**Template for Participant Information Sheet & Consent Form**

*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.*

1. **Project title**

*(Please include the full project title as used in the IRB Application Form. A simplified title within brackets can be included if the project 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 also include this paragraph.)* You are invited to participate in a research study. This information sheet provides you with information about the research. The Principal Investigator (the research doctor or 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.
3. **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 (age, gender, health status etc.)*
4. **What is the approximate number of participants involved?**
5. **What will be done if I take part in this research?** *(Please describe the research procedures to be followed by the participant and indicate if research data will be retrieved from patient’s medical records, if applicable.)*
6. **How will my privacy and the confidentiality of my research records be protected?**

For example: Only the principal investigator has your identifiable information (e.g. names, IC nos.) and this will not be released to any other person, including members of the research team. Identifiable information will never be used in a publication or presentation. All your identifiable health information and research data will be coded (i.e. only identified with a code number) at the earliest possible stage of the research.

For infectious diseases, please include: Your identifiable information (e.g. names, IC nos.) will not be released, unless required by law (E.g. Infectious Disease Act).

1. **What are the possible discomforts and risks for participants?** *(Please provide details, where relevant)*

Example for research taking blood: You may experience some pain and bruising when blood is collected from your vein. Fainting is an occasional adverse event due to blood-taking.

1. **What is the compensation for any injury?** *(Please state the compensation and/or treatment available to the subject in the event of research-related injury. If no injury and/or compensation are expected, it should be explicitly stated.)*

Example for clinical trials only: If you follow the directions of the PI in charge of this research and you are physically injured in spite of the procedure or trial substance properly given under the plan for this research, the [*name of institution*] will pay the medical expenses for the treatment of that injury. Payment for management of the normally expected consequences of your treatment will not be provided by the [*name of institution*]. By signing this consent form, 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, if applicable.)*
2. **What are the possible benefits to me and to others?**

For example: There is no direct benefit to you by participating in this research. The knowledge gained will 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 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 [*blood/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** [*insert number*] and **email** [*insert email*] for all research-related matters and in the event of research-related injuries.

For an independent opinion regarding the research and the rights of research participants, you may contact the Human Protection Administrator (Attn: Ms Julie Sabaratnam, at telephone 6303 6691 or email at juliesabaratnam@sutd.edu.sg).

**Consent Form** *(Please make the necessary research-specific amendments)*

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

**[Name of Principal Investigator]**

**[Name of Organization]**

**[Contact number of PI]**

I hereby acknowledge that:

1. My signature is my acknowledgement that I have agreed to take part in the above research.
2. I have received a pamphlet (or a copy of this information sheet) that explains the use of my [*blood/tissue/data*] in this research. I understand its contents and agree to donate my [*blood/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 [*blood/tissue/data*] will be discarded.
4. I will not have any financial benefits that result from the commercial development of this research.
5. Any personal information (i.e., my name and contact information) that is collected in this study that can be associated directly to me remains confidential. My personal identifiers will be coded to protect my privacy. My personal information will be discarded when the research has been completed.
6. The research team will keep the coded data indefinitely in a place where only the research team will be able access the data.
7. I allow/ do not allow my coded data (without personal identifiers) to be used in future research. I understand that all future related research will be subject to the approval of an Institutional Review Board.
8. I give/ do not give permission for this interview to be recorded on a digital audio recording device.
9. I give/ do not give permission for this interview to be recorded on a digital video recording device.
10. I give/ do not give permission for this interview to be recorded using a digital camera.
11. I give permission to be quoted in any subsequent publications resulting from this research; and for the following personal identifiers to be disclosed in the investigators’ academic publications, if any:

[ ] surname [ ] first name [ ] organization name [ ] my title

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

1. I agree/ do not agree to be re-contacted for subsequent interview, if necessary.
2. I agree/ do not disagree to be contacted for further study.
3. (If applicable) I agree to the use of my medical records for this research.

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

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| 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.)*

***For Principal Investigator’s Information Only***

**(US FDA §46.116)**

**General requirements for informed consent**

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others, which may reasonably be expected from the research;

(4) a disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study.