

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

For information to assist with the completion of this form, see the staff of RC. All responses to questions must be provided on this form. Submit completed application to:

*The Chair*

*MNU Research Ethics Committee The Maldives National University*

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| **PART A** |  |
| 1. Project Title |  |
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| 2. Expected commencement date of this project | 3. Expected completion date of this project |

1. Chief Supervisor (Person with ultimate responsibility for the research, if not a student) Title Given Name Surname

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| Staff Position: |  | Qualifications |
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| Staff ID: |  |  |
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| Faculty/Centre: |  |  |
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| Telephone |  | Email: |

1. Student Investigator (or if the project is towards a qualification) Title Given Name Surname

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| Student Number: |  | Is this research for Dissertation / Masters – thesis / masters –  coursework / PhD / other? Specify which: |
|  |  |  |
| Contact Address: |  |  |
|  |  |  |
| Telephone: |  | Email (Required): |
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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. | | |

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| 7. If this is a student project, does it require Faculty/Centre approval (e.g. program of study  approval)? | | |
|  | Yes | No |
| 8. If this project requires Faculty/Centre approval (e.g. program of study approval), has it been: | | |
| *a)* Submitted | *i)* Approved | *ii)* Not yet approved |
| *b)* Not yet submitted |  |  |
| 9. Is the Investigation: | A follow-up of a previous study? Yes No | |
| If ‘Yes’, did the earlier study have ethics approval? Provide details of the institution (if not MNU) and give the approval number of the earlier project | | |
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| What was the title of that study? | | |
| 10. Funding |  |  |
| Is this research being funded? | Yes | No |
| *If ‘Yes’,* please detail amount and source of  funds | |  |

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| **PART B** |  |  |
| 11. Project Details  Keywords: Provide a list of, and definitions for, any technical terms and acronyms, which may assist the committee to understand this application: | | |
| Term: | Simple Explanation: | |
| **Rationale and Background for the Project:** | | |
| Has the research proposal, including design and methodology, undergone a peer review process? | Yes | No |
| *If ‘Yes’,* provide details: |  |  |

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| Give a brief plain English description of the aims of this project, the proposed research design and  methods, and the anticipated outcomes. |
| AIMS / RESEARCH QUESTION |
| RESEARCH DESIGN / METHODS |
| ANTICIPATED OUTCOMES |

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| 12. Potential benefits, risks and harms | |
| *(a)* What are the possible benefits of this research? | |
| (i) | To the participant: |
|  |  |
| (ii) | To the wider community: |
| *(b)* What are the possible risks or harms of this research to the participants? | |

Outline possible risks or harms. How do the likely benefits of the research justify possible risks to participants?

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| 13. Participants |  |  |
| How many participants do you intend to  recruit? | | |
| Describe the expected demographics of participants: | | |
| Age |  | Gender |
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| Nationality |  | Any other characteristic |

Additional demographic details:

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| *(a)* Justify the number of participants you intend to recruit. Also consider issues such as: Is this a  planned sample or a convenience sample? What number or proportion of people expected to be recruited is likely to participate? | | |
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| *(b)* Are there any screening, inclusion or exclusion criteria for participants in this study? | Yes | No |
| Describe the criteria. Will these be communicated to participants; if yes, how; if no, why not? | | |
| 14. Method of recruitment |  |  |
| (Tick only the applicable boxes) |  |  |
| *(a)* Email |  |  |
| *(b)* Mail out |  |  |
| *(c)* Letter box drop |  |  |
| *(d)* Advertisement, poster, flyer |  |  |
| *(e)* Recruitment through third party (e.g. via an organisation, professional association, other  person, etc.) | | |
| *(f)* Personal contact |  |  |
| *(g)* Participants from previous study |  |  |
| *(h)* Telephone |  |  |
| *(i)* Snowball sampling (participants recommended to other potential participants) | | |
| *(j)* From a designated public space (e.g. shopping centre, city area, community facility) | | |
| 15. Describe the process through which participants will be recruited. | | |

Consider details such as: From where will participants be recruited? 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 organisation or membership list)? 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)? How will participants respond to you or ‘sign up’ if they wish to participate in this study?

