SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

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

STUDY INFORMATION

Study Title:
Using AS01 adjuvant to improve immune response in older adults through trained immunity

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

Singapore General Hospital
Principal Investigator:
Dr. Chan Yuen Yue Candice
Department of Infectious Diseases
Tel: 6321 3479
Institution Mainline: 6222 3322
24-hour contact: 8123 0967

PURPOSE OF THE RESEARCH STUDY

As people grow older, their immune system - the body's natural defence against diseases - becomes weaker, making them more vulnerable to infections and less responsive to vaccines. This was clearly seen during the COVID-19 pandemic, where older adults were more likely to develop severe illness. Researchers have made an interesting discovery about AS01, an ingredient already used in successful vaccines like the shingles vaccine. They found clues that AS01 might work like a general fitness trainer for the immune system, potentially making it stronger and better at fighting off various types of infections, not just specific ones. To confirm this possibility, we are conducting this research study with adults aged 21-59 to test whether AS01 by itself can boost and train the immune system, how long this boost lasts, and if it actually helps you fight off other infections more effectively.

In this research, we will give participants the yellow fever vaccine, which will be used as a "viral challenge." This means the vaccine safely mimics a viral infection, allowing researchers to see how your immune system responds after receiving AS01.

If successful, this could lead to new ways to protect older people during disease outbreaks, particularly in the crucial early stages before specific vaccines become available.

We are inviting healthy adults aged 21 to 59 years old to participate in this research study, who have not received yellow fever vaccine and AS01-adjuvanted vaccine.

This research study targets to recruit 40 participants from Singapore General Hospital.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

The study involves the following:

Study drug:

1. AS01 adjuvant
   It has been licensed and approved for use together with the recombinant zoster vaccine (Shingrix). Shingrix vaccine normally contains 2 separate vials: a 0.5ml vial containing the AS01 adjuvant system and another vial containing the varicella zoster virus (VZV) glycoprotein E (gE) antigen. While these vials are typically reconstituted together for administration, however in this study, subject will only receive the AS01 adjuvant vial (0.5ml) without reconstitution with the gE antigen. AS01 0.5ml will be given as intramuscular injection in the deltoid muscle.
2. Yellow fever (Stamaril) vaccine
   Yellow fever vaccine containing the YF17D strain has been licensed and approved for use. 1 dose, 0.5ml after reconstitution will be given as subcutaneous injection at Day 30 or Day 90.

You will be randomised to receive AS01 adjuvant or placebo. Randomisation means assigning you to one of two groups by chance, like tossing a coin or rolling dice. You will not know which group you are in, but the study doctor will know. If it becomes necessary for your care, your study doctor will be able to tell you whether you are taking the placebo or the study drug. A placebo is a medication with no active ingredients. It looks like the real thing but is not. In addition, you will also be randomised to receive Yellow fever (Stamaril) vaccine either at Day 30 or Day 90

If you are female of child bearing potential, you will need to undergo urine pregnancy test on the day of vaccination. You will also need to commit to use adequate, reliable contraception or abstain from sexual intercourse for at least 10 days after vaccination

You will be educated to refrain from self-administration of other prescription-only or other over-the-counter anti-inflammatory drugs. At any time after vaccination, you will be trained to observe for symptoms, reactions or side-effects. A diary will be given to you to record such events, should the occur during the period. Should you develop symptoms that require intervention, you should inform your study doctor or coordinator for medical evaluation and receive the appropriate therapy if necessary.

Medical history:

We will collect information (data) from you and/or from your medical records if any. This is to ensure potential participant is indeed a healthy volunteer that fit the recruitment inclusion/ exclusion criteria. The information will include your demographics (age, gender, race), past medical history, diagnosis, treatments, and medications.

Biological materials:
We will take blood from your arm using a syringe and needle, at each visit as scheduled in the table below. Blood sample collected at screening is to check on your blood count, blood sugar level and if you have prior dengue infection. While blood samples collected from all other visits will be used to test the effect of the vaccine on the natural defenses of your body. All tests will be done in Singapore and for research purpose. It will not be used in research involving human-animal combinations, which is restricted by Singapore law.

The Institutional Review Board waiver under Section 37(3) of the Human Biomedical Research Act 2015 (“HBRA”) for the removal of human biological materials is not required. This is because we will collect samples from adults with mental capacity to personally give consent for this research study.

