TEMPLATE FOR PARTICIPANT INFORMATION SHEET AND CONSENT FORM

*Please remove this text box when finalizing the document

In this template:

- [Square brackets in blue text] indicate instructions to researchers only and should not be included in the consent form.
- (Brackets in yellow highlight) indicate where specific information is to be inserted.
- Yellow-highlighted text without brackets indicates words or phrases that should be looked at carefully whether to retain, modify or delete it as relevant to your study.
- Text formatting*:
  - Headings : Arial, font size 11, Bold, All caps
  - Sub-headings : Arial, font size 11, Bold
  - Text (Description) : Arial, font size 11
  - Line spacing : 1.0

  *Where necessary, use bigger font size for research involving patients with visual impairment.
- Write in simple language, at Primary 6 reading level or lower.
- Avoid medical/ scientific/ technical language; or if they must be used, to include in brackets simple definitions or explanations for such terms.
- Remove text in red, text in blue, yellow highlight.
- Change *text in italics* to standard lettering.
- Delete this "TEMPLATE FOR PARTICIPANT INFORMATION SHEET AND CONSENT FORM" text box when finalizing the document.

INFORMED CONSENT FORM

1. Study Information

Protocol Title:

(Use the full protocol title as used in the DSRB Application)

Principal Investigator & Contact Details:

(Please include full name, address and phone number)
[*For all studies, please include minimally your Institution's mainline. For more than minimal risk studies, please include the mobile number of PI or Study Coordinator, in addition to your Institution's mainline]

(Delete this section if this is an investigator-initiated study without specific grant funding]
Study Sponsor:

[If Investigators intend to recruit participants aged 12 to 20 years old (with sufficient understanding and intelligence), where their agreement regarding participation in the research study will be documented using this consent document, along with consent from their legal representative, please add the following paragraph] If you are a parent or legal guardian giving consent for a child to participate in the study, please note that the word "you" refers to your child.

2. Purpose of the Research Study

You are invited to participate in a research study. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research study, the study will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in the study, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You are invited because (e*xplain why participant is being approached for recruitment)*

This study is carried out to find out (*insert explanation here)*

This study will recruit *(insert number of participants)* participants from *(state whether from the PI's institution, or multiple institutions)* over a period of *(state recruitment and/or study period).* About *(state number of participants recruited in this or previous related studies)* participants will be involved in this study.

3. What procedures will be followed in this study

If you take part in this study, you will be randomised to receive *(delete or expand as necessary)*. Randomisation means assigning you to one of *(insert number of study groups)* groups by chance, like tossing a coin or rolling dice.

[If study involve double blinding. please add the following statement] No one (*including you and the study doctor*) will know which group you are in. If it becomes necessary for your care, your study doctor will be able to find out whether you are (*taking the placebo or the study drug*).

If you take part in this study, you will be asked to (*insert brief explanation of study procedures here)*.

Your participation in the study will last *(insert length of time participant will be required for the study)*. You will *(take the study medication / use the study device)* for about *(insert number of times study intervention will be performed)* and be followed up for *(state length of time of follow-up within the study)*. You will need to visit the doctor's office *(state number of times)* times in the course of the study.

[Insert detailed schedule of visits and procedures, assessments, questionnaires as relevant. For multiple visits and procedures, insert a table for participant's ease of understanding]
If you agree to take part in this study, the following will happen to you:

Visit 1 (Week 0)

Visit 2 (Week 2)

Final Visit (Week 4)

When your participation in the study ends, you will no longer have access to *(the study medication/device)*, unless special additional arrangements are made by the Principal Investigator.

Biological materials:
The following samples ("biological materials") will be obtained: *(Describe in lay language and simple terms with the types of samples that will be collected, and details of sample collection, the specific research purpose for which the biological materials are intended to be used, as necessary).*

Example:
We will take blood ("biological materials") from your arm using a syringe and needle, every 3 months. Each time, we will take about 2.5ml (half a teaspoon) of blood. In total, we will take about 10ml (2 teaspoons) over a period of one year. The blood sample will be tested for HbA1c (a test to measure the average blood sugar level over the previous 3 months), in Singapore and for research purpose.