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| 16. Specific Categories of Participants |  |  |  |
| Does the project seek to recruit participants who are: (provide a response for each question) | Yes – seek to recruit | No – will not recruit | Possibly – coincidental recruitment only |
| *(a)* Pregnant Women? |  |  |  |
| *(b)* Minors, i.e. children under 18  years of age? If yes, a copy of Police Report check must be  provided. |  |  |  |
| *(c)* People in dependent or  unequal relationships? |  |  |  |
| *(d)* People highly dependent on  medical care who may be unable to give consent? |  |  |  |
| *(e)* People with a cognitive  impairment, an intellectual disability, or mental illness? |  |  |  |
| *(f)* People who may be involved in  illegal activities? |  |  |  |
| *(g)* People in other countries? |  |  |  |
| *(h)* Will participants be  identifiable by their membership of a cultural or minority group? |  |  |  |
| *(i)* People whose primary  language is other than Dhivehi? |  |  |  |
| For each *‘Yes’* describe how your research complies with the relevant ethical concerns. | | | |
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| **If you have responded ‘yes’ to (g), (h) or (i),** address relevant issues including: In which countries or regions? Are there any special cultural sensitivities that need to be considered? Are there any licenses or permissions needed for access? 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? Will this research involve access to, use, collection, or acquisition of any culturally sensitive data or material? Are there any local or cultural factors which make it problematic to  comply with ethical standards? | | | |

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| 17. Databanks |  |  |
| *(a)*Does the project involve information sourced from databanks? | Yes | No |
| If ‘Yes’, state which one(s). Provide a description of the data to be accessed. | | |
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| *(b)* Will data to be obtained from the databank be individually identifiable or re-identifiable? | Yes | No |
| *(c)* Will data to be obtained be non-identifiable? | Yes | No |
| *(d)* Was any form of consent given by the people whose data is being obtained? | Yes | No |
| (If ‘Yes’, provide a copy of this. If no, justify how access will be obtained) | | |
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| *(e)* How will privacy and confidentiality of the data be maintained during the research? | | |
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| *(f)* How will permission for access to the data be obtained? Are there any conditions of access? Attach a copy of any relevant approvals. | | |
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| *(g)* Does this research involve linkage of data sets? | Yes | No |

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| 18. Privacy Protection |  |  | |
| *(a)* 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 |
| *If ‘Yes’,* does the research involve the collection, use or disclosure of information from a private sector organisation? | Yes | No | Go to Qn 19 |
| *If ‘Yes’,* will you be collecting, using or disclosing health information | Yes | No | Go to Qn 19 |
| *If ‘Yes’,* will consent be obtained from the individuals to whom the health information relates? | Yes | No | Go to Qn 20 |

19. Procedures

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| Describe the procedures to which participants will be subjected or the tasks they will be asked  to carry out.  Describe step by step what is being asked of your participants. | | |
| Also consider here:  If the project involves research on institutions or workplaces, give details about the location/s at which the research is to be conducted. 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)? What is the status of the proposed participants (e.g. their level of seniority or employment security in the institution or workplace)? How will you minimise any wider risks to institutional or workplace relationships? Are there any risks to the organisation/s involved? Will permission be required for access (e.g. consent from a CEO or  Government Department)? | | |
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| Attach copies of all instruments, surveys, interview questions, questionnaires, etc. | | |
| 20. Data |  |  |
| *(a)* Will photographs be taken? | Yes | No |
| If photographs or video-recordings include identifiable or personal data, consent should be  obtained for their recording and use. | | |
| *(b)* Will video-recordings be made? | Yes | No |
| Consider what will be done with any video or tape recordings - short term and long term.  Provide information below | | |
| *(c)* Will interviews or focus groups be tape- recorded? | Yes | No |
| *(d)* 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. Will individual participants be identifiable? Will participants be able to give feedback on or edit any transcripts or tapes? Will participants have any later opportunity to agree on any excerpts or quotes to be used in publications? Describe what photographs will be taken and why. Will people be  identifiable from the photographs? | | |
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| 21. Data Analysis |  |  |
| Explain how the information or data will be analysed, including any statistical tests or qualitative  analyses (***simply referring to a software package is not sufficient here***). | | |
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| 22. Disclosure and consent: |  |  |

