A logo of a door with a key

Description automatically generated

**Form C- Application for Full Ethics Approval**

**Information and Instructions**

*Please fill this application form and attach all the required documents along with the application form addressed to research ethics secretariate to* [***research.ethics@mnu.edu.mv***](mailto:research.ethics@mnu.edu.mv)

*Kindly please refer to research ethics policy available at* [*https://mnu.edu.mv/research-development/*](https://mnu.edu.mv/research-development/)

|  |  |  |  |  |  |  |  |  |  |  |
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| **Part A** *All the parts must be filled. If it is not applicable, please write* ***NA*** | | | | | | | | | | |
| **1. Project Title:** | | |  | | | | | | | |
| **2. Expected commencement date:** | | |  | | | | | | | |
| **3. Expected completion date:** | | |  | | | | | | | |
| **4. Chief Supervisor Detail *(Person with ultimate responsibility for the research, if not a student)*** | | | | | | | | | | |
| 1. Name (Full name as in the NID card): | | | | | | | | | | |
| 1. Staff Position: | | | | | | | | | | |
| 1. Qualifications: | | | | | | | | | | |
| 1. Staff ID: | | | | | | | | | | |
| 1. Faculty/Centre: | | | | | | | | | | |
| 1. Telephone: | | | | | | | | | | |
| 1. Email: | | | | | | | | | | |
| 5. **Student Investigator(s) (or if the project is towards a qualification)** | | | | | | | | | | |
| **Name** (Full name as in the NID card): | Student Number | Contact Address | Telephone | | Email | | Is this research for Dissertation / Masters – thesis / masters –  coursework / PhD / other? Specify which: | | | |
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| **6. If there is more than one investigator, name the individual, from those listed above, who is the main contact person for the project.** | | | | | | | | | | |
| 1. *Main Contact Person Name:* | | | |  | | | | *Contact Number:* | |  |
| **7. If this is a student project, does it require Faculty/Centre approval (e.g. program of study approval**)? | | | | | | | | | | |
| *Yes* | | | *No* | | | | | | | |
| **If this project requires Faculty/Centre approval (e.g. program of study approval), has it been:** | | | | | | | | | | |
| 1. *Submitted for approval* | | | *If submitted, is it approved*  *OR not yet approved* | | | | | | | |
| 1. *Not Submitted for approval* | | | | | | | | | | |
| **8. Is the Investigation *a follow-up of a previous study?*** | | | | | | | | | | |
| Yes | | | | | | No | | | | |
| ***9.* If you have answered Q8 ‘Yes’ then please fill the below details** | | | | | | | | | | |
| 1. *Did the earlier study have ethics approval?* | | | | | | Yes | | | No | |
| 1. *Provide Name of the Institution (if not MNU)]* | | | | | |  | | | | |
| 1. *Provide the ethics approval number of the earlier project* | | | | | |  | | | | |
| 1. *Title of the study* | | | | | |  | | | | |
| 1. *Is this research being funded* | | | | | | Yes | | | No | |
| 1. *Funding Amount (MVR)* | | | | | |  | | | | |
| 1. *Source of Fund* | | | | | |  | | | | |

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| **Part B: Project Details**  *All the parts must be filled. If it is not applicable, please write* ***NA*** | | | | | | | | | | | | | | |
| 1. **Keywords: Provide a list of, and definitions for, any technical terms and acronyms, which may assist the committee to understand this application:** | | | | | | | | | | | | | | |
| 1. *Term* | | | | | *Simple Explanation***:** | | | | | | | | | |
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| 1. **Rationale and Background for the Project** | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | |
| 1. **Has the research proposal, including design and methodology, undergone a peer review process?** | | | | | Yes | | | No | | | | | | |
| 1. *If you have answered the above question* ***yes,*** *please provide the detail* | | | | | | | | | | | | | | |
| 1. **Give a brief plain English description of the following** | | | | | | | | | | | | | | |
| 1. *Aims / Research Question(s):* | | | | | | | | | | | | | | |
| 1. *Research Design / Methods:* | | | | | | | | | | | | | | |
