review is required

Except for research involving human participants that has minimal risk as defined above, all human subjects research shall have IRB review prior to initiation of research by an investigator.

C. Exemptions from the IRB requirement

The following categories of clinical investigation are exempt from the requirement for IRB review:

(a) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(b) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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, according to applicable national food safety standards.

(c) Further, both undergraduate and graduate students in degree programs may on occasion engage in student-initiated or faculty-initiated projects involving human subjects that are designed to satisfy a course grade requirement and, therefore, count as “internal presentations” and are not designed or intended to contribute to “generalizable knowledge”

such as is normally understood in the definition of research investigation. Because the outcome of such internal course-related research is (1) part of the education requirement in a degree or course, (2) is presented only in the context of the specific course for which the student is registered, and (3) not intended for publication in peer-reviewed venues, the NSU IRB/ERC determines such projects to be "not research" under the definition provided in this policy statement. Notwithstanding, instructors of record in such courses are expected to assure (a) students are duly informed of pertinent ethical principles and practices that are part of responsible conduct of research, (b) to understand the paramount importance of individual human subject autonomy and human participants being safeguarded from harm to integrity of person and body, and (c) to assure confidentiality of personal data.

D. Waiver of IRB Requirement

On the application of a sponsor or sponsor-investigator, the NSU IRB/ERC may waive any requirement, including requirement for IRB review, for specific research activities or for classes of research activity.

E. IRB Membership

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in 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.

F. IRB Operations

The NSU IRB/ERC shall:

(a) Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator that no material changes have

occurred since previous IRB review; (3) for ensuring prompt reporting to the IRB of changes in research activity; and (4) for ensuring that 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 where necessary to eliminate apparent immediate hazards to the human subjects.

(b) Follow written procedures for ensuring prompt reporting to the IRB and appropriate institutional officials, and the Office of Research-NSU of: (1) Any unanticipated problems involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB; or (3) any suspension or termination of IRB approval.

(c) Except when an expedited review procedure is used, 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. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Quorum must include one scientific member and one non-scientific member within the majority of the members present.

G. IRB Review of Research

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by human subjects research protection standards.

(b) An IRB shall require that information given to subjects complies with the standard of prior explicit informed consent and that consent forms and procedures are adequate to this requirement. The IRB may require that information be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. In general, the BMRC stipulates obligations of investigators regarding informed consent to include:

1. Communicate all relevant information to the participants
2. Provide complete and comprehensive information
3. Provide opportunity and encouragement to ask question
4. Participate needs to provide sufficient time and opportunity in the research.
5. Exclude possibility of unjustified deception
6. Exclude possibility of intimidation and undue influence
7. Consideration of financial inducement should be based on poverty level of Bangladeshi population
8. Inform consent form must have sign by participant/legal guardian.
9. In case of a clinical trial / experiment informed consent is to be signed by the participant in presence of witness.
10. For a study without any intervention (Non-intervention type of study) involving large community it is necessary to have the consent of the community.
11. In case of illiterate participants the investigator shall verbally discuss the content of the Informed Consent Form in presence of a witness who is literate and capable of understanding.

12. Ensure that an individual or group or community is enough competent to understand and assess information about the research.

13. See that the consent is voluntary. The decision of a subject or group or community not biased by improper influences.

14. Ensure that the participant of group or community is given the detailed truthful information necessary to make a considered judgment about whether to participate.

15. Renew informed consent in case of any methodological change in the research.

The research protocol should also specify that the research has been approved by (1) the school Scientific Review Committee, (2) the NSU IRB/ERC and/or other IRB when inter-institutional collaboration is involved, and (3) when required, by the BMRC National Ethics Review Committee (NERC).

(c) An IRB shall require documentation of informed consent, except as follows:

(1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a *written* consent form if it finds 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 the research context*; or

(2) The IRB may, for some or all subjects, in the case of emergency research, find that an exception from informed consent is warranted.

(d) In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(e) An IRB shall notify investigators, the designated Institutional Official, and the Director, Office of Research-NSU, in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. For investigations involving an exception to informed consent, an IRB shall promptly notify in writing the investigator and the sponsor of the research when an IRB determines that it cannot approve the research because it does not meet the criteria for exception or because of other relevant ethical concerns deemed relevant by the IRB. The written notification shall include a statement of the reasons for the IRB's determination.

