|  |
| --- |
|  |

NUSMed Medical Sciences Department Ethics Review Committee (MSDERC)

# nus_logo_black_4cParticipant Information Sheet &

# Consent Form

(For Social, Behavioural and Educational Research studies)

*Please provide answers under these headings (from page 1 to 3) to write your informed consent.*

*Please include your* ***version number and date*** *(e.g. Version 1 dated dd/mm/yyyy) on the right footer of every page of the document.* ***(entire paragraph to be removed in final copy)***

**DERC Reference Code:** ***(to be filled once a code is being assigned for the study)***

1. **Protocol title**

*(Please include the full protocol title as used in the DERC Application Form. A simplified title within brackets can be included if the protocol title is too technically worded.)*

1. **Principal Investigator and co-investigator(s), if any, with the contact number and organization:**
2. **What is the purpose of this research?** *(Explain research briefly in layman’s terms)*

*(Please start with this opening paragraph.)* You are invited to participate in a research study. This information sheet provides you with information about the research study. The Principal Investigator (the person in charge of this research) or his/her representative will also describe this research to you and answer all of your questions. Read the information below and ask questions about anything you don’t understand before deciding whether or not to take part.

1. **Who can participate in the research? What is the expected duration of my participation? What is the duration of this research?**

(Please state inclusion and exclusion criteria e.g. age, gender, health status etc.)

1. **What is the approximate number of research participants involved?**
2. **What will be done if I take part in this research study?**

*(Please describe the research procedures to be followed by the participant)*

1. **How will my privacy and the confidentiality of my research records be protected?**

*For example:* Only the principal investigator has your personal data (e.g. names and contact information,) and this will not be released to any other person, including members of the research team. Personal data will never be used in a publication or presentation. All identifiable research data will be coded (i.e. only identified with a code number) at the earliest possible stage of the research. Personal data will be discarded <please state when>.

All data collected will be kept in accordance to the University’s Research Data Management Policy. Research data used in any publication will be kept for a minimum of 10 years before being discarded.

1. **What are the possible discomforts and risks for participants?**

(Please provide other details, where relevant**)**

1. **What is the compensation for any injury?**

*(Please state the compensation and/or treatment available to the research participant in the event of research- related injury. If no injury and/or compensation are expected, it should be explicitly stated)*

(For research studies conducted in Singapore only) If you follow the directions of the PI in charge of this research study and you are injured, the NUS will pay the medical expenses for the treatment of that injury. By giving your consent, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

1. **Will there be reimbursement for participation?**

(Please state reimbursement for transport cost and time spent in participating in the research study, if applicable. If there is more than 1 session and reimbursement will be pro-rated, please state so.)

1. **What are the possible benefits to me and to others?**

*For example:* There is no direct benefit to you by participating in this research study. The knowledge gained may benefit the public in the future *(please elaborate)*.

1. **Can I refuse to participate in this research?**

*For example:* Yes, you can. Your decision to participate in this research study is voluntary and completely up to you. You can also withdraw from the research at any time without giving any reasons, by informing the principal investigator and all your [*saliva/tissue/data*] collected will be discarded.

*For recruitment of patients, please include:* You are entitled to refuse to participate or discontinue participation at any time in this research. Refusal to participate or withdrawal from participation will not affect your medical management or cause loss of benefits to which you are otherwise entitled.

1. **Whom should I call if I have any questions or problems?**

Please contact the Principal Investigator, [*Name*] or Attn: [*Name of co-ordinator*] at **telephone \_\_\_\_\_\_\_ and email \_\_\_\_\_\_\_\_**) for all research-related matters and in the event of research-related injuries.

For an independent opinion specifically regarding the rights and welfare of research participants, you may contact a staff member of the National University of Singapore Institutional Review Board at telephone (+65) 6516 1234 [Mondays to Thursdays from 8.30am to 6pm, and Fridays from 8.30am to 5.30pm, except public holidays] or email at irb@nus.edu.sg.

**Consent Form**

*(Please make the necessary research-specific amendments and remove the points that are not applicable. You may remove the entire consent form if consent if not necessary for the study)*

**Protocol title:**

*(Please include the full protocol title as used in the DERC Application Form. A simplified title can be used if the project title is too technically worded.)*

**Principal Investigator with the contact number and organization:**

*(to state)*

I hereby acknowledge that:

1. I have agreed to take part in the above research.
2. I have received a copy of this information sheet that explains the use of my [*saliva/tissue/data*] in this research. I understand its contents and agree to donate my [*saliva/tissue/data*] for the use of this research.
3. I can withdraw from the research at any point of time by informing the Principal Investigator and all my[*saliva/tissue/data*] will be discarded.
4. I will not have any financial benefits that result from the commercial development of this research.
5. (*If applicable*) I consent / do not consent\* to have the coded data made available for future research studies. This will be subject to an Institutional Review Board’s approval.
6. *(If applicable)* I *agree / do not agree*\* to be re-contacted for future related studies. I understand that future studies will be subject to an Institutional Review Board’s approval.
7. *(If applicable)* I *agree / do not agree*\* to the photo-taking/ audio-recording / video-recording of my participation in the research. I understand that although my name will be not associated with the photographs/video-recordings used in publication/presentation, I may still be identified.
8. *(If applicable)* I *agree/do not agree*\* for the following personal data to be disclosed in any publication or presentation relating to this research, if any.

Surname  First name  Organisation Name  Position/Designation

Disagree (I wish to remain anonymous and only agree to be known as \_\_\_\_\_\_\_\_\_\_\_\_\_\_).

*\*please delete as appropriate*

*For clauses starting with “(If applicable)”, please delete if they do not apply to your research.*

\*\* This research has been explained to me in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (state language), which I understand, by \_\_\_\_\_\_\_\_\_\_\_\_ (name of translator) on \_\_\_\_\_\_\_ (date).

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_**

Name and Signature (Participant) Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_**

Name and Signature (Consent Taker) Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_**

\*\* Name and Signature (Translator) Date

*\*\*(Please include this section if the subject is unable to understand English and read any of the translated consent documents available.)*