**RESEARCH INFORMATION SHEET**

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| --- |
| **Research Title:** |
| **Name of Principal Investigator/ (MMC No.)\*:**  |
| **Name of co-Researcher(s)/ (MMC No.)\*:**1.2. |

*\*To be included if applicable*

**INTRODUCTION**

You [or the person under your care / guardian] are invited to take part voluntarily in a research project. This research is about ... [*introduce your research scope in a simple languange by avoiding techincal jargons appropriate for your research target subjects*]

It is important that you read and understand this research information before agreeing to participate in this study. If you agree to participate, you will receive a copy of this form to keep for your records.

Your participation in this study is expected to ...[*state the estimated time per subject to finish all data collection time*] . This study is estimated to include up to xxx participants.

**PURPOSE OF THE STUDY**

The purpose of this study are to determine ....[*state your complete research objectives in* ***lay terms***]

**TYPE OF RESEARCH**

This research will involve ....... [*Briefly state the type of research/intervention that will be undertaken for participants to know at the very beginning whether, for example, the research method involves an interview and/or taking of blood samples. For interventional research, details of the intervention has to be explained to the paricipant.*]

**PARTICIPANTS CRITERIA**

The research team members will discuss your eligibility to participate in this study. It is important that you are completely truthful with the staff including your health history [*if relevant ONLY*].

This study will include individual who are.....[*state your inclusion criteria, simplfy whenever possible*]

This study will not incude individual who are ....[*state your exclusion criteria, simplfy whenever possible*]

[*If the participant is selected as a “control” then it should be stated clearly on the inclusion and exclusion criteria using the similar template as above*]

**VOLUNTARY PARTICIPATION**

Your participation in this study is entirely voluntary.

You may refuse to participate in the study or you may stop your participation in the study at anytime, without any penalty or loss of benefits to which you are otherwise entitled [*state to the participant that the services they usually receive will not be affected in the event that they decline to participate.*]

Your participation may also be stopped by the research team at any time without your consent if it is found that you have violated the study eligibility criteria. The research team member will discuss with you if this matter arises.

**STUDY PROCEDURES**

*[Describe or explain the exact procedures that will be followed on a step by step basis, the tests that will be done and any intervention that will be given.]*

*[For a questionnaire based research, state briefly the scope of the question to be provided, the total number of questions ask and the estimated time required to fill in the questionnaire].*

*[For an interventional study, state the intervention/control in detail that the subject will receive including all the required visits expected. It is important to inform the participant that the allocation of a subject to either control or intervention group is done using a randomization method and whether a blinding procedure will be applied involving an inactive drug or placebo. Indicate also which procedure is routine and which is experimental].*

[*If the participant is selected as a “control” then it should be stated clearly the type of control treatment and/or procedure that they will receive*]

**RISKS**

*[State the possible risks that may arise from participation in the study. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.]*

*[Describe also the level of care that will be available in the event that harm does occur, who will provide the care and who will be responsible for it]*

Please contact, at any time, the following researcher if you experience any health problem either directly or indirectly related to this study.

**Dr. <researcher name> [MMC Registration No.\_\_\_\_\_\_\_\_\_\_\_\*] at <phone No.> or <H/P No.>.**

[\* if applicable]

**POSSIBLE BENEFITS [Benefit to Individual, Community, University]**

*[State the possible benefit that the participants will received from participating in this study].*

If you participate in this research, you/the community will have the following benefits: ..............

Your participation is also likely to help us find the answer to the research questions.

**REIMBURSEMENTS**

[*State clearly what the participants will receive as a result of their participation in the research. Reimbursements for expenses incurred as a result of participation in the research should be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities.*]

You will not receive any compensation or gifts for this study. However, you may get reimbursement for your traveling cost and loss of work time while in the study duration. [*if relevant*]

**CONFIDENTIALITY**

Your information will be kept confidential by the researchers and will not be made publicly available unless disclosure is required by law.

Data obtained from this study that does not identify you individually will be published for knowledge purposes.

Your original records may be reviewed by the researcher, the Ethical Review Board for this study, and regulatory authorities for the purpose of verifying the study procedures and/or data. Your information may be held and processed on a computer. Only research team members are authorized to access your information.

*(For studies involving biological sample, include this statement:*

*Excess samples from this research will not be used for other reasons and will be destroyed with the consent from the ethics commitee)*

**ENQUIRES**

If you have any question about this study or your rights, please contact;

<Name of Researcher> & <No. MMC>

<School>

<Faculty>

<Universiti Sultan Zainal Abidin

<Campus>

<Contact No. Office > <Contact No. HP>

If you have any questions regarding the Ethical Approval or any issue / problem related to this study, please contact;

Secretariat,

UniSZA Human Research Ethics Committee (UHREC)

Block E, Level 1,

Gong Badak Campus

Universiti Sultan Zainal Abidin

Tel. No. : 09-6688763

Email : uhrec@unisza.edu.my

**DECLARATION**

To be entered into the study, you or a legal representative must sign the Informed Consent Form (UniSZA-PTPIP-42-GP 001-BR 008(01)

By signing the informed consent form, you authorize the record review, information storage and data process as described above.