**Application for IRB/ERC Ethical Clearance**

 *(This form is adapted from the template used by the Bangladesh Medical Research Council.)*

***This research proposal should be reviewed by the NSU Scientific Review Committee (SRC) first. Without SRC approval this application/proposal will not be reviewed by the NSU IRB/ERC.***

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| **Ethics Review ID:**  |
| **SRC Approval ID:** |
| **Attachments (mandatory)**[ ]  1. Abstract Summary [ ]  5. Questionnaire-English [ ]  2. Full Research Proposal [ ]  6. Questionnaire-Bangla [ ]  3. Informed consent form-English [ ]  7. ‘Informed Consent’ certificate of all Investigators [ ]  4. Informed consent form-Bangla [ ]  8. SRC approval [to be added by OR-NSU] |

**Type of Application: [ ]** New **[ ]**  Renewal **[ ]** Resubmission **[ ]**  Amendment

**Project/Grant Type: [ ]** CTRG Grant **[ ]** Non-CTRG/ External Project **[ ]**  Student Project/ Thesis

**Review requested for: [ ]** April Session **[ ]**  August Session **[ ]** December Session **[ ]**  Expedited

*[Three IRB meetings will be convened annually. To request an expedited review, the submission of an expedited request memorandum, including a justification is mandatory.]*

**Research Project Title**

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**Principal Investigator**

|  |  |
| --- | --- |
| Name |  |
| Institute |  |
| NSU Faculty Initial |  |
| Educational Qualifications |  |
| Email |  |
| Mobile Number |  |

**Co-Investigator** (add cells as required)

|  |  |  |
| --- | --- | --- |
| Name | 1.  | 2.  |
| Institutional Affiliation |  |  |
| Educational Qualifications |  |  |
| Email |  |  |
| Mobile Number |  |  |

We, the undersigned, agree to obtain approval of the proposed research identified in this application for ethical clearance and for any changes to the research protocol involving the rights and welfare of research participants as well as prior approval of any changes of the research methods before undertaking any such changes in the research protocol. *[Include signatures from all PIs and all Co-Investigators]*

PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigator (1): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigator (2): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**1. Study Population**

**1.1. Participant type**

**[ ]** Illparticipant **[ ]** Non-ill or Healthy Participant

**1.2. Includes vulnerable participants?**

**[ ]** Yes **[ ]**  No

**If 1.2 is “yes”, check all that apply:**

**[ ]** Pregnant women **[ ]**  Fetuses **[ ]** Prisoners **[ ]** Cognitively impaired

**[ ]** Service providers **[ ]**  Destitute **[ ]** CSW **[ ]** Participants below 18

**[ ]**  Others (specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

**If 1.2 is “yes”,** **will this research specifically benefit the disadvantaged/ vulnerable participants** (in terms of economics, social justice, and/or other factors)**? [ ]** Yes **[ ]** No **[ ]** Not applicable

*If “yes”, explain below briefly:*

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|  |

**2. Proposed Sample Size** (Name and number of subgroups, e.g., Men, Women)**:**

|  |  |
| --- | --- |
| **Name/ Criteria** | **Number** |
| 1.  |  |
| 2. |  |
| 3. |  |
| **Total** |  |

**3. Research Project Information**

|  |  |
| --- | --- |
| Place where the research/ study will be conducted |  |
| Type of Research/Study |  |
| Duration of Study |  |
| Total Grant Fund/ Budget for the Research |  |
| Name of Funding Agency (if any) |  |

**4. Objectives of Research Study**

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**5. Rationale**

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**6. Conflict(s) of Interest: [ ]** Yes **[ ]**  No; if “yes,” explain briefly below:

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**7. Potential benefits:** **[ ]** Direct to research participants; **[ ]** Indirect (altruistic)

*If direct benefits to the research participants explain briefly:*

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**8. Risk/benefit analysis** (risks to research participants are minimized and reasonable in view of potential benefits identified): **[ ]** Yes **[ ]**  No; *provide brief comments below:*

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**9. Eventuality plan in place in case of adverse event and/or serious adverse event:**

**[ ]** Yes **[ ]** No **[ ]** Not applicable

**10. Data Oversight**:

1. There is adequate provision for data safety and monitoring: **[ ]** Yes **[ ]** No
2. Rules for halting research are explained and sufficiently detailed: **[ ]** Yes **[ ]** No