[If Investigators intend to use any of the following study procedures, please add the applicable section]
Medical history:
We will collect information (data) from your medical records. The information will include your past medical history, diagnosis, treatments, and medications *(describe whatever else data that will be collected for the disease or condition being studied and state the period of data extraction from medical records (e.g. x month before surgery to y months after surgery).)*

Questionnaire:
We will ask you to complete questionnaires about *(describe the type of questions that will be asked (e.g. your quality of life, your daily activities, your mood and how you have been feeling) and state the duration required to complete the questionnaire)*.

Videography:
This study involves video recording of *(describe the study procedures that would be recorded),* which is optional. The purpose is to *(describe why there is a need for video recording.) Consent for the optional videography will be sought from you.*

Example:
We will use an observational tool, called PICCOLO to access and monitor the quality of

parent-child interactions when the child is 24 months and 32 months. This PICCOLO assessment will be video recorded and then transcribed to provide additional documentation to support the data collected in this research study, and to provide positive feedback to the parents, plan individualized family interventions, and measure program effectiveness.

Photography:
This study involves photo taking of *(describe the body part or study procedures that would be captured) which is optional*. The purpose is to *(describe why there is a need for photo taking.) Consent for the optional photography will be sought from you*

Example:
We will take photographs of your front and back trunk, legs and arms and/or any target skin lesions/ eczema areas, which may include your face and private body parts. This is to provide additional documentation to support the data collected in this research study. You will need to undress prior to the photographs being taken. All accessories such as watches and necklaces should be removed. You may leave undergarments on. Any photos obtained and used in a report published as a result of this study will not identify you by name, and to the extent possible, the photos will be presented so that you are not recognizable (if a photograph bearing your face is required, a black "bar" will be placed over the eyes, and if applicable, other identifying features such as piercings, scars, tattoos). Your confidentiality will be protected to the best of our ability. However, absolute confidentiality cannot be guaranteed

[For research studies that require linkages of data with other sources (including, but not limited to healthcare billing information, government administrative data and/or research data such as health and health-related data, social data, education data, birth and death data, economic and housing data, and data from disease registries and databases, whether by itself or with the assistance of a data intermediary), researchers should explain the rationale for such data linkages in the DSRB application and describe the details in the section]
Data about you from other resources:
We will use data that identifies you like your name and national registration identity card (NRIC), to access and add data from other sources that is specific to you. This will give researchers more data about factors that might affect your health. For example, we may combine or link the data that we collect about you in this study with data from other sources. This includes but is not limited to healthcare billing information, government administrative data and/or research data such as health and health-related data, social data, education data, birth and death data, economic and housing data, and data from disease registries and databases, whether by itself or with the assistance of a data intermediary.

[If the study is supported by NMRC funding and/or where investigators are required by funding agency or publishers to deposit research data into research or scientific database, researchers should describe the details in the section. Please refer to the sample language below. You may delete or modify the information according to your study design]
Data deposition into scientific database:
We will deposit data collected in this study, including the data we collect about you to public and/or controlled-accessed scientific databases. It will not include your name or other data that directly identifies you. This will enable other researchers, whether locally or overseas, to use the data to investigate other important research questions.

4. What Happens to the Data and/or Samples Collected for the Research

Example # 1: (If Investigators intend to use the blood or tissue samples only for the

purposes of the current research, please add the following paragraph.)
Any blood or tissue samples obtained during the course of this study will be stored and analysed only for the purposes of this study for a period not exceeding (insert intended duration of storage), and will be destroyed after completion of the study. The blood or tissue samples (will/will not) be used for restricted human biomedical research involving human-animal combinations.

Example # 2: (If Investigators intend to use individually-identifiable health information only for the purpose of the current research, please add the following sentence.)
Any individually-identifiable data obtained during the course of this study will be stored and analysed for the purposes of this study and will not be used for future biomedical research.

