FORM xx: HREC Application

UNIVERSITI MALAYSIA SARAWAK

HUMAN RESEARCH ETHICS (Non-Medical)

APPLICATION FORM

PROJECT REFERENCE DETAILS

Date of Submission		
Title of the Research Project		
Type of research	Interventional ☐ Non-interventional ☐	Interventional research is when it requires participants to be given a 'treatment' and the study intends to see the effects of the treatment on the participant. Non-interventional studies do not involve 'treatment'.
Enter the name of the Principal Investigator/Supervisor		

1. PROJECT DETAILS

1.1 **EXECUTIVE SUMMARY IN PLAIN ENGLISH:** *Provide a brief summary of the project outlining the broad aims, background, key questions, research design/approach, the participants in the study and what they will be asked to do, and the importance or relevance of the project.* [This description must be in everyday language, free from jargon, technical terms or discipline-specific phrases. [No more than 300 words]

1.2 **AIMS OF AND JUSTIFICATION FOR THE RESEARCH:** *State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Also provide a brief description of current research/literature review, a justification as to why this research should proceed and an explanation of any expected benefits to the community.* [No more than 300 words]

1.3 **METHOD**

(a) *What data collection technique(s) will be used? [*Tick as many as apply]

- **Questionnaire (attach a copy)** ☐
- **Interviews (attach a copy)** ☐
- **Observation of participants without their knowledge** ☐
- **Audio- or video-taping interviewees or events (with consent)** ☐
- **Other** *(Please give details. Use no more than 50 words):* ***[Enter details here]*** ☐

(b) *What tasks will participants be asked to do? What is the estimated time commitment involved? How will data be analysed?* ***[Enter details here]***

1.4 **USE OF INDEPENDENT CONTRACTORS (OUTSOURCING)** *Will parts of this project be carried out by independent contractors? (e.g. interviewing, questionnaire design and analysis, sample testing, etc.)*

☐ YES ☐ NO

If YES, confirm that the independent contractor will be engaged on the basis of relevant qualifications and experience and will receive from the first named Principal Researcher, a copy of the approved ethics protocol and be made aware of their responsibilities arising from it. [The responsibility for effective oversight and proper conduct of the project remains with the Principal Researcher(s)]
[Enter details here]

1.5 MONITORING

(a) *How will researchers monitor the conduct of the project to ensure that it complies with the protocols set out in this application, and the University's human ethics guidelines?* [Address, in particular, cases where several people are involved in recruiting, interviewing or administering procedures, or when the research is being carried out at some distance from the Principal Investigator/Supervisor (i.e. interstate or overseas)]
[Enter details here]

2. PARTICIPANT DETAILS

2.1 TARGET PARTICIPANT GROUP

Please indicate the targeted participant group by ticking all boxes that apply. Expand any responses necessary in the space provided at "Other".

Adults (over 18 years old and competent to give consent)	☐	**Other** *(Please give details. Use no more than 50 words):* ***[Enter details here]***	☐
Children/legal minors (under 18 years old) (With parental consent)	☐		

2.2 NUMBER, AGE RANGE AND TARGET POPULATION

Provide number, age range and target population.
[Enter details here]

2.3 JUSTIFICATION OF PARTICIPANT NUMBERS [The quality and validity of research is an essential condition of its ethical acceptability. *Where applicable, provide a justification of sample size (including details of statistical power of the sample, where appropriate), explaining how this sample size will allow the aims of the study to be achieved.*

2.4 PARTICIPANT RECRUITMENT

(a) *Please indicate the method of recruitment by ticking the appropriate boxes. Tick all that apply.*

Mail out - *see below*	☐	**Email** - *see below*	☐	**Telephone**	☐
Advertisement - *see below*	☐	**Recruitment carried out by third party** (eg. employer, doctor) – *see below*	☐	**Recruitment carried out by researcher/s**	☐
Contact details obtained from public documents (eg. phone book)	☐	**Contact details obtained from private sources** (eg. employee list, membership database) – *see below*	☐	**Personal contacts**	☐
Participants from a previous study	☐	**Snowball** (participants suggest other potential participants)	☐	**Other** *(Please explain in no more than 50 words)*:	☐

- *If using a **mail out** or **email** who will be distributing it?*
  [Enter details here – no more than 50 words]

- *If using an **advertisement**:*
  - *explain where will it be placed?* [e.g. on waiting room wall, in newspaper, in newsletter]
    [Enter details here – no more than 50 words]
  - *have you attached a copy?*

    Yes ☐ No ☐ NA ☐ *If "No" please explain (no more than 50 words):* ***[Enter details here]***

- *If recruitment is to be conducted by a **third party**, (e.g., employer, doctor) have you attached an approval letter?*

  - requesting their assistance? [yes, no or not applicable]

  Yes ☐ No ☐ NA ☐ *If "No" please explain (no more than 50 words):* ***[Enter details here]***

  - confirming their willingness to assist?

