



## **APPROVAL GUIDELINES FOR ETHICAL CONDUCT OF RESEARCH**

*Approved Date: 14th May 2017*

*Revision Effective from: 16<sup>th</sup> July 2017*

### **1 Guiding principles**

#### **1.1 Communication with participants**

- 1.1.1 The researcher should provide detailed information about the research to the participants.
- 1.1.2 It is recognized that some level of deception may be required for certain research projects.
- 1.1.3 The information must be provided based on the approved format and must be written in plain language that can be readily understood by the participants.
- 1.1.4 The information sheet should provide the following information:
  - 1.1.4.1 The identity of the researchers (and supervisors for student research)
  - 1.1.4.2 The course or degree for which the project is a requirement (where appropriate)
  - 1.1.4.3 The purpose, aim and objectives of the project
  - 1.1.4.4 The nature and duration of the participants' involvement
  - 1.1.4.5 Steps taken to ensure confidentiality and anonymity
  - 1.1.4.6 Compensation for participation (if any)
  - 1.1.4.7 Risks of participation (if any)
  - 1.1.4.8 Subsequent tasks or procedures (if any)
  - 1.1.4.9 Contact details of the researcher and supervisors if appropriate. In order to protect the researcher from unwarranted calls, personal telephone numbers and addresses should not be given unless there is no alternative.
  - 1.1.4.10 Ethics approval number issued by the MNU REC.
- 1.1.5 An example Information Sheet template is provided in Appendix B.
- 1.1.6 In cases where the participants' literacy level compromises their ability to read and understand the information sheet, the information should be provided orally in a

manner that the participant fully understands what is involved in the research. A copy of the information sheet should still be provided to the participant.

- 1.1.7 Participation by individuals should be voluntary and the researcher should ensure all participants have given written consent. Written consent forms must clearly indicate that the participant:
  - 1.1.7.1 Understands the information given on the Information Sheet;
  - 1.1.7.2 Voluntarily consents to participate in the project;
  - 1.1.7.3 Understands that he/she may withdraw at any time without any prejudice or penalty including withdrawal of information provided;
  - 1.1.7.4 Agrees to publication of results, with the understanding that anonymity or confidentiality will be preserved;
  - 1.1.7.5 Cover any special provisions such as waiver of confidentiality, publicly available storage of research material, or use of video and photographs;
  - 1.1.7.6 Has been shown a copy of the ethics approval letter given by the MNU REC.
- 1.1.8 A template for a letter of Consent is provided in Appendix B.
- 1.1.9 It is recognized that in some cases written consent may not be appropriate or necessary. Where a participant's literacy level impairs his or her ability to read and understand a written consent form or provide one, they should be informed orally about the project. If a person is unable to provide written consent, then consideration may be given to audio or video recording oral consent or voluntary participation as consent. All exceptions to the written consent requirement must be fully explained in the ethics application.
- 1.1.10 In cases where deception is required for recruiting participants the participants must be provided with a debriefing. The debriefing should be provided in writing and should include a detailed review of the purpose of the research in lay person's terms and a clear explanation of why deception was necessary to achievement of the research aims.
- 1.1.11 Any benefits to the person or other groups that might be created by successful completion of the research may be referred to and they should be given the opportunity to withdraw from the study without penalty if they are not satisfied with the explanation.
- 1.1.12 A summary of the project results should be offered to participants when these become available at the end of the research.

## **1.2 Use of electronic media as a source of data**

- 1.2.1 Ethical issues need to be considered for research that involves using electronic media as a source of data. Such sources include data in the form of opinions and information posted by individuals to any electronic forum.
- 1.2.2 Comments and information posted on publicly available forums may be used without seeking further permission.
- 1.2.3 In the case of lists and forums which are only available to members of an association, or who have applied to become subscribers, the permission of the moderator to use data from the forum must be sought.
- 1.2.4 Individual contributors should not be identifiable in any use of the data, unless permission has been sought and granted from each individual to be cited. Such permission must conform with the informed consent principles, and other relevant principles of the ethics policy and guidelines.
- 1.2.5 Researchers creating new lists, electronic forums or social networking sites for the purpose of their research must inform all participants when the forum is established, and advise any new participant joining the forum, that comments and information posted to the forum are intended to be used for research purposes. The information provided must conform with the informed consent principles, and other relevant principles of the ethics policy and guidelines.
- 1.2.6 Research involving the posting of false or misleading information to a web site, list or other online forum is subject to the provisions in the ethics policy regarding deception. The application must explicitly demonstrate how the benefits of the research outweigh the harm done by the deception involved, the risks to the reputation of the University, and how participants will be debriefed after the research is complete.