| 1. *Target Population:* | | | | | | | | | | | | | | |
| 1. *Sample Size/Sample Selection Procedure:* | | | | | | | | | | | | | | |
| 1. *Anticipated Outcomes:* | | | | | | | | | | | | | | |
| 1. **Potential benefits, risks and harms. *Fill the Columns Below*** | | | | | | | | | | | | | | |
| 1. *Benefits to the Participants:* | | | 1. *Benefits to the wider community* | | | | | | | | | | | |
| 1. *Possible risks or harms to the Participants/Community (If there is no harm write it)* | | | | | | | | | | | | | | |
| 1. *Number of participants intend to recruit?* | | | |  | | | | | | | | | | |
| 1. **Describe the expected demographics of participants:** | | | | | | | | | | | | | | |
| 1. *Age* |  | | | 1. *Gender (Male/Female/Both)* | | | | | | |  | | | |
| 1. *Nationality* |  | | | 1. *Any other characteristic* | | | | | | |  | | | |
| 1. *Additional demographic details:* | | | | | | | | | | | | | | |
| 1. *Justify the number of participants you intend to recruit* | | | | | | | | | | | | | | |
| 1. *Is this a planned sample* | | | | | Yes | | | | | | | No | | |
| 1. *Is this a convenience sample* | | | | | Yes | | | | | | | No | | |
| 1. *What number or proportion of people expected to be recruited is likely to participate?* | | | | | | | | | | | | | | |
| 1. *Are there any screening, inclusion or exclusion criteria for participants in this study?* | | | | | Yes | | | | | | | No | | |
|  | | | | |  | | | | | | | | | |
| **If you have answered (j) Yes please answer the below** | | | | | | | | | | | | | | |
| 1. *Describe the criteria* | | | | |  | | | | | | | | | |
| 1. *Will these be communicated to participants* | | | | |  | | | | | | | | | |
| 1. *If you have answered () yes please explain how* | | | | |  | | | | | | | | | |
| 1. *If you have answered () No please explain why not* | | | | |  | | | | | | | | | |
| 1. **Method of recruitment *(Tick ONLY the applicable boxes)*** | | | | | | | | | | | | | | |
| 1. *Email* | | | | | | | | | | | | | |  |
| 1. *Mail out* | | | | | | | | | | | | | |  |
| 1. *Letter box drops* | | | | | | | | | | | | | |  |
| 1. *Advertisement, poster, flyer* | | | | | | | | | | | | | |  |
| 1. *Recruitment through third party (e.g. via an organization, professional association, other* | | | | | | | | | | | | | |  |
| 1. *person, etc.)* | | | | | | | | | | | | | |  |
| 1. *Personal contact* | | | | | | | | | | | | | |  |
| 1. *Participants from previous study* | | | | | | | | | | | | | |  |
| 1. *Telephone* | | | | | | | | | | | | | |  |
| 1. *Snowball sampling (participants recommended to other potential participants)* | | | | | | | | | | | | | |  |
| 1. *From a designated public space (e.g. shopping center, city area, community facility)* | | | | | | | | | | | | | |  |
| 1. **The process through which participants will be recruited.** | | | | | | | | | | | | | | |
| 1. *From where will participants be recruited?* | | | | |  | | | | | | | | | |
| 1. *How will you obtain contact information for potential participants? E.g. from publicly available information (such as telephone directory) or from private sources (such as organization or membership list)?* | | | | |  | | | | | | | | | |
| 1. *Will you be advertising (attach copy of advertisement) mailing or emailing (attach copy of letter), contacting through a work place or through a third party (identify who and how contact will be achieved)?* | | | | |  | | | | | | | | | |
| 1. *How will participants respond to you or ‘sign up’ if they wish to participate in this study?* | | | | |  | | | | | | | | | |
| 1. **Specific Categories of Participants Does the project seek to recruit participants who are: (provide a response for each question)** | | | | | | | | | | | | | | |
| **Category** | | **Yes – seek to recruit** | | | | **No – will not recruit** | | | | **Possibly – coincidental recruitment only** | | | | |
| 1. *Pregnant Women?* | |  | | | |  | | | |  | | | | |
| 1. *Minors, i.e. children under 18 years of age? If yes, a copy of Police Report check must be provided.* | |  | | | |  | | | |  | | | | |
| 1. *People in dependent or unequal relationships?* | |  | | | |  | | | |  | | | | |
| 1. *People highly dependent on medical care who may be unable to give consent?* | |  | | | |  | | | |  | | | | |