Example # 3: (If Investigators intend to keep the leftover blood or tissue samples and/or individually-identifiable/de-identified information for future research in any way beyond the completion of the study, then the following information must be disclosed here, and the participant or his/her legally acceptable representative must explicitly agree to this storage and future use in the signed Consent Form)

(a) Specific purpose for which the blood or tissue samples and/or individually-identifiable/de-identified information will be used, if this information is available; but if not available, the purpose may be stated as for general research;
(b) Whether the blood or tissue samples (will/will not) be used for future restricted human biomedical research involving human-animal combinations;
(c) Period of storage; and
(d) Provisions to ensure privacy and confidentiality; including whether the blood or tissue samples will be used in an individually-identifiable form.)

Example # 4: (If Investigators intend to transfer biological samples and/or data out of Singapore, please include either of the statements where relevant)
Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be stored in Singapore. Only anonymised biological samples and/or data will be transferred out of Singapore to *(Insert Name of overseas collaborator/company)*.

OR

Your biological samples and/or information containing your "Personal Data" will be transferred out of Singapore to *(Insert Name of overseas collaborator/company*) for the purposes described in this Informed Consent Form. *(Name of institution transferring the samples and/or data)* will take appropriate steps to ensure it complies with the data protection requirements in the Personal Data Protection Act while your 'Personal Data" to be transferred remains in its possession or under its control.

Example # 5: (If biological samples and/or data will not be transferred out of Singapore, please include)
Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will not be transferred out of Singapore.

5. Incidental Findings

Example # 1: (If the study expressly provides for re-identification in the case of an incidental finding, please indicate this and inform the participant that he/she has a choice whether he/she would wish to be re-identified and notified. The study should also list the types of anticipated incidental findings (if applicable) that may be discovered in the course of the study. Please refer to the sample language below. You may delete or modify the information

according to your study design.)
During the course of the study, there is a possibility that we might unintentionally come to know of new information about your/your child's health condition from (insert reasons e.g. the imaging scans, the genetic testing etc.) that is/are conducted as part of the study. These are called "incidental findings".

"Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may affect your/your child's current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to (*insert list of anticipated incidental findings, if applicable*).

You will be asked to indicate whether you wish to be re-identified and notified in the case of a clinically significant incidental finding that is related to you/your child.

If you agree to be re-identified and notified, your study doctor/a qualified healthcare professional will explain the incidental finding to you/your child and discuss and advise you on the next steps to follow. For this purpose, please inform the Principal Investigator or any of the study contact persons listed in this document whenever there are changes in your contact details. You may wish to do more tests and seek advice to confirm this incidental finding.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

If you do not wish to be re-identified and notified, your decision will be respected. However, in exceptional situations such as discovery of life-threatening incidental findings with available treatment options, you will be contacted to confirm your decision whether to learn more about the incidental findings. In rare situations where the incidental findings have public health implications and as required by the law (e.g. under the Infectious Diseases Act), you will be contacted and informed of the incidental findings.

Example # 2: (If research anticipates Incidental Findings, but provide NO provision for re-identification and notification, please include the following sample language below.)
"Incidental findings" are findings that have potential health or reproductive importance to a participant like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may cause you to feel anxious and may affect your current or future life and/or health insurance coverage. Examples of potential incidental findings that may be discovered during the course of this study may include but are not limited to (insert lists of anticipated incidental findings, if applicable).

It is possible that incidental findings may be detected or suspected in the course of conducting the study. As this is a research and there is no intention to perform medical diagnosis, the medical significance of the incidental finding may not be clear. Hence, there is no notification for incidental findings.

Example # 3: (If there will not be any incidental findings for the study, whether anticipated or unanticipated, please include the following sample language below.)
"Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. There will not be any incidental findings arising in this research.

6. Your Responsibilities in This Study

If you agree to participate in this study, you should follow the advice given to you by the study team. You should be prepared to visit the hospital *(insert number of visits here)* and undergo all the procedures that are outlined above.

7. What Is Not Standard Care or is Experimental in This Study

The study is being conducted because *(the intervention or device)* is not yet proven to be a standard *(investigation, treatment)* in participants with *(condition under investigation in this study)*. We hope that your participation will help us to determine whether *(investigation or treatment)* is equal or superior to existing *(investigation or treatment)*.

In this study, the *(state name of the device)* used is a prototype. A prototype is a first or preliminary version of a device from which other forms are developed.

