GUIDANCE ON REQUIREMENTS FOR INFORMED CONSENT DOCUMENTS

There are two parts to this guidance document:

Part A: Participant Information Sheet and Consent Form template

This guidance is developed (based on CIRB Participant Information Sheet and Consent Form ("Informed Consent Document (ICD)") template version 14) to assist Principal Investigators in the design of the specific research consent document. It gives a general overview of the information required for each consent element. The Principal Investigators will have to adapt the consent template to suit the specific research study and the research participants. It is not intended to be used without modification.

The consent document should be written in simple language, at Primary 6 reading level or lower, which means short sentences, short paragraphs and simple terms. Medical/ scientific/ technical language should be avoided or if they must be used, to include in brackets simple definitions or explanations for such terms.

Part B: Additional Consent Requirements for Genetic/ Genomic Testing

This guidance outlines the additional consent elements and provide examples of language in relation to genetic/ genomic testing. It is intended to supplement the CIRB ICD template.

Contents

Part A: Participant Information Sheet and Consent Form Template

The informed consent document (ICD) template consists of 2 parts:

(1) PARTICIPANT INFORMATION SHEET AND CONSENT FORM

- This part should include information for the current proposed research only.
- All sections (consent elements) are mandatory, except the following which can be deleted if not applicable.
    - IMPORTANT INFORMATION FOR FEMALE PARTICIPANTS
    - WHAT HAPPENS TO THE SAMPLES COLLECTED FOR THE RESEARCH
- Begin the section CONSENT FORM FOR RESEARCH STUDY on a new page.
- Include “Consent to be Re-identified and Notified in the case of an Incidental Finding” if the research study provides for such. Otherwise, it should be deleted.

(2) INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

- This part is optional. It has 2 examples:
    - Example # 1: (Data only)
    - Example # 2: (Data and Leftover Biological Materials)
- This part should only be included in the consent document:
    - If only research data will be kept for future research use; or
    - If research data and leftover biological materials will be kept for future research use in the labs for the researcher’s own-IRB approved research study.
- Begin the section INFORMATION & CONSENT FORM FOR FUTURE RESEARCH on a new page.
- This part should be removed from the consent document
    - If research data and leftover biological materials will be kept for future research use with a registered Tissue Bank. In this case, the Tissue Bank consent form should be used; or
    - If research data and biological materials will not be kept for future research use.

In this guidance:

- Bullet points in green text provide explanation to researchers on requirements for consent elements and should not be included in your consent document.

- [Square brackets in blue text] indicate instructions to researchers only and should not be included in your consent document. It is followed by *examples or standard statements in italics*, which are optional and should be deleted if not applicable.

- (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 leave it or delete it as relevant to your study.

- Standard statements are provided in standard lettering in black. Do not modify or delete unless otherwise indicated (i.e. yellow-highlighted or [square brackets in blue text]).

- Examples of language for the consent elements are provided in standard lettering in black. Modify in accordance to your research.

- Text formatting*:
    - Headings : Arial, font size 12, 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.

Completing the template:

- 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.

  Helpful links:
  Glossary of Lay Terms for Use in Consent Documents (on CIRB website)
  Plain English Glossary (via SingHealth Intranet link)

- Remove text in red, text in blue, yellow highlight.

- Change *text in italics* to standard lettering.

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Standard Statement:
You are being invited to participate in a research study. Your participation in this study is entirely voluntary. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read the information provided here carefully. If you agree to participate, please sign the consent form. You will be given a copy of this document.

[Include for study recruiting 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. Otherwise, delete.] *If you are a parent or legal guardian giving consent for a child to participate in the study, please note that the word "you", "my" and "I" refer to the child you are consenting for.*

STUDY INFORMATION

Study Title:
(Full study title as used in the ECOS Application)

This research study is recruiting at the following SingHealth institution(s). Please note that the word "SingHealth" refers to the institution where you are recruited into the study.

[Include for study involving single SingHealth institution as recruiting site. Otherwise, delete.]
(PI's Institution Name)
Principal Investigator:
(PI's Name)
(PI's Department)
Tel: (Insert PI's Office Number)
Institution Mainline: (Insert Number)
[For more than minimal risks studies, 24-hour contact of the PI or study coordinator should be included.]
24-hour contact: (Insert Number)

[Include for study involving multiple SingHealth institutions as recruiting sites. Otherwise, delete.] (Note to PI: Remove any unused placeholder for study sites before submitting the ICD to IRB for review. Informed consent taker is to indicate in the relevant checkbox the study site, where the research participant is recruited.)

☐ **(PI's Institution Name)**
Principal Investigator:
(PI's Name)
(PI's Department)
Tel: (Insert PI's Office Number)
Institution Mainline: (Insert Number)

☐ **(Site PI's Institution Name)**
Principal Investigator:
(Site-PI's Name)
(Site-PI's Department)
Tel: (Insert Site-PI's Office Number)
Institution Mainline: (Insert Number)

[For more than minimal risks studies, 24-hour contact of the PI or study coordinator should be included.]
24-hour contact: (Insert Number)

24-hour contact: (Insert Number)

☐ **(Site PI's Institution Name)**
Principal Investigator:
(Site-PI's Name)
(Site-PI's Department)
Tel: (Insert Site-PI's Office Number)
Institution Mainline: (Insert Number)
[For more than minimal risks studies, 24-hour contact of the PI or study coordinator should be included.]
24-hour contact: (Insert Number)

☐ **(Site PI's Institution Name)**
Principal Investigator:
(Site-PI's Name)
(Site-PI's Department)
Tel: (Insert Site-PI's Office Number)
Institution Mainline: (Insert Number)
24-hour contact: (Insert Number)

PURPOSE OF THE RESEARCH STUDY

- Describe the purpose of the study and present it clearly using lay language.
- Explain briefly why and how the participants was chosen to be invited to participate in the study.