**Check the appropriate answer for each of the following in the case of**

**Research Involving Human Subjects**

*N/A: Not Applicable*

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| **11. Risks to Participants** | Yes | No | N/A |
| 1. The study involves physical risks to the participants | **[ ]**  | **[ ]**  | **[ ]**  |
| 2. The study involves social risks to the participants | **[ ]**  | **[ ]**  | **[ ]**  |
| 3. The study involves psychological risks to the participants | **[ ]**  | **[ ]**  | **[ ]**  |
| 4. The study involves discomfort to the participants | **[ ]**  | **[ ]**  | **[ ]**  |
| 5. The study involves invasion of the body | **[ ]**  | **[ ]**  | **[ ]**  |
| 6. The study involves an experimental drug or device [if yes, answer for each of the following] | **[ ]**  | **[ ]**  | **[ ]**  |
| 6A. The experimental drug or device has a registration status for open sale in Bangladesh or other country | **[ ]**  | **[ ]**  | **[ ]**  |
| 6B. If not registered in Bangladesh, does the attached protocol provide full information about toxicity studies carried out in animal models or human volunteers. | **[ ]**  | **[ ]**  | **[ ]**  |
| 6C. If placebo is to be used, its use is justified and explanation is provided in the attached protocol as to why the study cannot be done without placebo | **[ ]**  | **[ ]**  | **[ ]**  |
| 7. The study involves invasion of privacy | **[ ]**  | **[ ]**  | **[ ]**  |
| 8. The study discloses information damaging to participants or others | **[ ]**  | **[ ]**  | **[ ]**  |
| 9. The study involves interview, in which case the attached protocol provides information and explanation about the context of the interview, length of time required, etc. | **[ ]**  | **[ ]**  | **[ ]**  |
| 10. Research participants will be informed about research results | **[ ]**  | **[ ]**  | **[ ]**  |

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| **12. Use of Records, Organs, and Fluids** | Yes | No | N/A |
| 1. The study involves use of hospital, medical, death, birth, or other records | **[ ]**  | **[ ]**  | **[ ]**  |
| 2. The study involves use of fetal tissue or abortus | **[ ]**  | **[ ]**  | **[ ]**  |
| 3. The study involves the use of organs or body fluids | **[ ]**  | **[ ]**  | **[ ]**  |

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| **13. Informed Consent** | Yes | No | N/A |
| 1. Are the participants to be clearly informed about the nature and purposes of the study? | **[ ]**  | **[ ]**  | **[ ]**  |
| 2. Are the participants to be clearly informed about procedures to be followed, including alternatives to be used? | **[ ]**  | **[ ]**  | **[ ]**  |
| 3. Are the participants to be clearly informed about physical risks? | **[ ]**  | **[ ]**  | **[ ]**  |
| 4. Are the participants to be clearly informed about questions affecting privacy? | **[ ]**  | **[ ]**  | **[ ]**  |
| 5. Are the participants to be clearly informed about procedures involving invasion of the body? | **[ ]**  | **[ ]**  | **[ ]**  |
| 6. Are the participants to be clearly informed about the benefits, direct or indirect, to be derived from the study? | **[ ]**  | **[ ]**  | **[ ]**  |
| 7. Are the participants to be clearly informed about their right to refuse to participate and to withdraw from the study without penalty? | **[ ]**  | **[ ]**  | **[ ]**  |
| 8. Are the participants to be clearly informed about how data will be handled confidentially? | **[ ]**  | **[ ]**  | **[ ]**  |
| 9. Are the participants to be clearly informed about compensation where there are risks, or loss of working time, or privacy is involved in any particular procedure? | **[ ]**  | **[ ]**  | **[ ]**  |

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| **14. Signed/ Verbal Consent Form** | Yes | No | N/A |
| 1. Will signed consent form/verbal consent be required from participants? | **[ ]**  | **[ ]**  | **[ ]**  |
| 2. Will signed consent form/verbal consent be required from parent or guardian (if participants are minors/not of legal age for consent)? | **[ ]**  | **[ ]**  | **[ ]**  |