Study Schedule:
Your participation in the study will last for 2 or 4 months depend on which group you will be in. You will need to visit the doctor's office 14 to 17 times in the course of the study.

If you agree to participate in this study, you should follow the advice and directions given to you by the study team.

For participants who are randomised to receive Yellow fever (Stamaril) vaccine at **1 month**

Visit	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**	**Visit 10**	**Visit 11**	**Visit 12**	**Visit 13**	**Visit 14**
Study Calendar	**Screening**	**D 0**	**D 1**	**D 7**	**D 14**	**D 30**	**D 32**	**D 33**	**D 34**	**D 35**	**D 36**	**D 37**	**D 44**	**D 60**
Informed consent	X													
Eligibility check	X													
Medical history	X													
Physical examination	X													
Vital signs measure	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urine Pregnancy Test	X	X				X								
Blood sampling (Estimated volume in teaspoon)	6.5ml (1.5)	26ml (5)	26ml (5)	26ml (5)	26ml (5)	29.5 ml (6)	3ml (1)	3ml (1)	26ml (5)	3ml (1)	3ml (1)	26ml (5)	26ml (5)	29.5ml (6)
Randomisation		X												
AS01 Adjuvant or placebo		X												
Yellow Fever (Stamaril) vaccine						X								
Adverse event record		X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medication check		X	X	X	X	X	X	X	X	X	X	X	X	X

For participants who are randomised to receive Yellow fever (Stamaril) vaccine at **3 month**

Visit	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**	**Visit 9**	**Visit 10**	**Visit 11**	**Visit 12**	**Visit 13**	**Visit 14**	**Visit 15**	**Visit 16**	**Visit 17**
Study Calendar	**Screening**	**D 0**	**D 1**	**D 7**	**D 14**	**D 21**	**D 30**	**D 60**	**D 90**	**D 92**	**D 93**	**D 94**	**D 95**	**D 96**	**D 97**	**D 104**	**D 120**
Informed consent	X																
Eligibility check	X																
Medical history	X																
Physical examination	X																
Vital signs measure	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Urine Pregnancy Test	X	X							X								
Blood sampling (Estimated volume in teaspoon)	6.5ml (1.5)	26ml (5)	26ml (5)	26ml (5)	26ml (5)	26ml (5)	26ml (5)	26ml (5)	29.5 ml (6)	3ml (1)	3ml (1)	26ml (5)	3ml (1)	3ml (1)	26ml (5)	26ml (5)	29.5ml (6)
Randomisation		X															
AS01 Adjuvant or placebo		X															
Yellow Fever (Stamaril) vaccine									X								
Adverse event record		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medication check		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

The study is being conducted because AS01 by itself is not yet proven to be a standard immune-boosting treatment in older adults with age-related immune decline. We hope that your participation will help us to determine whether AS01 alone can effectively strengthen the immune system and provide broader protection against infections compared to having no treatment.

The study will involve the use of a placebo (inactive agent), single blinding (one party is unaware of the intervention assignment), and randomization (study drug selection by chance), which are usually only done for research studies.

In this study, the use of AS01 adjuvant alone and procedures are being performed for the purposes of the research and are not part of your medical care.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

AS01 Adjuvant or placebo:
Common side effects you might experience are pain, redness, and/or swelling at the injection site. You might also experience general body reactions such as muscle aches, feeling tired, headache, chills/ shivering, fever, stomach discomfort, nausea, and/or vomiting. These reactions usually appear within the first few days and are typically mild to moderate. They generally go away on their own within a few days. These are signs that your body is building protection. Not everyone experiences these side effects, and some people may experience side effects not mentioned here.

Yellow Fever (Stamaril) vaccine:
Common side effects are headaches, muscle aches, mild fever. These usually last 5-10 days. At the injection site, you might experience swelling, pain, and/or a small lump.

As with any vaccination, there is a possibility of an allergic reaction, such as a rash, swelling of the lips or face, difficulty breathing, or a sudden drop in blood pressure (making you feel dizzy or light-headed). Anyone with a known hypersensitivity to eggs or egg products should not participate in this study. If such a reaction occurs, it is usually almost immediately after vaccination. Therefore, we require that you remain at site for 30 minutes so that we can provide immediate medical attention if needed. This can occur rarely in about 2 cases per 100,000 vaccinations.