Example:
The purpose of this research study is to (explain in lay language why the research is being done, ensuring it is consistent with the Specific Aims described in your ECOS Application).

You were selected as a possible participant in this research study because (briefly explain why participant is being approached about participation, without the need to list all the inclusion criteria).

This research study targets to recruit (insert number of participants) participants from (state PI's institution). [Include for multi-site study. Otherwise, delete.] *About (insert total number of participants) participants are expected to take part in this research study at multiple hospitals and medical facilities in (state countries of those study sites).*

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

- Describe the study procedures (similar to that in protocol or in CIRB application form) chronologically using simple language, short sentences, and short paragraphs.
- If there are several study procedures or if they are complex, the use of subheadings may help organize this section and increase readability.
- If practical, prepare a timeline chart or schematic to supplement description of the study procedures and tests for research that requires more than one visit.
- If you are collecting biological materials, describe the purpose for which these biological materials will be used (e.g. specific research purpose or any purpose other than research), whether the biological materials will be exported or removed from Singapore to a place outside Singapore).
- If you are collecting blood samples, state the frequency and the amount of blood required in volume and in teaspoons as part of this study. E.g. 5ml (1 teaspoon), 15ml (1 tablespoon).
- If the research involves photography or videotaping that captures individually-identifiable features, submit a separate consent form. The template is available on CIRB website.

- This section should include
  - How long the participants will be involved in the research;
  - If and how often they will need to meet the researcher, visit a clinic;
  - How long these visits will be;
  - What exactly will happen if they take part in the research. E.g. access to personal medical records/ samples, questionnaire, interview, measurement, sample collection, blood tests, investigations.

Example:

[Explain in simple language, the research activities the participants will be engaged in. Use bullet points or separate paragraphs for each research activity, or tabulate study procedures alongside the study visits, for readability.]

The study involves the following:

Study drug/ Study device:

(Describe whether the study drug has been approved by Health Sciences Authority (H.S.A.) Singapore for the treatment for the disease or condition being studied, or whether the study device is a prototype.) You will (take the study drug/ 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)

[Include for study involving randomisation. Otherwise, delete.] *You will be randomised to receive (expand with details of study as necessary). Randomisation means assigning you to one of (insert number of study groups) groups by chance, like tossing a coin or rolling dice.* [Include for study involving double blinding. Otherwise, modify as relevant for your study or delete.] *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).*

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), [Include if videography is optional. Otherwise, delete] *which is optional*. The purpose is to (describe why there is a need for video recording.) [Include if videography is an optional component. Otherwise, delete] *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, [Include if photography is optional. Otherwise, delete] *which is optional*. The purpose is to (describe why there is a need for photo taking.) [Include if photography is an optional component. Otherwise, delete] *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.

Biological materials:
We will collect the following samples ("biological materials"):
(Expand with the types of samples that will be collected, and details of sample collection, whether the removal of samples is solely for research purpose, OR in excess of samples primarily removed for a therapeutic or diagnostic purpose, OR leftover from samples primarily removed for therapeutic or diagnostic purpose, as necessary).

(Describe in lay language and simple terms, the following details:

a) The specific research purpose for which the biological materials is intended to be used; and
b) Whether the biological materials will be used for any purpose other than research and if so, the specific purpose of which the biological materials will be used; and
c) Whether the biological materials will be exported or removed from Singapore to a place outside of Singapore; and
d) Whether the biological materials will be used in restricted human biomedical research involving human-animal combination.

Example:
We will take blood 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. It will not be used in research involving human-animal combinations, which is restricted by Singapore law.

[Include this NEGATIVE statement for HBRA section 12(2)(c) applicable to study involving Scenario # 1 or # 2 or # 3. Otherwise, delete.] The Institutional Review Board waiver under Section 37(3) of the Human Biomedical Research Act 2015 ("HBRA") for the removal of human biological materials is not required. This is because we will collect samples from the following individuals:

- [Scenario # 1: Include for study involving collection of biological materials from adults with mental capacity to personally give consent. Otherwise, delete.] Adults with mental capacity to personally give consent for this research study.
- [Scenario # 2: Include for study involving collection of biological materials from minors aged 12 to 20 years, who have sufficient understanding and intelligence to understand what is proposed in the research. Otherwise, delete.] Minors (children) who have sufficient understanding and intelligence to understand what is proposed in the research, whereupon consent will be obtained from both the minors and their legal representative.
- [Scenario # 3: Include for study involving collection of leftover biological materials from vulnerable groups (i.e. adults or minors lacking mental capacity or minors lacking sufficient understanding and intelligence to give consent). Otherwise, delete.] Adults who lack mental capacity / minors who have cognitive difficulties/ disabilities / minors who do not have sufficient understanding to personally give consent for this research study, whereupon consent will be obtained from their legal representative. These are leftover samples that have been primarily removed for a therapeutic or diagnostic purpose as part of medical care, and that are no longer required for any clinical purposes.