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| Explain how participants will consent to participate in this study and how they are informed of  their rights.  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. If the project involves participants who may have difficulty understanding English,  how will their consent be established? | | |
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| Attach copies of your Information Sheet and Consent Form or script for oral consent processes. | | |
| *(a* Does the project collect information from which individual participants can be identified? | Yes | No |
| *If yes,* could the research be conducted using non- identifiable information? | Yes | No |
| *(b* Does this project use any form of implicit or passive consent? | Yes | No |
| *(c* Will there be any deception of participants including limited disclosure, concealment and covert observation? | Yes | No |
| If ‘Yes’ to any of these, please provide detailed justification: | | |
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| 23. Intrusiveness |  |  |
| Please answer all questions in this section |  |  |
| *(a)* 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 |
| *(b*)Are you collecting personal details or private information? | Yes | No |
| *(c)* 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). How will you ensure that the relationship does not impair participants' free and  voluntary consent and participation in the project? | Yes | No |

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| *(d)* Could your research evoke anxiety or lead to  the recall of painful memories? | Yes | No |
| *(e)* 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 |
| *(f)* Will any procedure be used which may have an unpleasant or harmful side effect? | Yes | No |
| *(g)* Does the research use any stimuli, tasks, or procedures, which may be experienced by subjects as stressful, noxious, or unpleasant? | Yes | No |
| *(h)*Will you induce or create physical pain beyond mild discomfort? | Yes | No |
| 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). | | |
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| 24. Reimbursement |  |  |
| Is any reimbursement, payment, inducement or  other reward being offered to participants in the study? | Yes | No |
| 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.). | | |
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| 25. Feedback and Research Outcomes |  |  |
| Research outcomes should be made accessible to participants in a way that is timely and clear.  What feedback will be given to participants? How will feedback be given?  How do you plan to make the outcomes of the research more widely available (e.g. thesis,  journal paper, web page, book, etc.)? | | |
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| 26. Data Storage |  |  |
| (a) During the Study:  How and where will data be stored during the study? How will data security be managed? | | |

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| (b) Following the Study:  Describe the data which will be stored. Will any individually identifiable data be stored? | Yes | No |
| Will data be utilised for any future research or potentially be made available to other researchers? | Yes | No |
| If 'Yes', describe what data, whether or not individually identifiable, and what consideration has been given to participant consent. | | |
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| When and how will data be disposed of? |  |  |
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| 27. Other Ethical Issues |  |  |
| Are there in your opinion any other ethical issues involved in the research? | Yes | No |
| Include here issues such as:   * Are there any competing interests or possible conflicts of interest? * Are there any restrictions on publications resulting from this study? * 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? * Are there any risks involved to any member of the research team that have not already been addressed? * If a researcher will be working in remote locations, provide information on how the researcher’s personal safety will be maintained.   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. |  |  |
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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* | | |

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| Chief Investigator / Supervisor / Student if for an award | | | |
| Name: (please print) | Given Name |  | Surname |
| Signature: |  |  | Date: |

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| Co-investigator(s) |  |  |  |  |
| Name:  (please print) | Given Name |  |  | Surname |
| Signature: |  |  |  | Date: |
| Student Researcher(s) | | | | |
| Name:  (please print) | Given Name |  |  | Surname |
| Signature: |  |  |  | Date: |
| Authorisation – Dean or Head of Centre | | | | |
| I authorise 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: |

**Actions taken by Research Ethics Committee**

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| Application Number |  |
| Send for further clarifications |  |
| Approved by: |  |
| Date: |  |