## **1.3 Payments to research participants**

- 1.3.1 Payment of participants in research raises special ethical issues and should be considered with care. Any payment to the participants needs to take account of the following points:
  - 1.3.1.1 Any payment should be made with the approval of the MNUREC. The amount and reason for the payments should be clearly spelt out in the application to the MNUREC, the information sheet and any advertising of the research
  - 1.3.1.2 Payments must not be, or be perceived to be, an inducement to participate in research;

- 1.3.1.3 Researchers should consider whether a gift or voucher might be more appropriate than cash;
- 1.3.1.4 Payments should not be used to encourage participants to undertake dangerous or harmful acts;
- 1.3.1.5 Participants should be informed that they have the right to withdraw from the research, irrespective of whether or not payment is involved;
- 1.3.1.6 Payments to any dependent persons or children under 18 years of age must not be made without prior approval by their parents or guardians

#### **1.4 Storage, security and destruction of data**

- 1.4.1 Researchers should ensure protection of the privacy of research participants.
- 1.4.2 All personal information must be handled in a way that ensures secure custody of data.
- 1.4.3 Researchers, supervisors and teachers must ensure that personal information is protected by security safeguards against unauthorised access, use, modification, disclosure and other misuse. Appropriate security and backup systems should be used to protect against loss of such data.
- 1.4.4 The application to the MNUREC should clearly describe who is entitled to have access to personal information collected, and what conditions are set for such access. The application should also state personal information will be used in the writing up or other means of completion of the project.
- 1.4.5 Research information collected for the approved project shall not be used, without the written consent of the information giver, for another purpose unless it is in the public arena or is available in a non-identifying manner which follows the ethics guidelines.
- 1.4.6 Participants should be provided with information on what will happen to the data collected after completion of the research (e.g. how and where it will be stored, and for how long).
- 1.4.7 Personal information should not be kept for longer than is necessary to complete the particular project and to allow for academic examination, challenge or peer review. Where it is proposed to keep such information for a longer period, this must be justified in the application for ethical approval.
- 1.4.8 Research information collected and/or stored electronically must be protected by secure password access

## **2 Determining the Approval Procedure**

- 2.1 Use the Screening Questionnaire (Appendix C) to determine whether low risk approval or a full ethics approval is required for the project.

## **3 Related Forms and Guidelines**

- 3.1 Application for Blanket Approval (for teaching exercises)
- 3.2 Application for Low Risk Approval
- 3.3 Application for Full Ethical Approval
- 3.4 Screening Questionnaire

APPENDIX A

 <p>ދިވެހިރާއްޖޭގެ ជាតީގެ ގައުމީ ޔުނިވަރސިޓީ THE MALDIVES NATIONAL UNIVERSITY</p>	<h2 style="margin: 0;">Form A- Application for Blanket Approval</h2> <p style="margin: 0;"><i>For Course Coordinators</i></p>
--	---

**Section A: Details of Subject**

Course Name	Click here to enter text.
Subject Code	Click here to enter text.
Credit points	Click here to enter text.
Subject Coordinator	Click here to enter text.
Email Address of subject coordinator	Click here to enter text.

**Section B: Details of Assessment/Research based component**

Give a brief description of the research based component	Click here to enter text.
Aims / Objectives	
Research procedures are involved	Click here to enter text.
Description of research participants	Click here to enter text.

**Section C: Ethical Consideration**

Ethical consideration of the project: Describe how each of the given concerns (if any) will be addressed by the students. If the risk/concern is low indicate so.	
Voluntary, informed consent	Click here to enter text.
Privacy & confidentiality	Click here to enter text.

Risk to Participants	Click here to enter text.
Permission for access to participants from other individuals or bodies	Click here to enter text.
Storage and subsequent destruction of data	Click here to enter text.
Dissemination of research	Click here to enter text.

### Declaration by Coordinator

I hereby undertake the responsibility of ensuring that relevant ethical considerations are addressed in this research based component of the course. I specifically will ensure the lecturers and students involved in this subject:

- are made aware of the need for seeking ethics approval for all research involving human participants and that a blanket approval has been taken for this course
- follow the ethical considerations required in the involvement of human subjects and the students are asked to document all ethics procedures followed in the submission of their assessed work.