[Include this statement for HBRA section 12(2)(c) applicable for study involving collection of fresh biological materials solely for research purposes or extra biological materials (in excess of the biological materials primarily removed for a therapeutic or diagnostic purpose) from vulnerable groups (i.e. adults or minors lacking mental capacity or minors lacking sufficient understanding and intelligence to give consent). Otherwise, delete.] We will also collect research samples from the following individuals who are unable to personally give consent for this research study, whereupon consent will be obtained from their legal representative. The SingHealth Centralised Institutional Review Board has waived the requirement that the removal of the samples be primarily for a therapeutic or diagnostic purpose under Section 37(3) of the Human Biomedical Research Act 2015 ("HBRA"). [Include for study involving collection of biological materials in excess of biological materials primarily removed for a therapeutic or diagnostic purpose. Otherwise, delete.] These research samples are in addition to the samples required for clinical care purposes. The research samples will be obtained at the same time when samples are removed as part of medical care.

- Adults who lack mental capacity
- Minors who have cognitive difficulties/ disabilities
- Minors who do not have sufficient understanding

[Modify as relevant for your study.] *Your participation in the study will last (insert length of time participant will be required for the study). You will need to visit the doctor's office (state number of times) times in the course of the study.*

[Modify as relevant for your study.] *If you agree to participate in this study, you should follow the advice and directions given to you by the study team.*

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

- Clearly identify study procedures that are not standard care or are experimental.

Example:

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

[Delete or modify as relevant for your study.] *In this study, the (state name of the device) used is a prototype*.

[Delete or modify as relevant for your study.] *The study will involve the use of a placebo (inactive agent), blinding (one or more parties unaware of the intervention assignment), and/or randomization (study drug selection by chance), which are usually only done for research studies.*

[Delete or modify as relevant for your study.] *In this study, (intervention or investigation or treatment or procedures) are being performed for the purposes of the research, and are not part of your medical care.*

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

- All research procedures have some risks or side effects.
- Describe any reasonably foreseeable risks, discomforts, inconveniences and their likelihood. Explain how these will be managed.
- If your research involves collection of tissue samples, administration of study drugs and/or other study procedures, which the associated risks, discomforts and/or inconveniences are not found in the examples provided, describe them appropriately.

Examples: (If your research involves collection of tissue samples, administration of study drugs and/or other study procedures, which the associated risks, discomforts and/or inconveniences are not found in the examples provided, describe them appropriately.)

Collection of blood:
Taking blood may cause momentary discomfort, pain, bleeding, bruising or swelling at the site of the needle stick. Rarely, taking blood may cause fainting or infection. [Delete or modify as relevant for your study.] *If possible, the research blood sample(s) will be collected at the same time you have blood drawn for medical 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 relevant for your study.] *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:
[Include only if data and/or biological materials will be de-identified (coded) for use. 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.

POTENTIAL BENEFITS

- Describe the probable benefits of participation in the research. If the participants will not benefit directly from participation, clearly state this fact.
- Benefits may be divided into benefits to the individual, benefits to the community or society as a whole as a result of finding an answer to the research question.
- Be sure to distinguish between a likely direct benefit (e.g. from therapeutic or intervention research) and a possible indirect benefit (e.g. talking about or reflecting on an experience may lead to a better understanding of oneself).
- Payment or compensation for participation (e.g. gift voucher, token of appreciation) is not a benefit and should not be discussed in this section.

(Note to PI: For H.S.A regulated clinical trials involving children who lack mental capacity to give consent to being a participant, or the children lack sufficient understanding and intelligence to give such consent, it must be shown that there is a reasonable prospect that participation in the clinical trial will directly benefit the children, or there is some direct benefits for the group of children participants involved in the trial. Refer to SHS-RSH-CIRB-225 Research Involving Children on Docupedia (intranet only).)

Example # 1: (Direct Benefits)
If you participate in this study, you may reasonably expect to benefit from the study (investigation / intervention / drug) in the following way: (explain how participant might benefit).

Example # 2: (Indirect Benefits)
There is no assurance you will benefit from this study. However, your participation may add to the medical knowledge about the use of this (study drug/ medication / device / intervention /investigation).

Example # 3: (No Benefits)
There is no benefit from participation in this study. However, your participation in this study may add to the medical knowledge about the use of this (intervention / investigation / the condition being studied).

IMPORTANT INFORMATION FOR FEMALE PARTICIPANTS

- This element is Optional. Delete this section if it is not applicable.
- If applicable, include a statement that the particular intervention or study procedure may involve risks to the woman participant (or to the embryo or foetus, if the participant is or may become pregnant) which are currently unforeseeable.

[Delete or modify as relevant for your study.] 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.

ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

- Describe any alternative treatments or appropriate procedures that should be considered before the participants decide whether to participate in the study. It is important to explain and describe the established standard treatment.
- If there are no alternatives, clearly state so and that the research procedures will not be done.

[Include for research, where alternatives procedures/ treatments are available. Otherwise, delete.] *If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution, this would be (investigation / treatment / procedure).*

[Modify as relevant for your study. Otherwise, delete.] *This procedure has the following potential benefits: (Insert list of possible benefits of the "standard" alternative) and the following potential risks: (Insert list of possible risks from the "standard" alternative).*

You may discuss the possible risks and benefits of the alternatives with your doctor or the Principal Investigator to make an informed decision whether to take part in this study.

[Include for research, where NO alternatives are available. Otherwise, delete.] *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.*

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

- Participants should not be charged research-related costs.
- List what is being done for research purpose and will not be charged.
- State whether participants will receive payment for their participation in the research (e.g. reimbursement for transportation cost). If yes, indicate the amount. If no, clearly state so.

