# Participant Information Sheet and Consent Form

|  |
| --- |
|  |
| 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. |
| **STUDY INFORMATION** Protocol Title: (Full protocol title as used in the AMCS-IRB 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. [Include for study recruiting participants aged 13 to 20 years old where participants’ assent will be documented using this consent document, along with consent from their parent or 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” refers to your child.* 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 were 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.
* 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. [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.] 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. If you agreed to be re-contacted, your personal data will be kept for 7 years. If you who did not agree to be re-contacted, your personal data will be discarded at the end of the study. The data collected from you and other respondents will be totalled in the computer system for analysis.Only the Principal Investigator and data administrator will have full access to the data with personal identifiers. Other Institute research analysts will only have access to coded data (without personal identifiers). The overall research findings (without personal information) will be shared with[Include where the information will be shared]. By signing the Informed Consent Form, you agree to the above arrangement and access to your records. If you agree to participate, the interviewer will ask you for your name and contact number. This is for the purpose of allowing us to clarify any information with you if necessary. This would also help us to contact you again for future rounds of the study. Please be assured that your contact details will be kept strictly confidential.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 appIRBiation) 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. Page 11 of 23 SHS-RSH-CIRB-3207 Version 1.1 – 20 Aug 2020 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. 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 IRBORDS * 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.
* 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 Principal 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 ACMS Data Protection Policy, the full version of which is available at ACMS website. WHO HAS REVIEWED THE STUDY * Include the standard statement.

Standard Statement: This study has been reviewed by the ACMS IRB for ethics approval. If you have questions about your rights as a participant, you can call the ACMS IRB office at +65 6291 3758 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 ACMS Institutional Review Board. |

|  |
| --- |
| **Consent Form** |
| 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.**STUDY INFORMATION** **Protocol Title:** (Full protocol title as used in the ACMS-IRB 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. (For Questionnaires, please insert sentence for agreement to each part of the research)[example for agreement sentences]I agree/ do not agree\* to take part in the current survey on [insert survey title]. I agree/ do not agree\*to be re-contacted by [insert research institute] for the purposes of verifying any information that I have provided.I agree/do not agree\* for audio recording [include other modes of recording survey if needed] to be conducted during the duration of the survey. I agree/ do not agree\* to be re-contacted for the participation in the second and/or third part of the study if required. I understand that I can still change my mind after agreeing to be re-contacted. I understand that any further studies using the data collected will be subject to approval by the Institutional Review Board. \*Please delete as appropriate. I understand that PI and data administrator will have full access to all the data collected, including my personal information and that the overall research findings (without personal information) will be shared with government ministries/agencies for policy-making purposes.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 ACMS 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’s parent/ legal guardian/ legal representative |  | 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 ACMS 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 |

 |
| *\*For person administrating the consent***Consent to Participate in Research**

|  |  |
| --- | --- |
| Study Tile: | (Please insert study title here) |

You are being invited to participate in the above research study.Before you agree, the investigator must tell you about: 1. the purpose, procedures, and duration of the research;
2. any procedures which are experimental;
3. any reasonably foreseeable risks or discomforts,
4. any potential benefits of the research;
5. any alternative procedures or treatments; and
6. how confidentiality will be maintained.

Where applicable, the investigator must also tell you about: 1. any available compensation or medical treatment if injury occurs;
2. the possibility of unforeseeable risks;
3. circumstances when the investigator may halt your participation;
4. any added costs to you;
5. what happens if you decide to stop participating;
6. when you will be told about new findings which may affect your willingness to participate; and
7. how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.If you have questions about this research study, you may contact the Principal Investigator, (Name of Principal Investigator) at \_\_(Contact Details)\_\_\_\_.In case of any injuries during the course of this study, you may contact the Principal Investigator, (Name of Principal Investigator) at \_\_(Contact Details)\_\_\_\_.*Note: For all studies, please include minimally your Institution’s mainline. For more than minimal risk studies, please include the mobile number of PI or Study Coordinator, in addition to your Institution’s mainline. [Please delete this note after reading.]*If you want an independent opinion of your rights as a research subject, you may email the ACMS-IRB Secretariat at enquiry@academycms.org. Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Participant | Signature of Participant | Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Witness | Signature of Witness | Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Investigator /Person Administering Consent | Signature of Person Administering Consent | Date |