Applicant's Name			
Faculty/Centre			
Signature		Date	

### Actions taken by Research Ethics Committee

Application Number	
Send for further clarifications	
Approved by:	
Date:	



## Form B- Application for Low Risk Ethical Approval

The purpose of this form is to give Research Ethics Committee sufficient information to make an informed judgment about the ethics of your application.

Personal details			
Applicant's details			
Date of applicant	/ /		
Full name of applicant			
Contact address			
Phone number		Email	
Program of study		Faculty/Centre	
Supervisor details			
Principal supervisor			
Current qualifications			
Current employment		Work	
Other personnel			
Project details			
Title of the project			
Proposed date of commencement of data collection	/ /	Expected date of completion of data collection	/ /
Interest in topic			
Is this research being funded			
Authorised official stamp of the organisation.			



Details of the project	
Research question(s)	
Justification	
Procedure for recruiting participants and obtaining informed consent	
Procedures in which research participants will be involved	
Procedures for handling information and materials produced in the course of the research	

Ethical Issues	
Access to participants	
Informed consent	
Confidentiality	
Potential harm to participants	
Participants' right to decline to participate and right to withdraw: (1) Indicate what activities you require participants to do in your study. (2) Indicate how much participants' time will be required	
Arrangements for participants to receive information	
Use of the information	
Conflicts of interest	
Procedure for resolution of disputes	

Other ethical concerns relevant to the research	
Cultural and social considerations	

### Legal issues

Copyright	
Ownership of data or materials produced	
Any other legal issue relevant to the research	
Place in which the research will be conducted	
<p>Has this application in whole or part previously been declined or approved by another ethics committee?</p> <p style="text-align: center;"><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>	
<p>For research to be undertaken at other facilities under the control of another ethics committee, has an application also been made to that committee?</p> <p style="text-align: center;"><input type="checkbox"/> Yes    <input type="checkbox"/> No</p>	
Is any of this work being used in a thesis to be submitted for a degree at the MNU?	
Further conditions	

### Informing relevant departmental head/s

Is your proposed research about subjects/papers or programmes within the Faculty/Centre of .....?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, have you informed the relevant Head (s) of Department?	<input type="checkbox"/> Yes <input type="checkbox"/> No

### Applicant agreement

I agree

- a. to ensure that the above-mentioned procedures concerning the ethical conduct of this project will be followed by all those involved in the collection and handling of data.
- b. in the event of this application being approved, the researcher agrees to inform the Research Ethics Committee of any change subsequently proposed.
- c. to submit for approval any amendments made to the research procedures outlined in this application which affect the ethical appraisal of the project.

Signature of applicant

Date / /

### Supervision agreement

I agree

- a. that this application has been developed with my supervision and has my support. I have checked that all the information requested in the checklist below is included.
- b. I agree to support the student to follow the above-mentioned procedures concerning the ethical conduct of this project.

Signature of Principal supervisor:

Date / /

Signature of a Co-supervisor:

Date / /

### CHECK LIST

Before submitting this form to the Research Ethics Committee, please ensure that you have completed the following and attached these as appendices

- Letter(s) to: participants, e.g. children, caregivers, principal, teachers.
- Information sheet, introductory letter for each type of participant.
- Consent form(s) for each type of participant.
- Questionnaire/survey questions/interview questions.
- Reference list.
- Every page of your ethics application form has been numbered.

### Actions taken by Research Ethics Committee

Application Number	
Send for further clarifications	
Approved by:	
Date:	



## From 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*

### PART A

1. Project Title

2. Expected commencement date of this project      3. Expected completion date of this project

<input type="text"/>	<input type="text"/>
----------------------	----------------------

4. Chief Supervisor (Person with ultimate responsibility for the research, if not a student)

Title                                      Given Name                                      Surname

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Staff Position:            Qualifications     

Staff ID:     

Faculty/Centre:     

Telephone            Email:     

5. Student Investigator (or if the project is towards a qualification)

Title                                      Given Name                                      Surname

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

Student Number:            Is this research for Dissertation / Masters – thesis / masters –  
coursework / PhD / other? Specify which:     

Contact Address:     

Telephone:            Email (Required):     

6. If there is more than one investigator, name the individual, from those listed above, who is the main contact person for the project.

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

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

## 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:

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

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?

13. Participants

How many participants do you intend to recruit?

Describe the expected demographics of participants:

Age

Gender

Nationality

Any other characteristic

Additional demographic details:

(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?