| 1. *People with a cognitive impairment, an intellectual disability, or mental illness?* | |  | | | |  | | | |  | | | | |
| 1. *People who may be involved in illegal activities?* | |  | | | |  | | | |  | | | | |
| 1. *People in other countries?* | |  | | | |  | | | |  | | | | |
| 1. *Will participants be identifiable by their membership of a cultural or minority group?* | |  | | | |  | | | |  | | | | |
| 1. *People whose primary language is other than Dhivehi?* | |  | | | |  | | | |  | | | | |
| 1. **For each *‘Yes’* describe how your research complies with the relevant ethical concerns**. | | | | | | | | | | | | | | |
| 1. **If you have responded ‘yes’ to (g), (h) or (i),** address relevant issues including: | | | | | | | | | | | | | | |
| 1. *In which countries or regions?* | | | | |  | | | | | | | | | |
| 1. *Are there any special cultural sensitivities that need to be considered?* | | | | |  | | | | | | | | | |
| 1. *Are there any licenses or permissions needed for access?* | | | | |  | | | | | | | | | |
| 1. *How will you take into account the opinions and expectations of participants and their communities about any effects the research may have on them, their post-research welfare and the application of any results of the research?* | | | | |  | | | | | | | | | |
| 1. *Will this research involve access to, use, collection, or acquisition of any culturally sensitive data or material?* | | | | |  | | | | | | | | | |
| 1. *Are there any local or cultural factors which make it problematic to comply with ethical standards?* | | | | |  | | | | | | | | | |
| 1. **Databanks** | | | | | | | | | | | | | | |
| 1. *Does the project involve information**sourced from databanks***?** | | | | | Yes | | | | No | | | | | |
| ***If you have answered 12 a ‘Yes’ then provide answers for the below*** | | | | | | | | | | | | | | |
| 1. *State which one(s)* | | | | |  | | | | | | | | | |
| 1. *Provide a description of data to be accessed* | | | | |  | | | | | | | | | |
| 1. *Will data to be obtained from the databank be individually identifiable or re-identifiable?* | | | | | Yes | | | | No | | | | | |
| 1. *Will data to be obtained be non-identifiable?* | | | | | Yes | | | | No | | | | | |
| 1. *Was any form of consent given by the people whose data is being obtained?* | | | | | Yes | | | | No | | | | | |
| 1. *If you have answered (f) provide a copy of this as an attached document with the application. If no, justify how access will be obtained* | | | | | | | | | | | | | | |
| 1. *How will privacy and confidentiality of the data be maintained during the research?* | | | | | | | | | | | | | | |
| 1. *How will permission for access to the data be obtained? Are there any conditions of access? Attach a copy of any relevant approvals. (Note: This approval can be a letter or a form)* | | | | | | | | | | | | | | |
| 1. *Does this research involve linkage of data sets?* | | | | | Yes No | | | | | | | | | |
| 1. **Privacy Protection** | | | | | | | | | | | | | | |
| 1. *Is this research relevant to public health or safety, or to the management, funding or monitoring of a health service?* | | | | | Yes No | | | | | | | | Go to Qn 19 | |
| 1. *If ‘Yes’, does the research involve the collection, use or disclosure of information from a private sector organization?* | | | | | Yes No | | | | | | | | Go to Qn 19 | |
| 1. *If ‘Yes’, will you be collecting, using or disclosing health information* | | | | | Yes No | | | | | | | | Go to Qn 19 | |
| 1. *If ‘Yes’, will consent be obtained from the individuals to whom the health information relates?* | | | | | Yes No | | | | | | | | Go to Qn 20 | |
| **14. Procedures** | | | | | | | | | | | | | | |
| 1. *Describe the procedures to which participants will be subjected or the tasks they will be asked to carry out.* 2. *Describe step by step what is being asked of your participants* | | | | | | | | | | | | | | |
| **Also consider here the following: (If it is not applicable write NA)**   1. *If the project involves research on institutions or workplaces, give details about the location/s at which the research is to be conducted.* | | | | | | | | | | | | | | |