 |
| **参加研究同意**

|  |  |
| --- | --- |
| 研究专目：  | (Please insert study title here) |

您受邀参与上述研究。在您同意之前，研究者必须告知您以下事项：1. 本研究的目的、操作方式和研究时长；
2. 任何实验性的操作；
3. 任何合理的可预知风险或不适；
4. 本研究的任何可能益处；
5. 任何替代操作或治疗；以及
6. 如何维持任何与此研究有关的资料保密性。

如适用，研究者也必须告知您以下事项：1. 任何赔偿或药物治疗（如果出现损伤）；
2. 不可预知之风险的可能性；
3. 研究者可能中止您的参加的情况；
4. 您需承担的任何额外费用；
5. 您决定停止参加后的安排；
6. 何时通知您可影响您参与意愿的新发现；以及
7. 参与本研究的人数。

如果您同意参与，您必须得到一份经签名的本文件副本以及本研究的一份书面摘要。如有研究相关疑问，您可随时联系\_\_\_\_\_\_(研究人姓名)\_\_\_\_\_\_，电话\_\_\_\_(联络号码)\_\_\_\_\_。如果您对于您作为研究受试者的权利或在损伤发生后所应采取的措施存有疑问，您可随时联系\_\_\_\_\_\_(研究人姓名)\_\_\_\_\_\_，电话\_\_\_\_(联络号码)\_\_\_\_\_。注意事项：所有研究都必须在此文件注明研究人员所属机构的联络号码。高风险研究需在此文件注明研究人员所属机构的联络号码以及研究人员的手机号码。[请在阅读此项目后删除此项目]如果您需要寻求一份对于您研究受试者权利的独立见解，请电邮新加坡中医研究院的IRB秘书处， research@academycms.org ，电话：6471-3266。 您是自愿参与本研究的；拒绝参与或决定停止参与将不会给予您任何不利，也不会导致您损失任何利益。签署本文件即意味着我们已向您口头声明了本研究（包括上述信息），而您自愿同意参与此研究。

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 参与者姓名 | 参与者签名 | 日期 |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 见证人姓名 | 见证人签名 | 日期 |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 研究人员姓名 | 研究人员签名 | 日期 |

**Kebenaran untuk Menyertai Penyelidikan**

|  |  |
| --- | --- |
| Tajuk Kajian:  | (Please insert study title here) |

Anda dipelawa untuk menyertai kajian penyelidikan di atas.Sebelum anda bersetuju, penyelidik mesti memaklumkan kepada anda mengenai: 1. tujuan, prosedur, dan tempoh penyelidikan;
2. sebarang prosedur yang dianggap percubaan;
3. sebarang risiko atau ketidakselesaan yang diduga;
4. sebarang faedah penyelidikan yang mungkin diperoleh;
5. sebarang prosedur atau rawatan alternatif; dan
6. bagaimana kerahsiaan akan dipelihara.

Di mana sesuai, penyelidik juga mesti memaklumkan kepada anda mengenai: 1. sebarang pampasan atau rawatan perubatan yang ada jika berlaku kecederaan;
2. kemungkinan berlakunya risiko yang tidak diduga;
3. keadaan-keadaan di mana penyelidik mungkin akan menghentikan penyertaan anda;
4. sebarang kos tambahan yang harus ditangggung oleh anda;
5. apa yang akan berlaku sekiranya anda memutuskan untuk menghentikan penyertaan;
6. apabila anda diberitahu mengenai dapatan baru yang mungkin akan menjejas kesanggupan anda untuk mengambil bahagian; dan
7. berapa ramai orang akan menyertai kajian ini.