(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  | <input type="checkbox"/> |
| (b) Mail out   | <input type="checkbox"/> |
| (c) Letter box drop  | <input type="checkbox"/> |
| (d) Advertisement, poster, flyer   | <input type="checkbox"/> |
| (e) Recruitment through third party (e.g. via an organisation, professional association, other person, etc.) | <input type="checkbox"/> |
| (f) Personal contact   | <input type="checkbox"/> |
| (g) Participants from previous study   | <input type="checkbox"/> |
| (h) Telephone  | <input type="checkbox"/> |
| (i) Snowball sampling (participants recommended to other potential participants)                             | <input type="checkbox"/> |
| (j) From a designated public space (e.g. shopping centre, city area, community facility)                     | <input type="checkbox"/> |

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?

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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(b) Minors, i.e. children under 18 years of age? If yes, a copy of Police Report check must be	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

provided.

- |  |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|
| (c) People in dependent or unequal relationships?  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (d) People highly dependent on medical care who may be unable to give consent?             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (e) People with a cognitive impairment, an intellectual disability, or mental illness?     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (f) People who may be involved in illegal activities?                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (g) People in other countries?   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (h) Will participants be identifiable by their membership of a cultural or minority group? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| (i) People whose primary language is other than Dhivehi?                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

For each 'Yes' describe how your research complies with the relevant ethical concerns.

**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?

#### 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.

- (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)

(e) How will privacy and confidentiality of the data be maintained during the research?



(f) How will permission for access to the data be obtained? Are there any conditions of access? Attach a copy of any relevant approvals.

(g) Does this research involve linkage of data sets? Yes  No

### 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

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)?

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?

#### 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***).

#### 22. Disclosure and consent:

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?

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:

### 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

(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).

#### 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.).

#### 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.)?

#### 26. Data Storage

(a) During the Study:

How and where will data be stored during the study? How will data security be managed?

(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.

When and how will data be disposed of?

#### 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 safety will be maintained.

If 'Yes', please explain in more detail.

--

**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	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:

**Authorisation – Dean or Head of Centre**

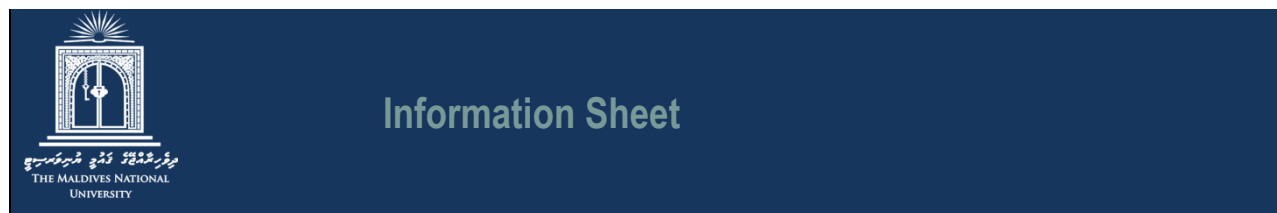
I authorise this project to proceed in the [faculty name] subject to approval by the MNU's Research Ethics Committee.

Name: (please print)	Given Name	Surname
Signature:		Date:

**Actions taken by Research Ethics Committee**

Application Number	
Send for further clarifications	
Approved by:	
Date:	

*This form is adopted from those usually used in Australian universities, more particularly in the Murdoch University*



### Information for Participants

You are invited to participate as a subject in the research project [*name of project*].

The aim of this project is [*aim of project*].

Your involvement in this project will be [*description of tasks and procedures, and estimation of time required*], and the right to withdraw from the project at any time, including withdrawal of any information provided without any penalty.

As a follow-up to this investigation, you will be asked to [*description of any subsequent involvement*].

In the performance of the tasks and application of the procedures there are risks of [*description of any risks foreseen and add mitigation undertaken*].

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: the identity of participants will not be made public without their consent. To ensure anonymity and confidentiality, [*description of steps taken to ensure anonymity and confidentiality*].

The project being carried out [as a requirement for course or degree (where relevant)] by [name of principal researcher] under the supervision of [name of the supervisor (where relevant)], who can be contacted at [telephone number(s)]. He/she/they will be pleased to discuss any concerns you may have about participation in the project.

The project has been reviewed **and approved** by the Maldives National University Ethics Committee



## Consent form

[Researchers name]

[Contact Address]

[Date]

CONSENT FORM

[Name of Project]

I have read and understood the description of the above-named project. On this basis I agree to participate as a subject in the project, and I consent to publication of the results of the project with the understanding that anonymity will be preserved.