Use of a placebo (inactive agent), blinding (one or more parties unaware of the treatment assignment), and randomization (study drug selection by chance) are only done for research studies. *(Modify as relevant for your study.)*

Although *(Investigation or Treatment)* may be part of standard medical care, in this study this/these procedure(s) are only being performed for the purposes of the research, and are not part of your routine care.

8. Possible Risks and Side Effects

[Investigators are reminded that virtually all research procedures have some risks or side effects which MUST be explained in some detail to the participant. It is **NOT** satisfactory to make statements like "This is a well-established drug/test/procedure which has no significant side effects". The risk of choosing not to participate in the research study or not having the intervention/investigation should be clearly stated and explained, as well as risks of any ALTERNATIVE intervention/drug/investigation. Modify the following section as relevant to your study] *(Insert Intervention or Procedure)* may have the following side effects or risks *(Explain reasonably foreseeable risks or inconveniences here; it may be best to list them in detail)*.

Allergic reactions can occur with any drug. Common symptoms may include: rash, itching etc.

Rarely, a severe and possibly life-threatening allergic reaction can occur. Symptoms of a severe reaction include: swelling of the face, difficulty breathing, or a sudden drop in blood pressure that may cause dizziness. If you have any of these symptoms, call your doctor at once.

(Intervention or investigation) is still being tested; therefore, you may experience other side effects that have not yet been reported. However, you will be kept informed of any significant new findings that may relate to your willingness to continue to take part in this study.

If you experience any new symptoms, you should contact your doctor or the Principal Investigator as soon as possible.

In addition, as you cannot (take any other medication) to treat your *(insert condition here)* while you are (receiving the study medicine), there is a possibility your condition may worsen. If this occurs, your doctor will *(explain rescue/crossover/alternative therapy)*.

Collection of blood:
Obtaining blood can cause pain, bleeding, bruising, or swelling at the site of the needle stick.

Fainting sometimes occurs and infection rarely occurs. [Include if relevant for your study] If possible, the research blood sample(s) will be collected at the same time you have blood drawn for clinical care or through an existing catheter already inserted into a vein.

Collection of urine, stool, saliva, cheek cell samples:
Collection of urine, stool, saliva, cheek cell may cause inconveniences and momentary discomfort. [Include only if the study involves cheek swabbing] A cheek swab could cause irritation in the cheek where the swab was taken.

Questionnaires/ surveys/ interviews:
[Delete or modify as necessary] Some of the questions might make you feel uncomfortable or upset. You may refuse to answer any of the questions and/or take a break at any time during the study.

Personal privacy and confidentiality:
[If data and/or biological materials will be de-identified (coded) for use, please include the following sample language below. Otherwise, modify as relevant for your study] This study uses information that may affect your privacy. To protect your confidentiality, only a unique code will be used to identify data and/or biological material that we collected from you.

As there will be a link between the code and your identifiable information, there is still a possibility of data breach. A data breach is when someone sees or uses data without permission. If there is a data breach, someone could see or use the data we have about you. Even without your name, there is a chance someone could figure out who you are. They could misuse your data. We believe the chance of this is very small, but it is not zero.

9. Possible Benefits from Participating in the Study

If you participate in this trial you may reasonably expect to benefit from the trial *(investigation / intervention / drug)* in the following way: *(explain how participant might benefit)*
OR
There is no assurance you will benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the use of this *(medication / device / intervention /investigation)*. *(This means there may be no benefit to the participant)*
OR
There is no known benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the use of this *(medication / device / intervention /investigation)*.

10. Important Information for Women Participants

[Delete or modify as necessary]
The effect of *(the study drug/intervention/investigation)* on a baby's development is not known. Therefore, pregnant and breast-feeding women may not take part in this study. Women who have a chance of becoming pregnant must have a negative pregnancy test at study entry and use birth control during the study. If you become pregnant during this study, you must stop taking *(the study drug)* and call your doctor or the Principal Investigator immediately.

11. Alternatives to Participation

[If applicable, PI must explain to participants the alternatives to the trial intervention/drug/investigation and the benefits and risks of the alternatives. This is so that

the participants can make a truly informed choice about participation.]
If you choose not to take part in this study, you will receive standard care for your condition. In our institution this would be *(investigation / treatment / procedure)*.