Jika anda bersetuju untuk mengambil bahagian, anda mesti menerima satu salinan dokumen yang telah ditandatangani dan ringkasan bertulis mengenai penyelidikan ini.Jika anda mempunyai soalan mengenai penyelidikan ini, anda boleh menghubungi Penyelidik Utama, \_(Nama Penyelidik Utama)\_\_di \_(Butir-butir Hubungan)\_\_\_ pada bila-bila masa sekiranya anda mempunyai soalan mengenai penyelidikan ini.Anda boleh menghubungi \_(Nama Penyelidik Utama) di \_(Butir-butir Hubungan)\_ sekira berlakunya sebarang kecederaan terhadap diri anda sewaktu penyelidikan ini dijalankan. *Perhatian: Bagi semua kajian, sila masukkan sekurang-kurangnya butir hubungan utama institusi anda. Bagi kajian melebihi risiko minimal, sila masukkan nombor telefon bimbit Penyelidik Utama atau Penyelaras Kajian, di samping butir hubungan utama institusi anda. [Sila memadam nota ini selepas membaca]*Jika anda ingin pendapat bebas mengenai hak anda sebagai subjek dalam kajian ini, anda boleh menghubungi sekretariat ACMS-IRB di research@academycms.org .Penyertaan anda dalam penyelidikan ini adalah secara sukarela, dan anda tidak akan didenda atau kehilangan faedah sekiranya anda enggan mengambil bahagian atau memutuskan untuk berhenti.Menandatangani dokumen ini bermakna bahawa kajian penyelidikan ini, termasuk maklumat di atas telah diterangkan kepada anda secara lisan, dan anda secara sukarela bersetuju untuk menyertainya.

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Nama Peserta | Tandatangan Peserta | Tarikh |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Nama Saksi | Tandatangan Saksi | Tarikh |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Nama Penyelidik / Orang yang Mentadbir Kebenaran | Tandatangan Orang yang Mentadbir Kebenaran | Tarikh |

**ஆராய்ச்சியில் பங்கேற்பதற்கு இணக்கம்**

|  |  |
| --- | --- |
| ஆய்வுத் தலைப்பு : | (Please insert study title here) |

மேலே சொல்லப்பட்டு இருக்கும் ஆராய்ச்சி ஆய்வில் பங்கேற்பதற்கு நீங்கள் அழைக்கப்படுகிறீர்கள். பங்கேற்க நீங்கள் சம்மதிக்கும் முன், பின்வருவன பற்றி உங்களுக்கு ஆய்வாளர் தெரிவிக்க் வேண்டும்: 1. நோக்கம், செய்முறைகள், மற்றும் ஆராய்ச்சியின் கால அளவு;
2. சோதனைகளில் பயன்படுத்தப்படுபவையாக இருக்கும் செய்முறைகள்;
3. ஏதேனும் நியாயமாக எதிர்பார்க்கக் கூடிய அபாயங்கள் அல்லது அசௌகரியங்கள்;
4. ஆராய்ச்சின் ஏதேனும் உள்ளார்ந்த பலன்கள்;
5. ஏதேனும் மாற்று செய்முறைகள் அல்லது சிகிச்சைகள்; மற்றும்
6. இரகசியத்தன்மை எவ்வாறு பாதுகாக்கப்படும்.

