NOTRE DAME UNIVERSITY
LOUAIZE
جامعة سيدة اللويزة
GAUDIUM DE VERITATE

APPENDIX 3
STEPS FOR IRB REVIEW PROCEDURE

Dear Researcher,
Use this document as a guide to complete the IRB Protocol form and ensure that all necessary documents are uploaded with the IRB Protocol Form (Appendix 2).

Prior to the implementation of the proposed research, the primary researcher:

First, may consult with the Faculty representative on the IRB Committee prior to submission of a research proposal to discuss any issues relating to human, animal, and environment/place and the possibility of ethical considerations for the successful carry-out of the study.

Second, plan the research proposal to be able to fill out the IRB Protocol Form (Appendix 2). Provide all the needed proof (when applicable) to support when submitting the IRB Protocol Form.

Use the following checklist will help the principal researcher determine what needs to be attached when the IRB Protocol Form is filled out. The needed proof is clarified in the IRB Protocol Form as well.

☐ Sample Creation Proof: Attach a document to show how the research sample will be contacted or solicited. Include the recruitment email message, letter, telephone number and contact name, etc. as part of the details. (Attach this document when submitting the IRB Protocol Form.)

☐ Securing Sample Safety Proof: Attach documents to show details related to human, animal, and environment/place samples to ensure safety and informed consent to contextualize ethical reason as to why proposing to study the research sample. The researcher's **Informed Consent Protocol** must be in line with the particular research field. Attach these documents when submitting the IRB Protocol Form. (Attach these documents when submitting the IRB Protocol Form.)

☐ Tools Proof: Attach the following documents: The tools and the communiqué documents to identify the apparatus/ instruments tests and/or checklists that will be used as part of the design, procedure, and/or data collection; a description of the tools to show ethical consideration is adapted (show how the research sample is informed about tool use, confidentiality, privacy, etc., and whaht the informed consent communiqué will be as a form to be signed or verbatim be read out to research sample to acknowledge tool use during the research timeframe. (Attach these documents when submitting the IRB Protocol Form.)

☐ Data Wellness Proof: Attach the following documents to clarify ownership of the data to the research sample, to show how the researcher will inform the research sample about their right to access to the data, to show how the researcher will inform the research sample how the researcher will have the right to ask for more information if needed after data collection is initially over, and to show where the data will be stored and how access privacy will be maintained. Also, attach the dateline as to how long the researcher will use or keep the collected data and how the data will be destroyed. (Attach these documents when submitting the IRB Protocol Form.)

Third, reveal the source of funding **when applicable** to show who will fund the research. (Attach the proof of the signed funding approval with the needed signature(s) when submitting the IRB Protocol Form.)

There are two possibilities for Affiliation or Sponsorship funding:
☐ (1) If NDU as the Sponsorship body is supporting a proposed research study, the principal researcher will need to acknowledge funding support and just attach it to the IRB Protocol Form. The researcher should show a signature from the Sponsoring body; this may be from the NDU Administration, represented by the Administration Officer OR from the researcher's Faculty, represented by the Department Chair and Dean. Please note that securing funding for the research is not part of IRB decision making; it is just to complete file information. (Attach the document when submitting the IRB Protocol Form.)

☐ (2) If an Affiliation or Sponsorship body (other than NDU) is supporting a proposed research study, the principal researcher will need to acknowledge funding support and just attach it to the IRB Protocol Form.
Please note that securing funding for the research is not part of IRB decision making; it is just to complete file information (Attach the document when submitting the IRB Protocol Form.)

Fourth, submit the IRB Protocol Form with **all** the documented proof attached.
The IRB will review the application to ensure that all the necessary documents/materials are submitted for review. Research projects are evaluated according to the research potential level of risks to research subjects/environment, and as determined by the IRB. The risks to which research subjects may be exposed are classified as physical, psychological, social, and/or economic. The IRB holds all research proposals to the same standards.