| 1. *Is there any existing relationship between the researcher and the participants (e.g. teacher, supervisor or line manager, student on placement, consultant, current or recent employee)?* | | | | | | | | | | | | | | |
| 1. *What is the status of the proposed participants (e.g. their level of seniority or employment security in the institution or workplace)?* | | | | | | | | | | | | | | |
| 1. *How will you minimize any wider risks to institutional or workplace relationships? Are there any risks to the organization/s involved?* | | | | | | | | | | | | | | |
| 1. *Will permission be required for access (e.g. consent from a CEO or the Government Department)?* | | | | | | | | | | | | | | |
| 1. *Attach copies of all instruments, surveys, interview questions, questionnaires, etc.* | | | | | | | | | | | | | | |
| **20. Data** | | | | | | | | | | | | | | |
| 1. *Will photographs be taken?*   *If photographs or video-recordings include identifiable or personal data, consent should be obtained for their recording and use.* | | | | | | | Yes No | | | | | | | |
| 1. *Will video-recordings be made?* | | | | | | | Yes No | | | | | | | |
| 1. *Consider what will be done with any video or tape recordings - short term and long term. Provide information below* | | | | | | | | | | | | | | |
| 1. *Will interviews or focus groups be tape- recorded?* | | | | | | | Yes No | | | | | | | |
| 1. *Will the photographs, videos or audio- recordings be made available to participants for checking? If yes, give details.* | | | | | | | Yes No | | | | | | | |
| **Describe what will be video or audio recorded and how this will be done. (If it is not applicable NA)** | | | | | | | | | | | | | | |
| 1. *Will individual participants be identifiable?* | | | | | | | Yes No | | | | | | | |
| 1. *Will participants be able to give feedback on or edit any transcripts or tapes?* | | | | | | | Yes No | | | | | | | |
| 1. *Will participants have any later opportunity to agree on any excerpts or quotes to be used in publications?* | | | | | | | Yes No | | | | | | | |
|  | | | | | | | | | | | | | | |
| **21. Data Analysis** | | | | | | | | | | | | | | |
| *Explain how the information or data will be analyzed, including any statistical tests or qualitative analyses.*  *(simply referring to a software package is not sufficient here).*   1. *Quantitative Analysis: (If not applicable write NA)* | | | | | | | | | | | | | | |
| 1. *Qualitative Analysis: (If not applicable write NA)* | | | | | | | | | | | | | | |
| **22. Disclosure and consent** | | | | | | | | | | | | | | |
| 1. *Explain how participants will consent to participate in this study and how they are informed of their rights.* | | | | | | | | | | | | | | |
| 1. *Where alternate forms of consent are requested, outline in detail the process by which consent will be obtained, e.g. return of an anonymous survey, recorded consent for an interview, verbal agreement.* | | | | | | | | | | | | | | |
| 1. *If the project involves participants who may have difficulty understanding English, how will their consent be established?* | | | | | | | | | | | | | | |
| **Attach copies of your Information Sheet and Consent Form or script for oral consent processes. This should be in the MNU information and Consent Form template.** | | | | | | | | | | | | | | |
| 1. *Does the project collect information from which individual participants can be identified?* | | | | | | | Yes No | | | | | | | |
| 1. *If yes, could the research be conducted using non- identifiable information?* | | | | | | | Yes No | | | | | | | |
| 1. *Does this project use any form of implicit or passive consent?* | | | | | | | Yes No | | | | | | | |
| 1. *Will there be any deception of participants including limited disclosure, concealment and covert observation?* | | | | | | | Yes No | | | | | | | |
| If you answered ‘Yes’ to any of the questions below, please provide a detailed justification. ***When writing your justification, clearly indicate the corresponding question number.*** | | | | | | | | | | | | | | |
| 1. **Intrusiveness** | | | | | | | | | | | | | | |
| **Please answer all questions in this section** | | | | | | | | | | | | | | |