பொருந்தும் இடங்களில், பின்வருவன பற்றியும் ஆய்வாளர் உங்களுக்குத் தெரிவிக்க வேண்டும்: 1. காயம் ஏற்பட்டால் இருக்கின்ற ஏதேனும் இழப்பீடு அல்லது மருத்துவ சிகிச்சை;
2. எதிர்பாராத அபாயங்களுக்கான சாத்தியம்;
3. ஆய்வாளர் உங்கள் பங்கேற்பை நிறுத்தக் கூடிய சூழ்நிலைகள்;
4. உங்களுக்கு ஆகும் ஏதேனும் கூடுதல் செலவுகள்;
5. பங்கேற்பதை நிறுத்த நீங்கள் முடிவு செய்தால் என்ன நடக்கும்;
6. பங்கேற்கும் உங்கள் விருப்பத்தை பாதிக்கக் கூடிய புதிய கண்டுபிடிப்புகள் பற்றி உங்களுக்கு எப்போது சொல்லப்படும்; மற்றும்
7. ஆய்வில் எத்தனை பேர் பங்கேற்பார்கள்.

பங்கேற்க நீங்கள் சம்மதித்தால், இந்த ஆவணத்தில் கையெழுத்திடப்பட்ட நகல் ஒன்றும், ஆராய்ச்சி பற்றிய எழுத்தபூர்வமான தொகுப்புரை ஒன்றும் உங்களுக்கு கொடுக்கப்பட வேண்டும்.ஆராய்ச்சி பற்றி உங்களுக்கு கேள்விகள் இருந்தால் எந்த சமயத்திலும் \_\_(Name of Principal Investigator)\_\_ அவர்களை \_\_\_(Contact Details)\_\_\_ -ல் நீங்கள் தொடர்பு கொள்ளலாம்.ஆராய்ச்சியின் போது நீங்கள் காயம்பட்டால் உங்களது ஆய்வாளர், \_\_(Name of Principal Investigator)\_\_ அவர்களை \_\_\_(Contact Details)\_\_\_ -ல் நீங்கள் தொடர்பு கொள்ளலாம்.*குறிப்பு: அனைத்து ஆய்வுகளுக்கும், தயவு செய்து குறைந்தபட்சம் உங்கள் மருத்துவமனையின் தொலைபேசி எண்ணை குறிப்பிடவும். மேலும்* அதிக *பட்ச ஆபத்தான ஆய்வுகளுக்கு, மருத்துவமனையின் தொலைபேசி எண் மற்றுமின்றி உங்களது ஆய்வாளர்  அல்லது ஆய்வு வழிநடத்துனர்  தொலைபேசி எண்ணை குறிப்பிடவும். [தயவு செய்து படித்த பின்னர் இந்த குறிப்பை நீக்கவும்.]*நீங்கள் ஒரு ஆராய்ச்சி பங்கேற்பாளராக, உங்கள் உரிமைகளை பற்றி ஒரு சுதந்திரமான கருத்து வேண்டும் என்று விரும்பினால், நீங்கள் ACMS-IRB -டுடைய  செயலகத்துக்கு research@academycms.org -ல்  தொடர்பு கொள்ளலாம்.இந்த ஆராய்ச்சியில் உங்கள் பங்கேற்பு சுயவிருப்பமாகும். நீங்கள பங்கேற்க மறுத்தால் அல்லது நிறுத்த முடிவு செய்தால், நீங்கள் தண்டிக்கப்பட மாட்டீர்கள் அல்லது பலன்களை இழக்க மாட்டீர்கள். மேலுள்ள தகவல்கள் உள்ளிட்டு ஆராய்ச்சி ஆய்வானது உங்களுக்கு வாய்வழியாக விளக்கப்பட்டிருக்கிறது மற்றும் பங்கேற்பதற்கு நீங்கள் சுயவிருப்பத்தில் இணங்குகிறீர்கள் என்பது இந்த ஆவணத்தில் கையெழுத்திடுவதன் அர்த்தமாகும்.

|  |  |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| பங்கேற்பாளர் பெயர்  |  பங்கேற்பாளர் கையெழுத்து  | தேதி  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| சாட்சி பெயர்  | சாட்சி கையெழுத்து  | தேதி  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ஆய்வாளர் பெயர் | ஆய்வாளர் கையெழுத்து | தேதி  |

 |