SingHealth

Guidance on Requirements for Informed Consent Documents

For all new IRB applications (which involve obtaining informed consent from research participants) submitted from 1 July 2020, the Participant Information Sheet and Consent Form Template version 12 template must be used.

For existing IRB-approved studies with HBRA appropriate consent document, revision to this new template is not required.

This guidance is developed (based on Participant Information Sheet and Consent Form Template version 12) to assist Principal Investigator 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.

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

The consent document 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
    - ALTERNATIVE PROCEDURES/ TREATMENTS IF YOU DO NOT PARTICIPATE IN THE STUDY
    - 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.

SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:
(Full protocol title as used in the CIRB Application)

Principal Investigator:
(PI's Name)
(PI's Department)
(PI's Institution Name)

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 carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

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 study is to (state what is being studied). We hope to learn (state what the study is designed to discover or establish).

You were selected as a possible participant in this study because (explain why participant is being selected).

This 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 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:

If you agree to 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 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). You will need to visit the doctor's office (state number of times) times in the course of the study.

[Include for study involving randomisation. Otherwise, delete.] *If you agree to take part in this study, 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).*

[Include for study involving collection of biological materials. Otherwise, delete.] *If you agree to take part in this study, the following samples ("biological materials") will be obtained: (expand with details of sample collection as necessary).*

[Include for study involving collection of biological materials. Otherwise, delete.] *The biological material will be (describe in lay language and simple terms what will be done with the samples (e.g. specific research purpose for which the biological materials is intended to be used or any purpose other than research such as development of commercial diagnostic kits) and whether the samples will be tested in Singapore or overseas or combination of both). It will not be used in research involving human-animal combinations, which is restricted by laws imposed by the Ministry of Health, Singapore.*

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

POSSIBLE RISKS, DISCOMFORTS AND 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:

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 health information that may affect your privacy. To protect your confidentiality, only a unique code number 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.

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.*

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.*

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 clinical care or through an existing catheter already inserted into a vein.*

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.

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 (study drug/ medication / device / intervention / investigation).

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.

Example
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.

ALTERNATIVES PROCEDURES/ TREATMENTS IF YOU DO NOT PARTICIPATE IN THIS 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.
- For research study involving treatments and/or procedures, if there are no alternatives, clearly state so and that the research procedures will not be done.
- For research involving questionnaires/ surveys/ interviews, this section is not applicable and can be deleted.

Example # 1: (For research involving procedures/ treatments, where alternatives procedures/ treatments are available)
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). You may discuss the possible risks and benefits of the alternatives with your doctor.

Example # 2: (For research involving procedures/ treatments, where NO alternatives procedures/ treatments are available)
There is no alternative procedure or treatment 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

- There are two (2) parts in this section: 1. Costs of participation and 2. Payment for Participation.
- 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.

Part 1 - Example: (Costs of Participation)
There is no cost to you for participating in this research 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 institutions/ sponsor name).

The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you.

Part 2 - Example # 1: (Participants will receive payment or reimbursement)
You will be reimbursed for your time, inconvenience and transportation costs as follows:

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

PART 2 - Example # 2: (Participants will not receive payment or reimbursement)
You will not receive any payments or reimbursements for taking part in this study.

INCIDENTAL FINDINGS

- There are 2 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 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.

Standard Statement:
The biological materials collected for this research study will be deemed to be donated to (name of institution) 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 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).

However, any of your data that has 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.

[Include for research that involves collection of human biological materials. Otherwise, delete.]
The biological materials that have been collected for the study will not be returned to you. However, you retain your right to ask the Principal Investigator to discard or destroy any remaining samples if they have not been anonymised and/or have not been used.

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.
- Remove "AND MEDICAL" in the section header if the study recruits only non-patient participants.
- 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.
- According to SingHealth Cluster Research Data Management Policy - Clinical Trial and Clinical Research, research data should be retained in a secured storage facility for a minimum of 7 years after completion of research study or date of publication of the research using the research data, whichever is later. These documents should be retained by the Principle Investigator in a secure storage facility. They should be accessible for inspection and copying by authorized authorities.

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. Your study records and medical records, to the extent required by the applicable laws and regulations, will not be made publicly available. Only the study team will have access to the personal data being collected from you. In the event of any publication regarding this study, your identity will remain confidential.

[Include for research recruiting patient participants. Otherwise, delete.] *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 and study records to verify study procedures and data, without making any of your information public.*

[Include for research recruiting non-patient participants. Otherwise, delete.] *However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your 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 (Insert Name of Institution), and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above.

Any information containing your Personal Data that is collected for the purposes of this research will be stored in Singapore. To protect your identity, your Personal Data will be labelled with a unique code number. 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 number to your Personal Data. This will be kept in a safe place with restricted access. [Include if Investigators intend to transfer data out of Singapore as part of this research study. Otherwise, delete.] *To (state purpose of data transfer), your coded data will be transferred out of Singapore.*

[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 (Insert Name of Institution 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 (Insert Name of Institution 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 6323 7515 during office hours (8:30 am to 5:30pm).

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

- Include the standard statement.
- For more than minimal risk studies, please also include mobile number of the Principal Investigator or Study Coordinator.

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:

Principal Investigator
(PI's Name)

(PI's Department, Institution)
(PI's Phone Number)
(PI's Institution Mainline)

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

Protocol Title:
(Full protocol title as used in the CIRB Application)

Principal Investigator:
(PI's Name)
(PI's Department, Institution Name)

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.

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

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

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 parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

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/ Person obtaining consent	Signature	Date

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.