(f) An IRB shall conduct continuing review of research investigations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research investigation.

(g) An IRB shall provide in writing to the sponsor of research due notice involving an exception to informed consent. The IRB shall provide this information to the sponsor promptly so that the sponsor is aware that such disclosure has occurred.

(h) When some or all of the subjects in a study are children, an IRB must determine that the research study is in compliance with standards governing the rights, health, and safety of vulnerable populations.

H. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

Some categories of research may be reviewed by the IRB through an expedited review procedure.

An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized.

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 IRB chairperson from among the members of the IRB.

In reviewing the research according to expedited review procedure, 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 regular non-expedited full review procedure normally followed by the IRB.

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

I. Criteria for IRB approval of research.

(a) In order to approve research the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and that 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 be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, mentally disabled persons, or economically or educationally disadvantaged persons. This is especially crucial given Bangladesh's status as a lower middle-income country where economic and educational disadvantage is a common feature of the research context.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

(5) Informed consent will be appropriately documented.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. This may be assured through a Data Safety Monitoring Board.

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

(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

J. Review by institutional Authority.

Research covered by the foregoing provisions, that has been approved by the NSU IRB/ERC, may be subject to further appropriate review and approval or disapproval by officials of the institution, including the Institutional Official and/or Director, Office of Research. However, those officials may not approve the research if it has not been approved by an IRB. The university-wide IRB/ERC functions with independent authority to review, approve, and disapprove research protocol.

K. Suspension or termination of IRB approval of research.

The NSU IRB/ERC has 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 serious harm (adverse events, serious adverse events) 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, the NSU Institutional Official, the Director, Office of Research, and governmental authority as mandated by law.

L. Inter-institutional collaborative/cooperative research and deferral of review.

When an NSU investigator or research team is involved in a multi-institutional research investigation, the NSU IRB/ERC may defer to another qualified IRB review if it deems this action appropriate to avoid duplication of effort.

M. IRB records.

(a) The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals/protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries (adverse events) to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show (a) attendance at the meetings; (b) actions taken by the IRB; (c) the vote on these actions including the number of members voting for, against, and abstaining; (d) the basis for requiring changes in or disapproving research; and (e) a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(7) Statements of significant new findings provided to subjects by research investigators.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the university and/or government regulatory authority at reasonable times and in a reasonable manner.

N. Update of Policy Statement

Under delegated authority of the Vice Chancellor, the Director, Office of Research-NSU, reserves the authority to amend, revise, and update this policy statement as appropriate to internal and/or external factors pertinent to formulation and implementation of standard operating procedures governing responsible conduct of research generally and human subjects research protection in particular. Amended, revised, and/or updated policy statement shall be the current policy governing human subjects research at NSU when approved according to due process involving Academic Council, Syndicate, and Board of Trustees review. When such approved amendments, revision, and/or updates occur, this policy statement will reflect the date on which such changes occur. Earlier policy statements shall be archived for institutional record, but otherwise they shall remain accessible for reference.

O. References with URL:

1. Directorate General of Health Services, Ministry of Health and Family Welfare, *National Health Research Strategy*, January 2009, https://www.medbox.org/bangladesh/national-health-research-strategy/preview?q=

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3. Bangladesh Medical Research Council, *Ethical Guidelines for Conducting Research Involving Human Subjects* (2013), http://www.bmrcbd.org/application_form/EthicalGuidelines.pdf

4. World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, as adopted at the 64th WMA General Assembly, Fortaleza Brazil (October 2013), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

5. World Health Organization, *Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants* (2011), http://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf?sequence=1

6. Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2016), https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

7. Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries*, (2014), http://nuffieldbioethics.org/wp-content/uploads/2014/07/Ethics-of-research-related-to-healthcare-in-developing-countries-I.pdf

8. U.S. Electronic Code of Federal Regulations, Title 21, Chapter 1, Subchapter A, Part 56, current as of 12 December 2018, https://www.ecfr.gov/cgi-bin/text-idx?SID=7ce55e26bea007d7ceac6376e3933ac2&mc=true&node=pt21.1.56&rgn=div5#se21.1.56_1107

9. *Human Subjects Research Ethics Field Training Guide,* Johns Hopkins University School of Public Health (2010), https://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/ResearchEthicsFieldGuide_2010-02-25.pdf