Standard Statement

There is no cost to you for participating in this research study. [Include for research recruiting patient participants. Otherwise, delete.] *The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you.*

[Modify as relevant for your study. Otherwise, delete.] *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 institutions/ sponsor name).*

[Modify as relevant for your study, if participants will receive payment or reimbursement for single-visit study. Otherwise, delete.] *You will be reimbursed (insert payment amount), for transport, time, and inconvenience.*

[Modify as relevant for your study, if participants will receive payment or reimbursement for multiple-visits study. Please state that payment and that reimbursement will be pro-rated. Otherwise, delete.] *You will be reimbursed for transport, time, and inconvenience. You will receive (insert pro-rated payment amount) for each visit you have completed.*

[Include if participants will NOT receive payment or reimbursement. Otherwise, delete.] *You will not receive any payments or reimbursements for taking part in this study.*

INCIDENTAL FINDINGS

- There are 3 examples. Include the one that is applicable to your study.
- For study with incidental findings, but no provision for re-identification and notification, please provide your rationale and justification in Section F8 of the CIRB application form.

Example # 1: (For research with Incidental Findings, AND provision for re-identification and notification)

During the course of the study, there is a possibility that we might unintentionally come to know of new information about your health condition from (insert tests/ procedures that may give rise to incidental findings 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 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). You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.

If you agree to be re-identified and notified, your study doctor/ a qualified healthcare professional will explain the incidental finding to you and discuss and advise you on the next steps to follow. 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: (For research with Incidental Findings, but NO provision for re-identification and notification)

"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. 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: (For research with NO Incidental Findings, whether anticipated or unanticipated)
There will not be any incidental findings arising in this research. "Incidental findings" are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study.

WHAT HAPPENS TO THE SAMPLES COLLECTED FOR THE RESEARCH

- This element is Optional. Delete this section if the research does not involve the collection and use of biological materials.
- Describe what will happen to the biological materials when the research is completed.
- If any leftover biological materials will be kept for future research use, consent for future research should be obtained and documented:
  - Using the relevant Tissue Bank consent form, if the biological materials will be stored with a registered Tissue Bank; or
  - Using the "INFORMATION & CONSENT FORM FOR FUTURE RESEARCH (available at the end of this research study consent document template), if the biological materials will be stored for the researcher's own IRB-approved research.

The biological materials collected for this research study will be deemed to be donated to SingHealth as a gift. By agreeing to this, you give up your rights to the biological materials. If the use of your biological materials and/or your data results in intellectual property rights and commercial benefits, you will not receive any financial benefits or proprietary interest.

Example # 1: (Biological materials will be destroyed, NO Future Research)
The biological materials will be used only for the purpose of this research and will be discarded or destroyed upon completion of the research study.

Example # 2: (Biological materials will be stored Future Research)
The biological materials collected will be discarded or destroyed upon completion of the study, unless you give permission for any leftover samples to be kept for future use in other research studies. For this purpose, consent for future research will be sought from you.

PARTICIPANT'S RIGHTS

- Include the standard statement. Only the last paragraph is optional, which can be deleted if not applicable.

Standard Statement:
Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and will be contacted for further consent if required.

[Include if participants include minors who may turn 21 years old while still participating in the research, and the study team will be contacting them for re-consent when they turn 21 years old. Otherwise, delete.] *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.*

WITHDRAWAL FROM STUDY

- State the participant's rights to withdraw his/her consent and describe the limitations of such withdrawal.
- Describe the anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
- Replace "medical care" appropriately if the study recruits non-patient participants.

Example:

You are free to withdraw your consent and discontinue your participation in the study at any time, without giving any reasons and without your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study, or the study drug/ medication is stopped for any reason,

- (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).

[Include for research that involves collection of human biological materials. Otherwise, delete.] *Any remaining biological materials that have been collected for the study will be destroyed following the withdrawal of your consent if they are individually-identifiable and (i) have not been used for research; OR (ii) have been used for research but it is practicable to discontinue further use of the samples for the research.*

However, any research information or data obtained before your withdrawal of consent will be retained and may continue to be used. This is to allow a complete and comprehensive evaluation of the research study.

Your study doctor, the Principal Investigator of this study may stop your participation in the study at any time for one or more of the following reasons:

- 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.

RESEARCH RELATED INJURY AND COMPENSATION

- Include the standard statement that is relevant to your study.

Standard Statement # 1: (For investigator-initiated study)
If you follow the directions of the Principal Investigator of this research study and you are injured due to the study drug/ study device/ research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

Standard Statement # 2: (For industry-sponsored study involving study drugs and following ABPI Guidelines for compensation)
[Internal note to Investigators: Please double check this part against the relevant subject injury compensation clause in the Clinical Trial Agreement (CTA) or study agreement]
Compensation for the research related injury shall be paid by (Insert Sponsor Name) according to the Association of the British Pharmaceutical Industry's Clinical Trial Compensation Guidelines. There are limitations to compensation in the ABPI guidelines. A copy of the ABPI guidelines will be provided to you upon request.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

- Include the standard statement and modify as necessary.
- If participant's personal data will be disclosed to authorised service providers and relevant third parties, the researchers are responsible to make sure that such are covered in the project or confidentiality agreement.

Standard Statement:
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. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential and stored in Singapore. Your study records and medical records (if applicable), to the extent required by 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. 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.