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| **15. Biological Specimen** | Yes | No | N/A |
| 1. Is the biological specimen going to be stored indefinitely?*If yes, how long*? \_\_\_\_\_\_\_\_\_\_\_\_ | **[ ]**  | **[ ]**  | **[ ]**  |
| 2. Will the agreement of the research participants be sought for the use of the preserved specimen for purpose unrelated to the study, or will they be asked to re-consent? | **[ ]**  | **[ ]**  | **[ ]**  |
| 3. Will the samples be transmitted to another country or countries? *If yes, provide the name of the institution(s) as well as the country or countries where they are located*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **[ ]**  | **[ ]**  | **[ ]**  |
| 4. If the surplus/ unused specimen is taken to another nation, will it be returned? If the response is no, the useless or extra specimen must be discarded.*Who will be in charge of the specimen?* \_\_\_\_\_\_\_\_\_\_\_\_\_*When the specimen is delivered outside of Bangladesh, who will be in charge of it?* \_\_\_\_\_\_\_\_\_\_\_*Who will be the specimens’ owner(s)?* \_\_\_\_\_\_\_\_\_\_\_\_\_ | **[ ]**  | **[ ]**  | **[ ]**  |
| 5. Has a memorandum of Understanding (MoU) been made regarding specimen collection, storage, usage, and ownership?*Please attach a copy of the MoU if the answer is yes*. | **[ ]**  | **[ ]**  | **[ ]**  |

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| **16. Precautions** | Yes | No | N/A |
| Will precautions be taken to protect anonymity of participants? | **[ ]**  | **[ ]**  | **[ ]**  |

**Research Ethics Certificate**

A training on **Informed Consent is mandatory** and a copy of certificate (minimum 80% marks required) needs to be submitted. Informed consent training link is:

<https://globalhealthtrainingcentre.tghn.org/introduction-informed-consent/>

alternate link: <https://elearning.trree.org/>

Training on research ethics is also strongly recommended with completion of module quizzes in progress. An online training link on research ethics is: <https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/>

alternate link: <https://elearning.trree.org/>

**The validity period for a research ethics certificate is three years.**

*[For any queries please contact: Mostafizur Rahman, Officer, Office of Research-NSU*

*Email: mostafizur.rahman09@northsouth.edu, Ext: 6465, Phone: 01742202274]*

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| [To be completed by Reviewer]**Ethics Review Id:**  |
| **Primary Reviewer:** | **Review Date:** |
| **Reviewer’s recommendation: [ ]** Approved **[ ]**  Disapproved **[ ]** Revision Required **[ ]** Waived |
| Risk to research participants is: **[ ]** minimal **[ ]** moderate **[ ]** high |
| Participant selection is likely to be equitable: **[ ]** Yes **[ ]** No **[ ]** N/A |
| Research participant recruitment is adequate: **[ ]** Yes **[ ]** No **[ ]** N/A |
| Investigator’s protocol minimizes risk to research participants: **[ ]** Yes **[ ]** No |
| Study has adequate procedures to protect vulnerable research participants: **[ ]** Yes **[ ]** No **[ ]** N/A |
| Informed consent document is adequate for understanding of the research participants: **[ ]** Yes **[ ]** No **[ ]** N/A |
| Provisions to protect research participant privacy and confidentiality are adequate: **[ ]** Yes **[ ]**  No  |
| **Comment**:  |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Signature of Primary Reviewer** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Signature of Chair, NSU IRB** |

**Basic Instructions to Primary Reviewer on Order of Review**

1. **Read the consent document**

Note that the consent document should explain aspects of the study to potential research participants in lay (not technical) language. It should provide a reasonably clear introduction to the research protocol. You should at this time read the document to orient yourself about the overall design of the research proposed.

1. **Read the protocol summary**

Read the summary and assure yourself that the investigator has summarized the important aspects of the study in a way that facilitates IRB full committee review.

1. **Read the full protocol and supporting material**

Read the protocol and supporting materials to understand with a view to prior studies that are applicable to the study and that validate the research procedures outlined in the protocol (e.g., animal model studies done; safety studies done; efficacy studies done; rationale for a human study; phased clinical trial information; etc.). Assess whether there is evidence of detailed inclusion/exclusion criteria being met, recruitment procedures including advertisements, etc.

1. **Read the consent document again**

On this second reading of the consent document, record any suggested corrections or questions for the principal investigator.