The benefits are:

(Insert list of possible benefits from the standard care)

and the risks are:

(Insert list of possible risks from the standard care)

[While the standard care is mentioned in this section as the "alternative", the investigators should explain to the participant in such a way that the participant understands that the research intervention/procedures/tests is the alternative to the standard care that is being offered to the participant.]

[If there are NO alternatives are available for this research, please add the following statement. Delete or modify as necessary] There is no alternative to the study procedures. You can choose not to take part in this study. The study procedures will not be carried out.

12. Costs & Payments if Participating in the Study

If you take part in this study, the following will be performed at no charge to you: *(insert list of procedures / drugs/ tests for which the participant will NOT pay)*. These costs will be borne by *(insert sponsor name).*

If you take part in this study, you will have to pay for the following: *(insert list of procedures / drugs/ tests for which the participant WILL be required to pay)*

You will be reimbursed for your time, inconvenience and transportation costs as follows:

- If you complete the study, you will be paid *(insert payment amount)*.
- If you do not complete the study for any reason, you will be paid *(insert payment amount)* for each visit you complete.

Please note that the institution is being paid by the sponsor for the time spent by doctors in conducting this study. (*Delete this statement if not relevant)*

13. Voluntary Participation

Your participation in this study is voluntary. You may stop participating in this study at any time. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this study, you should tell the Principal Investigator.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you *(or your legally acceptable representative, if relevant*) will be informed in a timely manner by the Principal Investigator or his/her representative.

[Please indicate if there are any circumstances under which the participant or his/her legally acceptable representative will be contacted for further consent, e.g. the development of minors to make decisions] In the event of changes to the development of your capacity to make decisions (i.e. when you reach the age of 21 years old), you will be contacted for further consent.

14. Withdrawal From Study

If you withdraw from the study, or the study drug/ medication is stopped for any reason, you will be required to (*insert consequences of participant withdrawal and procedures for orderly termination*).

- *(Add anticipated consequences, if any, of discontinuing the study drug or device).*
- *(Clearly state the protocol-specific termination procedures).*
- *(Obligation for participant to return all study-related supplies, including unused study drug).*

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

(Insert this statement if any biological samples will be collected:
The biological samples collected for the study will be deemed to be gifted to *(name of institution/sponsor)* and will not be returned to you. You will also not have any right or claim to any share in the commercial gain derived from the research (if any). However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if the biological sample(s) is individually-identifiable and has not been used for the research/future research *(delete "future research" if not applicable)* or it has been used for research but it is practicable to discontinue further use of the biological sample(s) for the research/future research *(delete "future research" if not applicable)*.

Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons *(Delete and modify if necessary)*:

- Failure to follow the instructions of the Principal Investigator and/or study staff.
- The Principal Investigator decides that continuing your participation could be harmful to your health or safety.
- Pregnancy
- You require treatment not allowed in the study.
- The study is cancelled.

15. Compensation for Injury

If you follow the directions of the doctors in charge of this study and you are physically injured due to the trial substance or procedure given under the plan for this study, the *(name of institution/ sponsor)* 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 / sponsor)*.

(For PI-Initiated studies, please use this statement):
(Name of Institution) without legal commitment will compensate you for the injuries arising from your participation in the study without you having to prove (Name of Institution) is at fault. There are however conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator. (Note for PI: Please refer to the Investigator Manual.)

[For sponsored studies, following the APBI Guidelines for compensation, please use this statement] Compensation for the research related injury shall be paid by *Institution / Sponsor Name* according to the Association of the British Pharmaceutical Industry's Clinical Trial Compensation Guidelines. Broadly speaking, the ABPI guidelines recommend that without legal commitment, participants should be compensated by *Institution / Sponsor Name*

without having to prove that *Institution / Sponsor Name* is at fault. *There are limitations to compensation in the ABPI guidelines.* A copy of the ABPI guidelines will be provided to you upon request.

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.

16. Confidentiality of Study and Medical Records

Your participation in this study will involve the collection of "Personal Data". "Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number, medical conditions, medications, investigations and treatment history as well as socio-economic data.

