# Appendix A-III

### Full Board Ethical Clearance Application Form

If your research involves human subjects[[1]](#footnote-1), please read the [Institutional](http://www.zu.ac.ae/main/en/research/for_researchers/research_integrity/ethical_clearance.aspx) Review Board Policy. Complete ALL sections of this form. An incomplete application will not be reviewed, and may delay the approval process.

Completed forms must be submitted to the Institutional Review Board (IRB) for review.

**SECTION A**

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| --- | --- | --- | --- | --- |
| Project Title: |  | | | |
| Principal Investigator (PI): | Name: |  | School: |  |
| Title: |  | Department: |  |
| Telephone: |  | Email: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| List all Co-Investigators below, including those from other institutions: | | | | |
| Name | Responsibility on Research Project | Designation | University/ School | Email |
| 1. |  |  |  |  |
| 2. |  |  |  |  |
| 3. |  |  |  |  |

**SECTION B** - **Project funding, purpose and research design**

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| 1. Current or planned funding source (internal or external) | |
| Is project funding sought/achieved? | Yes (provide information below)  No |
| PI of Grant or Contract: |  |
| Funding Source: |  |
| Time period of Grant Funding: |  |

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| 2. Possible conflict of interest |
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| Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this research or otherwise have a potential conflict of interest regarding the conduct of this research?  Yes (provide information below)  No |
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| **3. Purpose of Research Project**  Provide a brief summary below (i.e. 300 words or less) of the purpose of the project in general terms, including background information as necessary, research question(s), and importantly, an explanation of why this research is needed.  NOTE that a guiding ethical principle for research includes ‘non-maleficence’, or the duty to prevent unnecessary risks of harm for subjects, and the verification that their participation in research must be essential to achieving scientifically or socially important aims. Human subjects research must be justified by its potential benefits, including (but not limited to) its contribution to knowledge, improving social welfare and individual wellbeing. |
| Please provide summary: |

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| **4. Description of the research design, methods and procedures**  (A copy of all data collection instruments must be attached with this application)  Provide a description below of the research design (including steps and methodology), what kinds of data will be collected, details on the primary outcome measurements, and follow-up procedures or actions anticipated.    Note: It must be designed or developed using methods appropriate to achieving the aims of the research proposal. |
| Please provide description: |

**SECTION C** - **Obtaining free and informed consent**

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| --- | --- | --- | --- |
| Individuals have the right to make free and informed decisions about their consent to participate in a research project. This consent includes having an understanding (in an appropriate language, at an appropriate language level) of what they are being asked to do and why, and that they willingly agree to participate without coercion or undue enticement to do so.    **Copies of any intended consent or information forms should be attached to this application.**  Guidelines for the Informed ConsentForm are included in the IRB Policy. | | | |
| 1. Vulnerable populations  If you are planning to involve any of the following population groups in this project, please detail below: | | | |
| Non-Bangla speakers | YES  NO | People in prison or detention | YES  NO |
| People with a cognitive disability | YES  NO | Children (under 14 years) | YES  NO |
| People with a physical disability | YES  NO | People who are illiterate | YES  NO |
| Investigators’ own students | YES  NO | Other IUB students | YES  NO |
| Please provide details | | | |

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| 2. Risk mitigation  Detail below any possible risk factors for subject involvement, including emotional distress, personal or cultural embarrassment, breach of confidentiality, economic harm, legal jeopardy, physical pain or injury, and intended method of mitigating such possible risks. |
| Please provide details: |

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| 3. Informed Consent  Informed consent will be obtained and documented  (Attach any consent forms proposed. If non-Bangla speakers or poor levels of Bangla language understanding are anticipated, then consent information should also be attached in the language of the proposed subjects.)  Informed consent will be obtained but I am applying for a waiver for documentation of informed consent.  I am applying for a waiver of informed consent. |
| Please provide details: |

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| 4. Are there any anticipated inducements for participation (e.g. monetary payment), or costs to be borne by subjects (e.g. travel costs)? |
| Please provide details: |

**SECTION D** - **Confidentiality and data storage**

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| 1. Confidentiality  How you will protect the confidentiality of the data collected, and protect against risks of breach of confidentiality or invasion of privacy. (For example, where will paper files and/or electronic data be stored? What security measures will be applied in each situation?; Specify your plans for de-identifying or maintaining anonymity of the data, especially if audio/video recordings or images will be collected; Specify procedures for data sharing with entities external to IUB; Provide a timetable and methods for destroying the data) |
| Please provide details: |

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| 2. Data security for storage and transmission. Select all that apply: | | | |
| For electronic data: | | For hardcopy data (including specimens, tapes etc.) | |
| Secure network: | YES  NO | Data de-identified by research team: | YES  NO |
| Password access: | YES  NO | Locked office: | YES  NO |
| Encryption: | YES  NO | Locked cabinet: | YES  NO |
| Portable storage: (e.g. laptop, flash drive) | YES  NO | Data coded by research team with master list secured and kept separately: | YES  NO |
| Other: (provide detail below) | YES  NO | Other: (provide detail below) | YES  NO |
| Please provide details: | | | |

**SECTION E** - **Data analysis and outcomes**

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| 1. How will the data be evaluated? Where and by whom will data analysis be performed? Are research assistants adequately trained and experienced to manage the type of data being collected? |
| Please provide details: |

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| 2. Detail the projected outcomes for this research project  Are there specific populations, organizations or locations likely to derive greatest benefit from the results of this project? What are the intended publication and dissemination vehicles and timelines? |
| Please provide details: |

**SECTION F** **- Attach all relevant documentation**

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| Copies of all data collection instruments, including surveys, interview questions, etc | YES |
| Copy of all consent and information forms, including translated forms, as appropriate | YES |
| Copy of any ethical approval for co-investigators external to IUB, or collaborative institutions | YES  N/A |
| Copy of CITI human subjects research completion reports | YES |
| Any other relevant documentation | YES  N/A |

**SECTION G**

I certify that all investigators involved in this research project have completed the required ethical clearance training, and that each of the co-investigators has accepted their role in this project.

I agree to a continuing exchange of information with the IUB IRB and to obtain approval before making any changes or additions to the project.

I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects.

Signature of PI: Date:

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|  |  |  |  |
| --- | --- | --- | --- |
| Date received |  | Date PI notified |  |
| Date checked and accepted |  | Date of change notification |  |
| Date(s) of committee review |  | Date committee approved |  |

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| Is demographic information collected with cultural sensitivity? | Yes No N/A |
| Is the consent requirement waived? | Yes No N/A |
| Is documentation of the consent process waived? | Yes No N/A |
| Has the Principal Investigator and Co-Investigators completed CITI training? | Yes No |
| Does the application meet ethical clearance requirements? | Yes No |
| Detail of any additional information required? | Yes No |
| Revisions required | Yes No |

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| Type of Approval: |
|  Approval   Approval with Modification   Denial   Deferral |

1. A human subject can be identified as a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information. [↑](#footnote-ref-1)