  Yes ☐ No ☐ NA ☐ *If "No" please explain (no more than 50 words):* [***Enter details here]***

- that has been drafted for the third party to send to potential participants?

Yes ☐ No ☐ NA ☐ *If "No" please explain (no more than 50 words):*
[Enter details here]

- *If contact details are to be obtained from **private sources**, have you attached an approval letter?*

  Yes ☐ No ☐ *If "No" please explain (no more than 50 words):*
  [Enter details here]

(b) *Describe how, by whom, where potential participants are to be identified or selected for this research*. [No more than 100 words]
[Enter details here]

(c) *Describe how, by whom, where potential participants are to be approached or invited to take part in this research*. [No more than 100 words]
[Enter details here]

2.5 DEPENDENT RELATIONSHIPS

[Dependent or unequal relationships (e.g. teacher/student, doctor/patient, student/lecturer, client/counsellor, warder/prisoner, and employer/employee) may compromise a participant's ability to give consent which is free from any form of pressure (real or implied)]. *Are any of the participants in a dependent relationship with any of the researchers, particularly those involved in recruiting for or conducting the project?*

☐ YES ☐ NO *(If YES, explain the dependent relationship and the steps to be taken by the researchers to ensure that participation is purely voluntary and not influenced by the relationship in any way*
[Enter details here]

2.6 PAYMENT OR INCENTIVES OFFERED TO PARTICIPANTS

Do you propose to pay, reimburse or reward participants?

☐ YES ☐ NO *(If YES, how, how much and for what purpose? Please justify the approach)*
[Enter details here]

3. INFORMATION FOR PARTICIPANTS AND INFORMED CONSENT

Before research is undertaken, the informed and voluntary consent of participants (and other properly interested parties) is generally required. Information needs to be provided to participants at their level of comprehension about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research. Such information is often provided in a written **Participant Information Sheet**. Each participant's consent needs to be clearly established (e.g., by using a signed **Consent Form**, returning an anonymous survey, or recording an agreement for interview).

3.1 PROVIDING INFORMATION FOR PARTICIPANTS

(a) *Will you be providing participants with information in a written Participant Information Sheet?*

☐ YES ☐ NO *(If NO, provide details of the protocol you will use to explain the research project to participants and invite their participation?)*
[Enter details here]

(b) *Will arrangements be made to ensure that participants who have difficulty understanding English/Malay can comprehend the information provided about the research project?*

☐ YES ☐ NO *(If YES, what arrangements have been made? If NO, give reasons.*
[Enter details here]

3.2 PARTICIPANT INFORMATION SHEET (IF APPLICABLE)

CONFIRM THAT THE PARTICIPANT INFORMATION SHEET WILL:

		YES	NOT APPLICABLE
1.	have UNIMAS official logo	☐	
2.	include clear identification of the University, the Department(s) involved, the project title, the Principal and Other Researchers (including contact details), and the study level if it is a student research project.	☐	
3.	provide details of the purpose of the research project	☐	
4.	provide details of what involvement in the project will require (e.g., involvement in interviews, completion of questionnaire, audio/video-taping of events), and estimated time commitment	☐	
5.	provide details of any risks involved and the procedures in place to minimise these.	☐	☐
6.	advise that the project has received clearance by the HREC	☐	
7.	(If the sample size is small), confirm that this may have implications for protecting the identity of the participants	☐	☐
8.	include a clear statement that if participants are in a dependent relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/management or treatment of health (if relevant)	☐	☐
9.	state that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied	☐	
10.	provide advice as to arrangements to be made to protect confidentiality of data, including that confidentiality of information provided is subject to legal limitations (see ** below)	☐	
11.	provide advice as to whether data is to be destroyed after a minimum period (if relevant)	☐	☐
12.	provide in the footer, the project HREC number, date, and version of the PIS	☐	
13.	provide advice that if participants have any concerns about the conduct of this research project that they can contact the Chair, Human Research Ethics Committee, UNIMAS, Phone: 082-582278; email: hrec@unimas.my	☐	

[**Re 10 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state these limitations]

PLEASE ATTACH A COPY OF THE PARTICIPANT INFORMATION SHEET TO YOUR APPLICATION

3.3 OBTAINING CONSENT

(a) *How will each participant's consent be established*?

