Policy on Ethics in Research

Approved by the University Council on March 18, 2016
Approved by the Board of Trustees on May 9, 2016

I. Introduction and Purpose

Congruent with the mission of Notre Dame University–Louaize (NDU), which promotes "*excellence in scholarship, lifelong learning, human dignity, and moral integrity*," the *Policy on Ethics in Research* is set to protect the rights, dignity, welfare, and privacy of both human and non-human subjects, and to protect the environment, in all research that involves the University. Its ultimate goal is to ensure that researchers adhere to the guidelines and principles, which prevent unethical practices consistent with recognized standards in the various academic disciplines.

Research projects usually involve complex social, legal, and ethical issues. The Policy and Procedures set forth in this document are applicable to all faculty, staff, and students at the University as well as to external research and administrative partners whose research activities involve human subjects, animals, and/or the environment.

II. Guiding Principles

Recalling on the

- Ethical principles, as determined by the University's mission and as prescribed by universal rules governing moral integrity, human rights, animal welfare, respect for the environment, which shall be observed at all times in any kind of research activity under the auspices of NDU;
- *Belmont Report* (***Appendix 1***)[1] and laws enforced in Lebanon, where applicable;
- University Research and Grants Policy;

Recognizing that

- Academic researchers understand the importance of obtaining Informed Consent (IC) from the participants, and parent/guardian, if applicable;
- Any research project must consider the rights, safety, risk-to-benefit ratio, and protection, not only of human beings, as specified in the *Belmont Report* but also of animals and/or the components of the environment involved in the study;
- After considering property rights, any researcher shall be bound to fully disclose the methods and results related to his/her research when requested by the Institutional Review Board (NDU-IRB) in order to ensure full transparency and accountability to the University and to the overall scientific community;

Affirming that

[1] The appendices are not part of the *Policy on Ethics in Research*.

- NDU research adheres to professional and moral processes; and
- The rights and well-being of subjects (human being or animal) are adequately protected.

***An NDU-IRB implements the present* Policy on Ethics in Research.**

III. Role and Responsibilities of the NDU-IRB

The NDU-IRB shall ensure that all individuals involved in research abide by the set policy and guiding principles. The following list is a summary of the most important responsibilities of the NDU-IRB:

- Offer advice, information, and guidance; rather than act as a legislative or judicial body;
- Recommend modifications, if necessary, for proposals submitted by the University researchers, regardless of the location of research activities;
- Oversee and determine intervals of periodic review, where appropriate;
- Recommend suspension or termination of research not conducted in accordance with IRB requirements or complicit in the foreseen or unforeseen possible serious harm to research subjects;
- Prepare an Annual Report to the University Research Board on the operations of the NDU-IRB;
- Ensure that appropriate mechanisms exist within the University to resolve issues related to ethical procedures and ethical violations when conducting research;
- Ensure the provision of appropriate training for all University academic and non-academic staff to equip them with the knowledge and competencies required for the ethical treatment of research subjects; and
- Ensure full confidentiality for all research participants during the mandate of the research process, unless a priori disclosure guidelines are agreed upon by all individuals involved.

Should the NDU-IRB recommend suspension or termination of a research project, the IRB shall make disclosure to the leading researcher(s) and research participants as well as all administrators concerned, including, but not limited to, the Vice-President for Research and Graduate Studies (AVPRGS), the Dean and Department Chair concerned. The NDU-IRB's report must include a complete statement providing evidence for disapproval with supporting evidence for the withdrawal of support.

IV. Composition of the NDU-IRB

The President designates the Assistant Vice President for Research and Graduate Studies (AVPRGS as having ultimate responsibility for the assurance and implementation of the fulfillment of all NDU-IRB roles and responsibilities and for the compliance with research guidelines and procedures.

In coordination with the Faculty Deans, the AVPRGS invites faculty members to express their interest to serve on the NDU-IRB. The selected members' names are forwarded to the President for final approval. Members are selected based on the need

of their particular expertise. They must be characterized by maturity, research experience, and academic expertise to qualify for membership as well as to be able to ascertain the acceptability of proposals in terms of risks and benefits, institutional commitments, regulations, applicable laws, and standards of professional conduct and practice.

Members of the NDU-IRB are appointed to a two-year term that is renewable.

The NDU-IRB may not at times have the necessary expertise to judge the soundness (scientific or non-scientific) of a research protocol and may possibly be unable to provide a fair and accurate risk assessment. For these protocols, the NDU-IRB chair, may call upon an ad-hoc committee for assistance to review the scientific merit by performing an in-depth review of the study, or legal counsel to assist the NDU-IRB in conducting its duties. The ad-hoc consultants/legal counsels have no voting rights and must disclose whether they have any conflicts of interest with the protocol.

V. Submissions and Review Procedures

Prior to the implementation of the research project, each researcher shall:

First, consult with the NDU-IRB prior to submission of a research proposal to discuss any issues relating to human, animal, and environmental subjects, and the possibility of ethical considerations for the successful carry-out of the project.

Second, secure the approval of the Department Chair and Dean concerned. In some circumstances, however, the NDU-IRB will consider delegating (should the Dean concerned communicate to the NDU-IRB in writing) to an appropriate person in the Faculty, as long as that person is experienced in the requirements for protecting research subjects and has the authority to sign for the Department Chair in this regard. The responsibility for local supervision of the project, however, remains with the Department Chair.

Third, submit the application form (***Appendix 2***), IC form (***Appendix 3***)[2], and other forms whenever applicable to the NDU-IRB. The NDU-IRB checks the application to ensure that all the necessary documents/materials have been submitted for NDU-IRB review.