Data about you from other resources:
[Include for study requiring access to data from NMRC Research Data Repository (BRAIN or TRUST platform) ONLY for data linkages. Modify as relevant for your study. Otherwise, delete.] (Note to PI: The rationale for the need for data linkages should be explained in Section E3 or Section G7 of ECOS Application.) *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.*

Data deposition into scientific database:
[Include for study supported by NMRC funding and/or where investigators are required by funding agency or publishers to deposit research data into research or scientific database. Modify as relevant for your study. Otherwise, delete. (Note to PI: Do not use this if research participants will be given a choice regarding data deposition. Instead, use "Information & Consent Form for Future Research".) *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.*

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records (if applicable) and study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by SingHealth, 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 SingHealth 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 (SingHealth or Sponsor Company). 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 (SingHealth or Sponsor Company). 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.*

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO HAS REVIEWED THE STUDY

- Include the standard statement.

Standard Statement:

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 8126 3660 during office hours (8:30 am to 5:30pm).

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

- Include the standard statement.

Standard Statement:

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact your study doctor, the Principal Investigator listed under STUDY INFORMATION section, at the beginning of this document.

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM FOR RESEARCH STUDY

Study Title:
(Full study title as used in the ECOS Application)

Declaration by Research Participant

- I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

- I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

- [Include only if you have added **Data about you from other resources:** under CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS section. Otherwise, delete.] 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.

- [Include only if you have added **Data deposition into scientific database:** under CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS section. Otherwise, delete.] 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.

- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons.

- By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

[Include if the videography is optional. Otherwise, delete.] **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.

[Include if the photography is optional. Otherwise, delete.] **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.

[Include if there is provision for re-identification and notification. Otherwise, delete.] **Consent to be Re-identified and Notified in the case of an Incidental Finding**
There may be potential incidental findings arising from this research. Please indicate whether you consent to re-identification and notification about the incidental finding:

☐ Yes, I wish to be re-identified and notified in the case of an incidental finding from this research. I can be reached by:

Phone/ Email:

☐ In the event that I cannot be reached, please contact the following person nominated by me: [Optional]

Name/ Phone/ Email:

☐ No, I do not wish to be re-identified and notified in the case of an incidental finding from this research. However, I understand that in exceptional or rare situations, I will be contacted as described in the Participant Information Sheet:

- In exceptional situations such as discovery of life-threatening incidental findings with available treatment options, I will be contacted to confirm my 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), I will be contacted and informed of the incidental findings.

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for _____ (Name of Participant) to participate in the research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant's	Signature/Thumbprint (Right / Left)	Date of signing

parent/ legal guardian/
legal representative

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

_____ _____ _____
Name of Investigator/ Signature Date

Person obtaining consent

Future Research - Example # 1: (Data only)

INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

This is an optional component that is separate from the research study. You may still participate in the research study if you say "No" to this. Please ask questions if you do not understand why we are asking for your permission.

In this Consent Form for Future Research, we seek your permission to keep all information collected about you (Personal Data and research data) for Future Research. Except if you withdraw your consent or there are limits imposed by law, there is no limit on the length of time we will store the data. Researchers will use the data for research long into the future.

This is what will be done with the data:

- We may use the data to answer additional research questions in other research studies which are outside the scope of the research study ("Future Research"). We may also share the data with other researchers within and/or outside of Singapore, for use in Future Research.
- [Modify as relevant for your study. Otherwise, delete.] We may deposit the data into a research data repository for long-term use by the wider research community, for use in Future Research. Researchers share information with each other by depositing data into research databases. These databases store information from many other research studies. Researchers can then study the combined information to learn even more about human health and diseases, to advance medical research.
- We may deposit the data into one or more open-access (public scientific database) and/or controlled-access research databases. Anyone on the Internet can access publicly accessible database. Only researchers (including private companies involved in publicly-funded research) who apply and are granted approval can access controlled-access databases.
- [Include for scenarios that allow data linkages with data from NMRC Research Data Repository (BRAIN or TRUST platform) ONLY. Modify if required. Otherwise, delete.] Where required, researchers may request that the research data be combined or linked with data from other sources, including but not limited to healthcare billing information, government administrative 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 databases, whether by itself or with the assistance of a data intermediary. This will enrich their data analysis and provide valuable information for policy and research into health and wellbeing of the population (public interest). The data intermediary will use strict privacy preserving policies, protocols and procedures to ensure security of the data and confidentiality of the individuals the records relate to.
- You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.
- We may also use the data for purposes other than research such as teaching, or training future researchers, development of health policy, or (to expand as necessary).

This is what will be done to protect confidentiality of the data:

- Any information that could identify you will be removed (de-identified) before this de-identified data is used and/or shared with other researchers and/or deposited into research data repository.
- The open-access and controlled-access research data repositories have robust procedures in place to protect confidentiality of the stored data. Although these repositories do not have your identifying information, it may be possible to identify you based on information in the databases when combined with information from other public sources (including information you tell people or post about yourself). We believe the chance of this happening is currently very low.
- If you decide at a later time that you do not want your data to be used for Future Research, you can contact the Principal Investigator or study team at any time. All the data that has not been used or shared with other researchers will be removed and discontinued from further use, unless this information has already been deposited into the research data repository or included in analyses or used in publications.

The use of your data in Future Research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.

CONSENT FORM FOR FUTURE RESEARCH

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.

- I do not agree to have my data stored for future use in other research studies.
- I agree to have my data stored for future use in other research studies, as described above. I understand that I will not be contacted again personally, for approvals to use and share my data for such Future Research. Research arising in the future, will be subject to review by the relevant institutional review board, where applicable.