| 1. *Are there any aspects of the study that are intrusive in areas ordinarily considered personal and private, or that could create apprehension and anxiety for participants?* | | | | | | | Yes No | | | | | | | |
| 1. *Are you collecting personal details or private information?* | | | | | | | Yes No | | | | | | | |
| 1. *Is there any kind of dependency relationship between the researcher and any of the participants? (e.g. if you are both clinician and researcher, if you are both class teacher and researcher, if you are personal friend and researcher, if you are a member of an identifiable group and researching the group).* | | | | | | | Yes No | | | | | | | |
| 1. *If you answered ‘Yes’ to part [c], how will you ensure that the relationship does not impair participants' free and voluntary consent and participation in the project?* | | | | | | | | | | | | | | |
| 1. *Could your research evoke anxiety or lead to the recall of painful memories?* | | | | | | | Yes No | | | | | | | |
| 1. *Will participants be asked to provide any information or commit any act, which might diminish self-respect or cause them to experience shame, embarrassment or regret?* | | | | | | | Yes No | | | | | | | |
| 1. *Will any procedure be used which may have an unpleasant or harmful side effect?* | | | | | | | Yes No | | | | | | | |
| 1. *Does the research use any stimuli, tasks, or procedures, which may be experienced by subjects as stressful, noxious, or unpleasant?* | | | | | | | Yes No | | | | | | | |
| 1. *Will you induce or create physical pain beyond mild discomfort?* | | | | | | | Yes No | | | | | | | |
| 1. *If you have responded ‘Yes’ to any of the above, explain how you will address the issues or risks which may emerge. If adverse consequences are possible, describe these and explain the risk management process that you will use (eg if interviews may cause distress provide details of support processes that will be put in place).* | | | | | | | | | | | | | | |
| 1. **Reimbursement** | | | | | | | | | | | | | | |
| 1. *Is any reimbursement, payment, inducement or other reward being offered to participants in the study?* | | | | | | | Yes No | | | | | | | |
| 1. *If 'Yes', state what will be offered, to what amount or value and for what purpose (e.g. a voucher as a prize, reimbursement to cover expenses etc.)* | | | | | | | | | | | | | | |
| 1. **Feedback and Research Outcomes** | | | | | | | | | | | | | | |
| 1. *Research outcomes should be made accessible to participants in a way that is timely and clear.*   *What feedback will be given to participants?* | | | | | | | | | | | | | | |
| 1. *How will feedback be given?* | | | | | | | | | | | | | | |
| 1. *How do you plan to make the outcomes of the research more widely available (e.g. thesis, journal paper, web page, book, etc.)?* | | | | | | | | | | | | | | |
| 1. **Data Storage** | | | | | | | | | | | | | | |
| 1. *During the Study: How and where will data be stored during the study? How will data security be managed?* | | | | | | | | | | | | | | |
| 1. *Following the Study: How and where will data be stored during the study? How will data security be managed?* | | | | | | | | | | | | | | |
| 1. *Describe the data which will be stored. Will any individually identifiable data be stored?* | | | | | | | 1. *Yes No* | | | | | | | |
| 1. *Will data be utilized for any future research or potentially be made available to other researchers?* | | | | | | | 1. *Yes No* | | | | | | | |
| 1. *If you have answer’s part* ***[d] 'Yes'****, describe what data, whether or not individually identifiable, and what consideration has been given to participant consent.* | | | | | | | | | | | | | | |
| 1. *When and how will data be disposed of? Explain.* | | | | | | | | | | | | | | |
| 1. **Other Ethical Issues** | | | | | | | | | | | | | | |
| 1. *Are there in your opinion any other ethical issues involved in the research?* | | | | | | | Yes No | | | | | | | |
| 1. *Are there any competing interests or possible conflicts of interest?* | | | | | | | Yes No | | | | | | | |