It is worth noting that research projects are reviewed according to the research potential level of risks to research subjects/environment, and as determined by the NDU-IRB. The risks to which research subjects may be exposed are classified as physical, psychological, social, and/or economic.

The NDU-IRB holds all research proposals to the same standards.

VI. Training

In order to comply with the policy, the NDU-IRB members and researchers from NDU who wish to conduct human and/or animal subject research at the University are required to complete the online training as outlined in the Collaborative Institutional Training Initiative (CITI)[3].

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[2] The appendices are not part of the *Policy on Ethics in Research*.

[3] The CITI Program is a subscription service, providing Research Ethics Education to all members of the research community. Online training can be obtained at https://www.citiprogram.org/

Appendix 1

Belmont Report Principles[4]

Three basic principles of the *Belmont Report* are central to the ethics in research, involving human subjects. These are:

- **Respect for persons-**applied by obtaining informed consent and considering privacy, confidentiality, and additional safeguards for vulnerable populations;
- **Beneficence-**applied such that the potential benefits of research are maximized and possible risks are minimized to the persons involved; and
- **Justice-**evidenced in the equitable selection of research participants.

[4] *Belmont Report*: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Appendix 2

Application Form

(Based on the *IRB Guidebook*[5])

Title of the Study	
Sponsored by	
Purpose	
Concise Summary of Project [200 words]	
Profile of the Research Subjects	
Recruitment Methods and Consenting Process	
Potential Risks (such as discomfort, inconveniences expected)	
Potential Benefits (solution to social/environmental problems, advance of knowledge, treatment of any kind, etc.)	
Subject Safety and Data Monitoring	
Procedures to Maintain Confidentiality	

Evaluation criteria: (For experimental purposes only, the NDU-IRB will adopt the evaluation criteria as developed in the *IRB Guidebook*.)

1. Are both risks and anticipated benefits accurately identified, evaluated, and described?

2. Are the risks greater than minimal risk? Has the NDU-IRB taken into account any special vulnerabilities among prospective subjects that might be relevant to evaluating the risk of participation?

3. Has due care been used to minimize risks and maximize the likelihood of benefits?

4. Are there adequate provisions for a continuing reassessment of the balance between risks and benefits? Should there be a data and safety monitoring committee?

[5] The *IRB Guidebook*: http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

Appendix 3

Informed Consent Form

(Based on IRB Guidebook)

GENERAL INFORMATION

Title of Research	[insert title]
Funding Agency/Sponsor, if any:	
Names of the Leading Researcher and Those Individuals Who Will Obtain Consent	
Contact Person Phone Office Hours	[Insert LR name in the absence of a contact person] [insert phone number]

RESEARCH STUDIES: MATERIALS & METHODS

Statement About the Research Studies	[the study involves ……]
Purpose(s) of the Research	
Expected Duration of the Subject's Participation	
Description of the Procedures to be Followed	
Detailed Experimental Procedures	
Approximate Number of Subjects Involved in the Study	
Profile of the Research Subjects	
Circumstances Under Which the Subject's Participation May be Terminated by the Leading Researcher Without Regard to the Subject's Consent	

RISKS & BENEFITS

Foreseeable Risks or Discomforts to the Subject	
Benefits Expected from the Research	
Disclosure	Description of appropriate alternative procedures or courses of treatment if any, that might be advantageous to the subject
Confidentiality Statement	Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained
Medium to High Risks	Explain as to whether any treatments are available in the case of injury, damage and, if so, what they consist of, or where further information may be obtained
Subject's Compensation to be expected (if any)	

Consent Statement (Based on *IRB Guidebook*)

Being informed that any particular treatment or procedure may involve risks, which are currently unforeseeable; I, [insert name], hereby state that my participation in the research study is voluntary. Any refusal to participate will involve no penalty or loss of benefits to which I am entitled. I may also discontinue participation at any time without penalty or loss of benefits to which I am entitled.

_____, _____,

Signature(s) of the participant(s) or guardian

Signature of the Leading Researcher (LR)

_____,

Signatures of the witnesses (where appropriate)

Evaluation criteria: (For experimental purposes only the NDU-IRB will adopt the evaluation criteria as developed in the *IRB Guidebook*).

l. Do the researchers plan to involve a particularly vulnerable subject population?

2. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits? Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?

3. Is the language and presentation of the information to be conveyed appropriate to the subject population? (Consider the level of complexity and the need for translation into a language other than English.)

4. Are the timing of and setting for the explanation of the research conducive to good decision making? Can anything more be done to enhance the prospective subjects' comprehension of the information and their ability to make a choice?

5. Who will be explaining the research to potential subjects? Should someone in addition to or other than the Leading Researcher be present?

6. Should subjects be reeducated and their consent required periodically?

7. Should the NDU-IRB monitor incoming data to determine whether new information should be conveyed to participating subjects? How often should this occur? Who is responsible for bringing new information to the attention of the NDU-IRB between scheduled reviews?

8. If a waiver of some or all of the consent requirements is requested, does the importance of the research justify such a waiver? Is more than minimal risk involved? Can the research design be modified to eliminate the need for deception or incomplete disclosure? Will subjects be given more information after completing their participation? Would the information to be withheld be something prospective subjects might reasonably want to know in making their decision about participation?

ACRONYMS

CITI	Collaborative Institutional Training Initiative
IC	Informed Consent
IRB	Institutional Review Board
NDU	Notre Dame University - Louaize
LR/PI	Leading Researcher/Principal Investigator
AVPRGS	Assistant Vice-President for Research and Graduate Studies