Disclosure of incidental findings arising from Future Research

- I wish to be re-identified and notified of any incidental findings that are medically actionable (with available treatment options).
- I do not wish to be re-identified and notified of any incidental finding that are medically actionable (with available treatment options). However, I understand that in exceptional or rare situations such as discovery of life-threatening findings), I may be contacted to confirm my decision whether to learn more about the incidental findings.

I understand the purpose and nature of this optional component (storage of data for future use). I have been given the Information & Consent Form for Future Research and the opportunity to discuss and ask questions about this optional component and am satisfied with the information provided to me.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The optional component (storage of data for future use) has been explained to the participant/ participant's legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this Information & Consent Form for Future Research had the optional component fully explained to him/her in a language understood by him/ her and clearly understands the purpose and the nature of this optional component.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative signing this Information & Consent Form for Future Research.
- I have taken reasonable steps to ascertain that the participant or the participant's legal representative has not been coerced into giving consent.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this Information & Consent Form for Future Research had the optional component (storage of data for future use) fully explained to him/her and clearly understands the purpose and the nature of this optional component.

Name of Investigator/ Person obtaining consent	Signature	Date

Future Research - Example # 2: (Data and Leftover Biological Materials)

INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

[Notes: Researchers need to decide at the start of the study what will happen to the leftover biological materials. If the researchers plan to store the leftover biological materials in a Tissue Bank, the Tissue Bank consent form should be used.]

This is an optional component that is separate from the research study. You may still participate in the research study if you say "No" to this. Please ask questions if you do not understand why we are asking for your permission.

In this Consent Form for Future Research, we seek your permission to keep all information collected about you (Personal Data and research data) and leftover biological materials (state the type of human biological materials that will be kept for future research) for Future Research. Except if you withdraw your consent or there are limits imposed by law, there is no limit on the length of time we will store the data and biological materials. Researchers will use the data and biological materials for research long into the future.

This is what will be done with the stored data and leftover biological materials:

- We may use the data and biological materials to answer additional research questions in other research studies which are outside the scope of the research study ("Future Research"). (Note to PI: For study recruiting (a) an adult who lacks mental capacity; OR (b) a minor who lacks mental capacity; OR (c) a minor who lacks sufficient understanding and intelligence to give consent, thereby requiring consent from their legal representative; AND the removal of tissue is solely for research purpose; OR in excess of tissue primarily removed for a therapeutics or diagnostic purpose, the scope of future research should be defined.)
- We may also share the data and biological materials with other researchers within and/or outside of Singapore, for use in Future Research. The biological materials will not be used in research involving human-animal combinations, which is restricted by Singapore law.
- [Modify as relevant for your study. Otherwise, delete.] We may deposit the data into research data repository for long-term use by the wider research community, for use in Future Research. Researchers share information with each other by depositing data into research databases. These databases store information from many other research studies. Researchers can then study the combined information to learn even more about human health and diseases, to advance medical research.
    - We may deposit the data into one or more open-access (public scientific database) and/or controlled-access research databases. Anyone on the Internet can access publicly accessible database. Only researchers (including private companies involved in publicly-funded research) who apply and are granted approval can access controlled-access databases.
    - [Include for scenarios that allow data linkages with data from NMRC Research Data Repository (BRAIN or TRUST platform) ONLY. Modify if required. Otherwise, delete.] Where required, researchers may request that the research data be combined or linked with data from other sources, including but not limited to healthcare billing information, government administrative 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 databases, whether by itself of with the assistance of a data

intermediary. This will enrich their data analysis and provide valuable information for policy and research into health and wellbeing of the population (public interest). The data intermediary will use strict privacy preserving policies, protocols and procedures to ensure security of the data and confidentiality of the individuals the records relate to.

- You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.
- We may also use the data and biological materials for purposes other than research such as teaching, or training future researchers, development of health policy, quality control, validation testing, or (*to expand as necessary*).

This is what will be done to protect confidentiality of the data and biological materials:

- Any information that could identify you will be removed (de-identified) before this de-identified data and biological materials are used and/or shared with other researchers and/or deposited into research data repository.
- The open-access and controlled-access research data repositories have robust procedures in place to protect confidentiality of the stored data. Although these repositories do not have your identifying information, it may be possible to identify you based on information in the databases when combined with information from other public sources (including information you tell people or post about yourself). We believe the chance of this happening is currently very low.
- If you decide at a later time that you do not want the data and biological materials to be used for Future Research, you can contact the Principal Investigator or study team at any time. All the stored data and biological materials that have not been used or shared with other researchers will be removed from the storage facility and/or destroyed, unless this information is already deposited into the research data repository or included in analyses or used in publications.

The leftover biological materials will be deemed to be donated to SingHealth as a gift. By agreeing to this, you give up your rights to the leftover biological materials. The use of your data and leftover biological materials in Future Research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.

If you have questions or wish to provide feedback on the purposes for which the leftover biological materials will be used, you may contact the Principal Investigator.

CONSENT FORM FOR FUTURE RESEARCH

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.

☐ I do not agree to have my data and leftover biological materials stored for future use in other research studies.

☐ I agree to have my data and leftover biological materials stored for future use in other research studies, as described above. I understand that I will not be contacted again personally, for approvals to use and share my data biological materials for such Future Research. Research arising in the future, will be subject to review by the relevant institutional review board, where applicable.

Disclosure of incidental findings arising from Future Research

☐ I wish to be re-identified and notified of any incidental findings that are medically actionable (with available treatment options).