[Include if data will be stored for a specific duration for future research. Otherwise, delete.] *In this Consent Form for Future Research, we seek your permission to keep your data for (state intended storage duration) for future research. The data will be kept in (state institution) for use by researchers.*

[Include if data will be stored for an indefinite period of time. Otherwise, delete.] *In this Consent Form for Future Research, we seek your permission to keep your data for future research. The data will be kept in (state institution). 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 your data. Researchers will use your data for research long into the future.*

This is what will be done with your stored data:

- We may use the data to answer additional research questions in other research studies (state the specific research purpose, if available). This is outside the scope of the research study but still related to (state the specific disease of condition).
- We may share the data with other researchers at (state institutions, etc.) and with researchers outside of Singapore (state collaborators, country, etc.)

[Include if stored data will be coded. Otherwise, delete.]

- *The stored data will be labelled with a code instead of information that directly identifies you (e.g. your name, NRIC, date of birth, etc.). We will keep a separate file (key) that links your code to your identifiable information.*
- *When we share your data with other researchers, it will be in a coded manner. They will not be able to identify you from the coded data.*
- *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 your stored data that has not been used or shared with other researchers will be removed and discontinued from further use, unless this information is already included in analyses or used in publications.*

[Include if stored data will be stripped of identifiers. Otherwise, delete.]

- *The stored data will be anonymized with the removal of all information that directly identifies you so that no one can identify which data came from you.*
- *This means that even if you decide at a later time that you do not want your data to be used for future research, we will not be able to remove your data and discontinue from further use.*

[Include if applicable. Otherwise, delete.] *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.

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)'s data obtained from the research study to be stored for future use in other research studies in the interest of medical progress as described in and on terms set out in the Information & Consent Form for Future Research.

I understand that his/her participation is voluntary and I can withdraw his/her participation at any time, without giving reasons.

The nature of this optional component has been explained clearly to me and I fully understand them.

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'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 in other research studies)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 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 Information & Consent Form for Future Research had the optional component (storage of data for future use in other research studies) fully explained to him/her and clearly understands the purpose and the nature of the participant's participation in the study.

_____ _____ _____

Name of Investigator/ Person obtaining consent | Signature | Date

Example # 2: (Data and Leftover Biological Materials)

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.

[Include if data and leftover biological materials will be stored for a specific duration. Otherwise, delete.] *In this Consent Form for Future Research, we seek your permission to keep your data and leftover biological materials (state the type of human biological materials that will be kept for future research) for (state intended storage duration) for future research. The data and biological materials will be kept in (state institution) for use by researchers.*

[Include if data and leftover biological materials will be stored for an indefinite period of time. Otherwise delete.] *In this Consent Form for Future Research, we seek your permission to keep your data and leftover biological materials (state the type of human biological materials that will be kept for future research) for future research. The data and biological materials will be kept in (state institution). 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 your data and biological materials. Researchers will use your data and biological materials for research long into the future.*

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

- We may use the data and biological materials to answer additional research questions in other research studies (state the specific research purpose/ tests, if available). This is outside the scope of the research study but still related (state the specific disease of condition).
- *[Delete if not applicable.] We may use the biological materials for (state if human biological materials will be used for any purpose other than research e.g. quality control, validation testing, etc.)*
- We may share the data and biological materials with other researchers at (state institutions, etc.) and with researchers outside of Singapore (state collaborators, country, etc.)

[Include if stored data and leftover biological materials will be coded. Otherwise, delete.]

- *The stored data and biological materials will be labelled with a code instead of information that directly identifies you (e.g. your name, NRIC, date of birth, etc.). We will keep a separate file (key) that links your code to your identifiable information.*
- *When we share your data and biological materials with other researchers, it will be in coded manner. They will not be able to identify you from the coded data and biological materials.*
- *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 decide at a later time that you do not want your data and biological materials to be used for future research, you can contact the Principal Investigator or study team at any time. All your 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 included in analyses or used in publications.*

[Include if stored data and leftover biological materials will be stripped of identifiers. Otherwise, delete.]

- *The stored data and biological materials will be anonymized with the removal of all information that directly identifies you so that no one can identify which data and biological materials came from you.*
- *Since the data and biological materials have been made anonymous, any results, obtained cannot be traced back to the original source, and no results or incidental findings will be reported.*
- *This means that if you decide at a later time that you do not want your data and biological materials to be used for future research, we will not be able to remove your data and biological materials from the storage facility.*

The leftover biological materials will be deemed to be donated to (name of institution) 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.

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.

[Delete if leftover biological materials will NOT be transferred out of Singapore for future research.]

☐ *I agree for my leftover biological materials to be transferred out of Singapore.*

☐ *I do not agree for my leftover biological materials to be transferred out of Singapore.*

[Delete if leftover biological materials will be stripped of identifiers.]

☐ *I wish to be re-identified and notified of any incidental finding arising from future research studies using my leftover biological materials.*

☐ *I do not wish to be re-identified and notified of any incidental finding arising from future research studies using my leftover biological materials. However, I understand that in exceptional or rare situations, I will be contacted:*

- *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 Disease 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)'s data and leftover biological materials obtained from the research study to be stored for future use in other research studies in the interest of medical progress as described in and on terms set out in the Information & Consent Form for Future Research.

I understand that his/her participation is voluntary and I can withdraw his/her participation at any time, without giving reasons.

The nature of this optional component has been explained clearly to me and I fully understand them.

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'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 in other research studies) 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 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 Information & Consent Form for Future Research had the optional component (storage of data and leftover biological materials for future use in other research studies) fully explained to him/her and clearly understands the purpose and the nature of the participant's participation in the study.

_____ _____ _____

Name of Investigator/ Person obtaining consent | Signature | Date