I understand also that I may at any time withdraw from the project, including withdrawal of any information I have provided.

I note that the project has been reviewed **and approved** by The Maldives National University Ethics Committee.

Name (please print) .....

Signature:

Date:

 <p>THE MALDIVES NATIONAL UNIVERSITY</p>	<h2 style="margin: 0;">Screening Questionnaire to Determine the Approval Procedure</h2> <p style="margin: 0;"><i>(adapted from Massey University)</i></p>
---	---

(Part A and Part B of this questionnaire must both be completed)

Name:
Project Title:

This questionnaire should be completed following, or as part of, the discussion of ethical issues.

### Part A

The statements below are being used to determine the risk of your project causing physical or psychological harm to participants and whether the nature of the harm is minimal and no more than is normally encountered in daily life. The degree of risk will then be used to determine the appropriate approval procedure.

If you are in any doubt you are encouraged to submit a FULL ethics review approval to the MNUREC.

Does your Project involve any of the following?

*(Please answer all questions. Please circle either YES or NO for each question)*

#### Risk of Harm

1. Situations in which the researcher may be at risk of harm.	YES / NO
2. Use of questionnaire or interview, whether or not it is anonymous which might reasonably be expected to cause discomfort, embarrassment, or psychological or spiritual harm to the participants.	YES / NO
3. Processes that are potentially disadvantageous to a person or group, such as the collection of information which may expose the person/group to discrimination.	YES / NO
4. Collection of information of illegal behaviour(s) gained during the research which could place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships.	YES / NO
5. Collection of blood, body fluid, tissue samples, or other samples.	YES / NO
6. Any form of exercise regime, physical examination, deprivation (e.g. sleep, dietary).	YES / NO
7. The administration of any form of drug, medicine (other than in the course of standard medical procedure), placebo.	YES / NO
8. Physical pain, beyond mild discomfort.	YES / NO
9. Any MNU teaching which involves the participation of MNU students for the demonstration of procedures or phenomena which have a potential for harm.	YES / NO
10. Participants whose identity is known to the researcher giving oral consent rather than written consent (if participants are anonymous you may answer	YES / NO



No).	
11. Participants who are unable to give informed consent.	YES / NO
12. Research on your own students/pupils.	YES / NO
13. The participation of children (seven (6) years old or younger).	YES / NO
14. The participation of children under eighteen (18) years old where active parental consent is not being sought.	YES / NO
15. Participants who are in a dependent situation, such as people with a disability, or residents of a hospital, nursing home or prison or patients highly dependent on medical care.	YES / NO
16. Participants who are vulnerable.	YES / NO
17. The use of previously collected information or biological samples for which there was no explicit consent for this research.	YES / NO

### Privacy/Confidentiality Issue

18. Any evaluation of organisational services or practices where information of a personal nature may be collected and where participants or the organisation may be identified.	YES / NO
--	----------

### Deception

19. Deception of the participants, including concealment and covert observations.	YES / NO
---	----------

### Conflict of Interest

20. Conflict of interest situation for the researcher (e.g. is the researcher also the lecturer/teacher/treatment-provider/colleague or employer of the research participants or is there any other power relationship between the researcher and research participants?)	YES / NO
---	----------

### Compensation to Participants

21. Payments or other financial inducements (other than reasonable reimbursement of travel expenses or time) to participants.	YES / NO
---	----------

### Procedural

22. A requirement by an outside organisation (e.g. a funding organisation or a journal in which you wish to publish) for MNUREC approval.	YES / NO
---	----------

## Part B

### FOR PROPOSED HEALTH RESEARCH ONLY

Not all health research requires review by the National Health Research Committee (NHRC).

Your study is likely to require NHRC review if it involves:

- a) health related research at Postgraduate or higher levels and
- b) human participants recruited in their capacity as:
  - consumers of health or disability support services; or
  - relatives or caregivers of such consumers; or
  - volunteers in clinical trials; or

- c) human tissue; or
- d) health information.

In order to establish whether or not NHRC review is required: (i) read the National Health Service Act; (ii) work through the ‘Does your study require NHRC review?’ flowchart; and (iii) answer Question 23 below.

If you are still unsure whether your project requires NHRC approval, please email the Ministry of Health for advice and keep a copy of the response for your records.

23. Is HDEC review required for this study? YES NO	YES / NO
--	----------

24. Is any NHRC/ National Agency approval required for this study? YES NO	YES / NO
---	----------

**Select the appropriate procedure to be used (choose one option):**