☐ I do not wish to be re-identified and notified of any incidental finding that are medically actionable (with available treatment options). However, I understand that in exceptional or rare situations such as discovery of life-threatening findings), I may be contacted to confirm my decision whether to learn more about the incidental findings.

I understand the purpose and nature of this optional component (storage of data and leftover biological materials for future use). I have been given the Information & Consent Form for Future Research and the opportunity to discuss and ask questions about this optional component and am satisfied with the information provided to me.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The optional component (storage of data and leftover biological materials for future use) has been explained to the participant/ participant's legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this Information & Consent Form for Future Research had the optional component fully explained to him/her in a language understood by him/ her and clearly understands the purpose and the nature of this optional component.

- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative signing this Information & Consent Form for Future Research.
- I have taken reasonable steps to ascertain that the participant or the participant's legal representative has not been coerced into giving consent.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this Information & Consent Form for Future Research had the optional component (storage of data and leftover biological materials for future use) fully explained to him/her and clearly understands the purpose and the nature of this optional component.

_____	_____	_____
Name of Investigator/ Person obtaining consent	Signature	Date

Part B: Additional Consent Requirements for Genetic/ Genomic Testing

NOTE:
This section covers the additional consent elements and language specific to genetic/ genomic testing, and is intended to supplement the CIRB Participant Information Sheet and Consent Form ('Informed Consent Document (ICD)") template.

Researchers will have to adapt the examples of language to suit the genetic/ genomic testing specific to their research study and the research participants.

PURPOSE OF THE RESEARCH STUDY

- Include a description of the underlying genetic/ genomic science (e.g. explanation of "genes", "DNA", "genome", "genetic test"; "genomic test" in simple, lay language, the disease(s) or condition(s) being studied.

Important:

- **If genetic/ genomic testing is optional,** researchers should provide research participant with a separate consent document that describes the optional genetic/ genomic testing in details and to document his or her decision in relation to the optional component. The main ICD document should have a statement that refers to the separate consent document for optional genetic/ genomic testing. The latter should be crafted using the CIRB ICD template as a base).

> **Example:**
> The purpose of this study is to (explain in lay language why the research is being done, ensuring it is consistent with the Aims described in your CIRB application form). The study also involves genetic/ genomic testing, which is optional. A separate document titled INFORMATION & CONSENT FORM FOR OPTIONAL GENETIC/ GENOMIC TESTING will provide details on this optional study.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

- Explain in simple, lay language the genetic/ genomic testing that will be carried out.

> **Example:**
> **Genetic testing**
> The study involves genetic testing. We will look at some genes to XXX (e.g. confirm your clinical diagnosis).
>
> **Genome-wide sequencing**
> The study involves genome-wide sequencing. It is an analysis of the complete set of genetic instructions (DNA) in a cell. This analysis looks for small changes (sequence variants) in the genetic instructions (related to ABC disease or XZY health traits).

- Describe what DNA sequence or other experimental data will be generated from the biological materials and/or data.

Example:
DNA sequence analysis
Using DNA from your blood and tissue sample, we will study your entire genetic sequence, known as "genome". The genome sequence will be read and this information will be stored.

Your genomic data will be used to find differences and similarities among people related to (ABC disease or XZY health traits). Your genomic data and health information will be studied along with information from other participants in this study.

- Describe whether researchers will return research results to the research participants:

  - Disseminate summary-level research results to the research participant (and if so, the plans for the dissemination);

  - Return individual research results* to the research participant (and if so, the plans for the return – what type of findings, when, how, and who will return the results), AND to the research participant's treating physician, AND if the results will be placed in the research participant's medical records.

Important:
***The individual research results refer to clinically relevant research results**, not incidental findings (i.e. study results that are not related to the purposes, objectives or variables of the proposed research).

The plan for offering research results to research participant should be carefully articulated at the outset of any study and made clear to potential research participant.

Researchers who plan to return individual results should consider the possibility that research participants might wish to opt out of receiving individual results during the consent process, and whether that is appropriate with respect to the study design. Researchers may find it helpful to provide research participants with various examples of result they might receive in order to establish expectations about the breadth of results that could be received, and to give research participants a framework for deciding which type of results they might be interested in receiving. If researchers provide multiple options for these types of results to receive, there must be a robust mechanism for tracking these choices.

Some types of results to consider when developing any plan for return include:
- Medically preventable conditions
- Medically relevant results with unclear treatment implications
- Results without personal health implications, but which may be useful for reproductive planning
- Results of uncertain significance

In research studies that do return results, it should be considered up front whether or not to return genetic/ genomic results for adult-onset disorders to children and/or their legal representative. For research recruiting children participants, the consent process should describe whether the return of results is dependent on the age of the research

participants and whether the researcher participants will be given the opportunity to provide consent for return of results when they reach 21 years (adult).

For men and woman of reproductive age and for women known to be pregnant at the time of enrolment, the informed consent process should include information about the relevance to reproductive planning of any results that are returned. Considerations of reproductive planning may also be relevant to parents of children involved in research.

Any plans to return research results must be IRB approved

Examples:
[Include or modify as necessary, if participants will receive aggregate research results.] Once the study has been completed, we will send you a summary of all the results of the study and what they mean.

[Include or modify as necessary, if participants will not receive individual research results.] In general, we will not give you any individual results from the study. The research and genetic/ genomic tests that are being done are experimental. The meaning of these test results is currently unknown. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be very rare occurrence.