Information and "Personal Data" collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access. Your personal data may be disclosed to third parties *(Insert examples of third parties which data may be shared with e.g. external funding agencies and/or research collaborators, etc)* for the purpose of *(Insert circumstances where data would be shared in this study e.g. seeking funding and/or research purposes for this research project, etc)*. In the event of any data sharing with third parties (e.g. funding agencies, research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.

However, the Sponsoring company *(Name of company, if relevant)*, Regulatory Agencies *(HSA, FDA, if relevant)* and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to all your original medical records regardless of where and whom you seek care from, to check study procedures and data, without making any of your information public. These may include data from other hospitals where you may have had medical consultations and/or procedures being carried out and the data is captured under the Next Generation Electronic Medical Records (NGEMR). Such data on NGEMR may be viewed and used if relevant to the study.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by *(name of institution)*, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above. To the fullest extent permitted by applicable law, under no circumstances will *(name of institution)* and/or its affiliates be liable for any direct, indirect, incidental, special or consequential loss or damages arising out of any data breach event.

[Include if there is NO intention to keep the data for future research. Otherwise, delete.] All data collected in this study are the property of *(name of institution / sponsor)*. The data will be used for the purpose of this research study only.

[Include if there is intention to keep the data for future research. Otherwise, delete.] All data collected in this study are the property of *(name of institution / sponsor)*. The data will be used for the purpose of this research study only, unless you give permission for your data to be made available for future use in other research studies. For this purpose, consent for future research will be sought from you. Research arising in the future, based on your "Personal Data", will be subject to review by the relevant institutional review board
[Please use this statement, if relevant] By participating in this research study, you are

confirming that you have read, understood and consent to the Personal Data Protection Notification available at (*provide hyperlink to institution's website on Personal Data Protection Notification*).

17. Who To Contact if You Have Questions

[For all studies, please include minimally your Institution's mainline. For more than minimal risk studies, please include the mobile number of PI or Study Coordinator, in addition to your Institution's mainline] If you have questions about this research study, you may contact the Principal Investigator, *(Insert Name and contact details here.)*

In case of any injuries during the course of this study, you may contact the Principal Investigator, *(Insert Name and contact details here).*

18. Who Has Reviewed The Study

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research participant, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at ethics.gri.nhg.com.sg.

If you have any complaints or feedback about this research study, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

[Please insert the following section if you intend to ask participants for permission to be contacted for future research. The Principal Investigator should undertake all necessary procedures to comply with the Personal Data Protection Act, e.g. ensuring that a secured system is in place to collect, store and maintain the participants' contact information]

19. Consent to be Contacted for Future Research (Optional)

You are being asked for permission to be contacted in the future for participation in research studies that you may be suitable for. If you agree to be contacted, your information and contact details will be entered and stored in a secured database in (*Name of Institution)*. Your information and contact details will not be released to any parties outside (*Name of Institution)* without your permission. When investigators from (*Name of Institution)* identify you to be suitable for a particular research study, the investigators or authorised personnel from (*Name of Institution)* will contact you to inform you about the research study. Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this study. Your decision will not affect your medical care or any benefits to which you are entitled. You may change your mind at any time by contacting *(Insert Name and contact details here).*

CONSENT FORM

Protocol Title:

(Use the full protocol title as used in the DSRB Application)

Principal Investigator & Contact Details:

[For all studies, please include minimally your Institution's mainline. For more than minimal risk studies, please include the mobile number of PI or Study Coordinator, in addition to your Institution's mainline] *(Include full name, address and phone number)*

I voluntarily consent to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

[Please use this statement, if relevant]
I understand that my individually identifiable information (Personal Data) and data collected about me may be combined or linked with data from other sources, including but not limited to healthcare billing information, government administrative data and/or research data such as health, and health-related data, social data, education data, birth and death data, economic and housing data, data from disease registries and database, whether by itself or with the assistance of a data intermediary.

[Please use this statement, if relevant]
I understand that the de-identified data collected about me in this study may be deposited in open-access or access-controlled scientific database for potential use by other researchers, whether locally or overseas, to answer other important research questions, to advance medical research

[Please use this statement, if relevant] By participating in this research study, I confirm that I have read, understood and consent to the (Institution) Personal Data Protection Notification.