| 1. *Is there a risk that the publication of your results could cause any kind of harm (including physical, psychological, spiritual, emotional, social and financial) to individual participants, to participants’ employability or professional relationships, or to their communities?* | | | | | | | Yes No | | | | | | | |
| 1. *Are there any risks involved to any member of the research team that have not already been addressed?* | | | | | | | Yes No | | | | | | | |
| 1. *If a researcher will be working in remote locations, provide information on how the researcher’s personal safety will be maintained.* | | | | | | | Yes No | | | | | | | |
| 1. *If a researcher will be entering participants’ homes or private properties, provide information on how the researcher’s personal safely will be maintained.*   *If 'Yes', please explain in more detail.* | | | | | | | Yes No | | | | | | | |

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| **DECLARATION**  *This application form must be signed by the Chief Investigator / Principal Supervisor who has been named on the front page and who accepts the legal and ethical responsibilities associated with this research project. Signatures of all Co- investigators and Student Investigators must also be provided if the project is a joint one. If the form is filled by a student for an award, the ultimate responsibility for ethics lies with the student.*  *I have read and will abide by the MNU’s policies dealing with research and ethics.*  *I declare that I and all participating researchers on this project will abide by the terms of ethics code. I accept the legal and ethical responsibilities associated with this research.* | | |
| **Chief Investigator / Supervisor / Student if for an award** | | |
| **Name: (please print)** | **Given Name:** Mariyam | **Surname:** |
| **Signature** |  | **Date:** |
| **Co-investigator(s)** | | |
| **Name: (please print)** | **Given Name:** | **Surname:** |
| **Signature** |  | **Date:** |
| **Student Researcher(s)** | | |
| **Name: (please print)** | **Given Name:** | **Surname:** |
| **Signature** |  | **Date:** |
| **Authorization – Dean or Head of Centre** | | |
| *I authorize this project to proceed in the [faculty name] subject to approval by the MNU’s Research Ethics Committee.* | | |
| **Name: (please print)** | **Given Name:** | **Surname:** |
| **Signature** |  | **Date:** |

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| **Section F: Supervisors Agreement *(\* Please note that without signature the form will be considered as incomplete)*** | | | | |
|  | This application has been developed under my supervision and has my full support. I confirm that I have reviewed and ensured the following:   * The students have ***completed all required documents*** as outlined at the end of the application form. * I have ***thoroughly reviewed and approved the students’ research proposals***, including the research questions, methodology, data collection tools (e.g., questionnaires), and ethical considerations. * I have verified the completed application form and ***ensured that all sections are accurately and properly filled out.*** | | | |
|  | Signature of the supervisor |  | Date: |  |

|  |
| --- |
| CHECK LIST |
| **Before submitting this form to the Research Ethics Committee, please ensure that all of the following items have been completed and attached as appendices.** All documents must be submitted in **PDF format only**. Please note that if any of the required PDF documents or relevant signatures are missing, the application will be returned to the applicant as an **incomplete submission**.  **Required Documents (PDF format only):**   1. **Ethics Screening Questionnaire** 2. **Completed Ethics B Form**, signed by both the applicant and the supervisor 3. **Research Proposal**, with page numbers on each page, including 4. **Data Collection Tools** (ResearchQuestionnaire with page numbers on each page, questionnaire guide, proforma etc.) 5. **Participant Information Sheet** (using the official MNU template) 6. **Consent Form(s)** for each category of participant involved in the study 7. **Reference List** (to be submitted as a separate document) 8. **Ethics Approval Letter** from the collaborating institution (if applicable) |