[Include or modify as necessary, if participants will receive individual research results.] It is possible that the genetic/ genomic test will show a link between your genetic information and a disease or condition. (Include an explanation regarding the meaning of a positive test result (e.g. If there is a positive test result, this means that you may develop, or that you may have XXX disease/ condition that we are testing for in this study.) This result has not been verified in a clinical laboratory/ certified genetic testing laboratory. You may want to undergo further testing and/or consult with your doctor to confirm this finding. The costs for any care that will be needed to diagnose or treat the disease/ condition would not be paid for by this research study. These costs would be your responsibility.

Knowing this information may help you make choices about you or your family's health care. However, some individuals prefer not to know about their genetic information. You will be asked to indicate whether you wish to be notified of the genetic test results and a copy of the results be placed in your medical records and shared with your doctor.

- Include a statement that the research participants may want to obtain professional genetic counselling before signing consent.

Important:
In genetic testing, a sample of blood or saliva can offer clues to one's body's genetic defects, a road map to predicting future problems ranging from Alzheimer's diseases to cancer. The results, however, might not be what patients want to hear, especially because the test results could reveal an inherited mutation that put themselves or their family members at risk. Therefore, the consent document should include a generic statement on the opportunity to consult with professional genetic counsellor prior to indicating decision for participation in the research.

Example:
You may want to consult professional genetic counselling prior to signing this consent form. (Expand with details whether the study team will provide the counselling free or charge or participant will have to seek for one themselves and at their own cost).

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

Important:
Research participants need to be informed of the risks associated with genetic or genomic research, including the risks related to studies in which large amounts of genomic data and health information may be collected, stored and broadly shared with other researchers.

Discussing the likelihood of the risks in the context of the particular study, as well as their potential severity, may help research participants better understand the nature of the various risks. However, it is also important that researchers do not overstate the risks when there is little or no evidence that they actually occur or cause harm. Researchers should describe the measures they are taking to reduce risks and the protections from risks that are in place.

Discussion of risk should be balanced with discussion of the potential benefits of research participation.

- Include a description of the psychological risks through receiving information that is unexpected or unwanted by the research participant. If the research results are to be returned, the uncertainty of findings, and personal and sensitive information about disease and disability risk, paternity, or ancestry may be difficult for research participants to understand and may sometimes be upsetting to research participants.

Psychological risks associated with return of research (genetic/ genomic) results

Example # 1:
As part of the research study, you may learn that you have genetic risks for disease or disability. This might be upsetting and, depending on what you learn, might create a need to make challenging decisions about how to respond.

Although your genomic information is unique to you, you share some genomic similarities with your children, parents, brothers, sisters, and other blood relatives. Therefore, learning your research results could mean something about your family members and might cause you or your family distress. Before joining the study, it may be beneficial to talk with your family members about whether and how they want you to share your results with them.

Example # 2:
Disclosure of genetic testing results such as being a carrier of a disease gene may cause you anxiety and psychological distress. You may wish to do more tests and seek advice to confirm this finding. The costs for any care that will be needed to diagnose or treat the disease would not be paid for by this research study. These costs would be your responsibility.

- Include a description of the social risks of disclosure of the genetic/ genomic results.

Note:
A statement regarding MOH-LIA 'Moratorium on Genetic Testing and Insurance' is required. For more information on the Moratorium, click here (internet – MOH website).

Social risks associated with return of research (genetic/ genomic) results

Example:
There may be a risk that genetic information obtained as a result of participation in research could be misused for discriminatory purpose that compromise or diminish your chances and the chances of your family of obtaining insurance (life insurance, disability, mortgage, or health) or certain types of employment. Some genetic information can help predict future health problems of you and this information might be of interest to your insurers. However, the Ministry of Health (MOH), Singapore has developed the MOH-LIA 'Moratorium on Genetic Testing and Insurance' that imposes a ban on the use of all genetic test results from human biomedical research in insurance underwriting. This means the insurers cannot request the disclosure of and/or use your genetic test results from this study in insurance underwriting. Your genetic test from this study will not be disclosed to any insurers without your written consent.

POTENTIAL BENEFITS

Important:
Research participants may or may not receive any direct benefits as a result of participating in research. A direct benefit is generally viewed as a benefit gained from an intervention that is being tested in the research that has the prospect of being an effective treatment or informing treatment selection.

However, the primary purpose of research is to provide benefits to society by advancing science or contribution to advances in health, so the social value or the research should be discussed as an indirect benefit. Other indirect benefits to individuals may include the opportunity to receive specialized care or genetic counselling (if provided as part of the study procedures), and learning about their genetic information (though the amount and types of results that they might receive is often unpredictable).

- Include a description of any benefits to the research participants or to others, which may reasonably be expected from the research.

Potential benefits to the research participants

Example # 1:
You may receive some results about your genomic information that is personally interesting to you. You may learn that you have risk factors for certain diseases and disorders, and you may learn that you are at low risks for other diseases and disorders.

Example # 2:
Through participation in this study, you may receive a diagnosis for your condition or have genetic confirmation of a suspected diagnosis based on your clinical symptoms.

Potential benefits to the society

Example:
Your participation will help medical researchers better understand various diseases and develop better treatments, which may help others like you in the future.

WHAT HAPPENS TO THE SAMPLES COLLECTED FOR THE RESEARCH

Important:

If genetic/ genomic testing is optional, researchers should only collect sufficient amount of biological materials for testing AND must not keep leftover samples for Future Research.