By signing and returning a Consent Form – *see 3.4 below*	☐	**By returning an anonymous survey**	☐
Via a verbal agreement	☐	**Via a person with lawful authority to consent** (e.g., parent, doctor) – *see 3.3(b) below*	☐
Via a recorded agreement for interview	☐	**Other** *(Please describe in no more than 50 words)*:	☐

(b) *If participants are unable to give informed consent, explain who will consent on their behalf and how such consent will be obtained.*

3.4 INFORMED CONSENT (IF APPLICABLE)

CONFIRM THAT THE INFORMED CONSENT WILL:

		YES	NOT APPLICABLE
1.	have UNIMAS official logo	☐	
2.	include the title of the project and names of researchers	☐	
3.	state that the project is for research purposes	☐	

4. state that involvement in the project is voluntary and that participants are free to withdraw at any time, and free to withdraw any unprocessed identifiable data previously supplied ☐
5. outline requirements of participants including, for example, whether interviews are to be audio and/or video-taped ☐ ☐
6. include arrangements to protect the confidentiality of data ☐
7. include advice that there are legal limitations to data confidentiality (see below)** ☐
8. (If the sample size is small) confirm that this may have implications for protecting the identity of the participants ☐ ☐
9. (Once signed and returned) be retained by the researcher ☐

[**Re 7 – it is possible for data to be subject to subpoena, freedom of information request or mandated reporting by some professions. Depending on the research proposal you may need to specifically state and explain these limitations]

PLEASE ATTACH A COPY OF THE INFORMED CONSENT TO YOUR APPLICATION

4. PRIVACY AND CONFIDENTIALITY

Privacy can be described as "…a complex concept that stems from a core idea that individuals have a sphere of life from which they should be able to exclude any intrusion." A major application of the concept of privacy is information privacy: the interest of a person in controlling access to and use of any information personal to that person. 'Confidentiality', a narrower more specific term than 'privacy' refers to the legal and ethical obligation that arises from a relationship in which a person receives information from or about another. In UNIMAS, the collection, storage, use and disclosure of personal information is regulated by Pekeliling Pentadbiran Bilangan 17 Tahun 2020: Polisi Perlindungan Data Peribadi dan Notis Polisi Privasi (2020). HREC must be satisfied that a research proposal conforms to this circular.

4.1 REPORTING PROJECT OUTCOMES

(a) *Will the project outcomes be made public at the end of the project?*

☐ YES ☐ NO *(If YES, give details of how the results will be made public (e.g., in journal articles book, conference paper, the media, working paper or other). If NO, explain why not.*
[Enter details here]

5 *Will a report of the project outcomes be made available to participants at the end of the project?*

☐ YES ☐ NO *(If YES, give details of the type of report and how it will be made available. If NO, explain why not.*
[Enter details here]

4.2 WILL THE RESEARCH INVOLVE:

	YES	NO
• complete anonymity of participants (i.e., researchers will not know the identity of participants as participants are part of a random sample and are required to return responses with no form of personal identification)?	☐	☐
• de-identified samples or data (i.e., an irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample of information relates)?	☐	☐
• potentially identifiable samples or data (i.e., a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)?	☐	☐
• participants having the option of being identified in any publication arising from the research?	☐	☐
• participants being referred to by pseudonym in any publication arising from the research?	☐	☐
• any other method of protecting the privacy of participants? *Please describe:* ***[Enter details here]***		

Note that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be clearly advised of this limitation in the Plain Language Statement.