[Please include the additional consent section below if videography is optional]
Consent for Videography
This component is optional. You do not have to agree to it in order to participate in the research study.

Please indicate your choice using the relevant checkbox.

☐ Yes, I agree to the videography.
☐ No, I do not agree to the videography.

[Please include the additional consent section below if photography is optional]
Consent for Photography
This component is optional. You do not have to agree to it in order to participate in the research study.

Please indicate your choice using the relevant checkbox.

☐ Yes, I agree to the photography.
☐ No, I do not agree to the photography.

[Please include the additional consent section below if you intend to store the participant's biological samples and/or data for future research]
Consent for the Use of Biological Specimen and/or Data for Future Research

☐ Yes, I agree to donate my <biological specimen and/or data> for future research as long as the research is related to <specific disease or conditions>.

☐ No, I do not agree to donate my <biological specimen and/or data> for future research.

[If you intend to store the participant's biological samples and/or data for non-specific future research, you will need to justify to the DSRB the reasons for doing so and include the additional consent section below]
☐ Yes, I agree to donate my <biological specimen and/or data> for future research.

Please also check one of these boxes:
☐ There are no restrictions on the kind of research that may be done with my <biological specimen and/or data>.

☐ The Investigator may use my biological specimen and/or data for future research as long as the research is related to <specific diseases or conditions>.

☐ No, I do not agree to donate my <biological specimen and/or data> for future research.

[Please include the additional consent section below if the research provides for re-identification in the case of an incidental finding]
Consent to be Re-Identified and Notified in the Case of an Incidental Finding

[The following is a sample language and you may delete or modify the consent options according to your study design]

☐ Yes, I agree to be re-identified and notified in the case of an incidental finding from this research.

In the event that I cannot be reached, please contact my next of kin

Name of next of kin:
Contact:

☐ No, I do not agree to be re-identified and notified in the case of an incidental finding from this research.

[Please include the additional consent section below if you intend to contact participants for future research]
Consent to be Contacted for Future Research

☐ Yes, I agree to be for contacted for future research that I may be eligible for.
I agree to be contacted via:

☐ Phone _____

☐ Mail _____

_____

☐ Email _____

☐ Others _____

☐ No, I do not agree to be contacted for future research.

_____	_____	_____
Name of Participant	Signature	Date

[Consent should be taken from the participant,unless consent from Legally Acceptable Representative has been specifically approved for the study by DSRB. Please insert the provision for the Legally Acceptable Representative's Name, Signature and Date if applicable]

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature	Date

[Please include "Translator Information" if the participant / legally acceptable representative is unable to understand English and read any of the translated consent document or short form consent forms available]

Translator Information

The study has been explained to the participant / legally acceptable representative in

_____ *<insert language>* _____ by _____ *<insert name of translator >* _____

[Please include "Witness Statement" if this is a human biomedical research that is regulated by the Human Biomedical Research Act. For other studies, a witness who is impartial to the study team is only required if the participant / legally acceptable representative is (i) illiterate or unable to read English / any of the fully translated Informed Consent Forms due to visual impairment or (ii) unable to personally sign and date the Informed Consent Form due to a physical disability. If translated Short Form Consent is used, an impartial witness must always be present]

Witness Statement

I, the undersigned, certify that:

- I am 21 years of age or older. [This is only applicable to human biomedical research. Please remove if not applicable]
- To the best of my knowledge, the participant/ the participant's legally acceptable representative signing this informed consent form has the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant/ the participant's legally acceptable representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Name of Witness	Signature	Date

1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.
2. However, if the participant/ the participant's legally acceptable representative is unable to read, and/ or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the study team.

Investigator Statement

I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the study.

Name of Investigator / Person administering consent	Signature	Date

The Parties (Investigator, Participant / Legally Authorised Representative & Witness) may execute this Informed Consent Form requiring a party's signature by using industry standard electronic signature software and delivered electronically by emailed portable document format ("PDF") document (or other mutually agreeable document format) and such electronic version shall be treated as an original. The Parties also agree that such signatures obtained or transmitted through electronic means, shall be binding and effective for all purposes as if the signatures were executed in-person.