6 DATA STORAGE, SECURITY AND DISPOSAL

6.1 DATA STORAGE

Does data storage comply with the University policy? [See: Pekeliling Pentadbiran Bilangan 17 Tahun 2020: Polisi Perlindungan Data Peribadi dan Notis Polisi Privasi]

☐ YES ☐ NO *(If NO, please explain.)*
[Enter details here]

5.2 DATA SECURITY

(a) *Will the Principal Researcher be responsible for security of data collected?*

☐ YES ☐ NO *(If NO, please provide further details. You may also use this space to explain any differences between arrangements in the field, and on return to campus.)*
[Enter details here]

(b) *Will data be kept in locked facilities in the Department through which the project is being conducted?*

☐ YES ☐ NO *(If NO, please explain how and where data will be held, including any arrangements for data security during fieldwork.)*
[Enter details here]

(c) *Which of the following methods will be used to ensure confidentiality of data?*
(Select all options that are relevant)

- data and codes and all identifying information to be kept in separate locked filing cabinets ☐
- access to computer files to be available by password only ☐
- access by named researcher(s) only ☐
- other *(please describe)* ***[Enter details here]*** ☐

(d) *Will others besides the named researchers have access to the raw data?*

☐ YES ☐ NO *(If YES, please explain who and for what purpose? What is their connection to the project?)*
[Enter details here]

5.3 DATA RETENTION AND DISPOSAL

[Research data and records should be maintained for as long as they are of *continuing value* to the researcher and as long as recordkeeping requirements such as patent requirements, legislative and other regulatory requirements exist. The minimum retention period for research data and records is seven years after publication, or public release, of the work of the research as stated in *The Malaysian Code of Responsible Conduct in Research (see Section 3)*.

Specify how long materials (e.g., files, audiotapes, questionnaires, videotapes, photographs) collected during the study will be retained after the study and how they will ultimately be disposed of.
[Enter details here]

6. POTENTIAL CONFLICT OF INTEREST

6.1 POTENTIAL CONFLICT OF INTEREST

Is there any affiliation or financial interest for researchers in this research or its outcomes or any circumstances which might represent a perceived, potential, or actual conflict of interest?

☐ YES ☐ NO *(If YES, give brief details?)*
[Enter details here]

[If you have declared a potential conflict of interest, you should include an appropriate comment on the Participant Information Sheet and Informed Consent]

6.2 COMPLIANCE WITH THE CODE OF CONDUCT FOR RESEARCH

[University researchers must disclose and manage Conflict of Interest in accord with the provisions of *The Malaysian Code of Responsible Conduct in Research*.

Is the Conflict of Interest noted above in section 6.1 being managed in accordance with *The Malaysian Code of Responsible Conduct in Research*?

☐ YES ☐ NO ☐ Not Applicable

7. DECLARATION BY RESEARCHERS

The information contained herein is, to the best of our knowledge and belief, accurate.

We have read the University's current human ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines The Malaysian Code of Responsible Conduct in Research, Buku Dasar Penyelidikan, Inovasi dan Enterprise UNIIMAS, and any other condition laid down by UNIMAS's Human Research Ethics Committee or its Sub-Committees. We have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge our obligations and the rights of the participants. We have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise.

If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.

We, the researcher(s) agree:

- *To only start this research project after obtaining final approval from the Human Research Ethics Committee (HREC);*
- *To only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;*
- *To provide additional information as requested by the HREC;*
- *To provide progress reports to the HREC as requested, including annual and final reports;*
- *To maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;*
- *To notify the HREC in writing immediately if any change to the project is proposed and await approval before proceeding with the proposed change;*
- *To notify the HREC in writing immediately if any adverse event occurs after the approval of the HREC has been obtained;*
- *To agree to an audit if requested by the HREC;*
- *To only use data and any tissue samples collected for the study for which approval has been given;*

All researchers associated with this project must sign

Researchers' Name (please PRINT)	Signature	Date

8. DECLARATION BY HUMAN RESEARCH ETHICS COMMITTEE (HREC)

DATE APPLICATION RECEIVED: / /

☐ *TECHNICAL REVIEW COMPLETED* ***[Attach proof with this submission]*** ☐ *ETHICAL REVIEW COMPLETED*

The HREC has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed and recommends approval of the project. The HREC considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and to deal with any emergencies and contingencies that may arise. [Note: If the *HREC* Chair is also a principal researcher for this project, the declaration should be signed by another authorised member of the *HREC*]

Comments/Provisos: _____

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Name of HREC Chair (in BLOCK LETTERS)	
Signature	
Date	