The most serious adverse reactions that may happen after vaccination with a yellow fever vaccine are the occurrence of:

- A yellow fever-like disease affecting vital organs, reported to occur within the 10 days of vaccination, associating fever, headache, muscle pain, and sometimes low blood pressure, liver disorder with yellow colour of your skin or eyes, unusual bruising or bleeding, and loss of normal functioning of the kidneys and lungs. This only happens at a rate of 5 cases per one million vaccinations.
- A medical condition affecting the brain and nerves, reported to occur within a month of vaccination, associating high fever, headache, confusion, stiff neck, inflammation of

brain and nerve tissues resulting in seizures or loss of movement or feeling in part or all of the body. It was reported 1 case per 100,000 vaccinations.

These reactions occur very rarely and may have a fatal outcome (leading to death). The risk appears to be higher in those aged more than 60 years old (although cases have also been reported in younger people), as well as immunocompromised individuals regardless of age.

These serious side effects are extremely rare, but it's important you're aware of them. The study team will monitor you closely and explain what symptoms to watch for.

It is possible that the Yellow Fever vaccine may not work as well as usual in people who receive AS01. This means the protection from the vaccine may be reduced or may not work as intended. If you travel in the future to countries where Yellow Fever is common, you may need to be re-vaccinated. You will be advised if you need to be re-vaccinated based on your blood test result.

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.

Personal privacy and confidentiality:
This study uses information that may affect your privacy. To protect your confidentiality, only a unique code will be used to identify data and/or biological material that we collected from you.

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

POTENTIAL BENEFITS

If you participate in this study, you will receive the Yellow Fever vaccine which normally provides protection against Yellow Fever. However, since Yellow Fever does not occur in Singapore or Asia, you may not directly benefit from this vaccination unless you plan to travel to areas where the disease is common (Africa or South America).

Your participation may however contribute to important medical research that could help develop new ways to protect older adults from infections.

IMPORTANT INFORMATION FOR FEMALE PARTICIPANTS

The effect of AS01 adjuvant and Yellow fever vaccine 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 call your doctor or the Principal Investigator immediately.

ALTERNATIVE IF YOU DO NOT PARTICIPATE IN THE STUDY

There is no alternative to the study procedures. You can choose not to take part in this study. The study procedures will not be carried out.

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

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: blood tests, physical examination, AS01 adjuvant/ placebo administration, and yellow fever vaccination. These costs will be borne by Singapore General Hospital.

You will be reimbursed for transport, time, and inconvenience. You will receive $60 for each visit you have completed.

INCIDENTAL FINDINGS

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

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

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

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.

WITHDRAWAL FROM STUDY

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

If you withdraw from the study, or the study drug is stopped for any reason, you will no longer be required to return for scheduled visits for data and blood sample collection.

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

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

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

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

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the study drug/ 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.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. “Personal Data” means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential and stored in Singapore. Your study records and medical records (if applicable), to the extent required by the applicable laws and regulations, will not be made publicly available. To protect your identity, your Personal Data will be labelled with a unique code. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code to your Personal Data. This will be kept in a safe place with restricted access. In the event of any data sharing with third parties (e.g. funding agencies, research collaborators) whether locally or overseas and publication regarding this study, your identity will remain confidential.

Data deposition into scientific database:
We will deposit data collected in this study, including the data we collect about you to public and/or controlled-accessed scientific databases. It will not include your name or other data that directly identifies you. This will enable other researchers, whether locally or overseas, to use the data to investigate other important research questions.

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

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

All data and samples collected in this study are the property of SingHealth. The data and samples will be used for the purpose of this research study only, unless you give permission for your data and samples 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

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

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

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

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

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

CONSENT FORM FOR RESEARCH STUDY

Study Title:
Using AS01 adjuvant to improve immune response in older adults through trained immunity

Declaration by Research Participant

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

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

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

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

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

_____	_____	_____
Name of participant	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

INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

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

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

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

- We may use the data and biological materials to answer additional research questions in other research studies, which are outside the scope of the research study ("Future Research").
- We may also share the data and biological materials with other researchers within and/or outside of Singapore, for use in Future Research. The biological materials will not be used in research involving human-animal combinations, which is restricted by Singapore law.
- We may deposit the data into research data repository for long-term use by the wider research community, for use in Future Research. Researchers share information with each other by depositing data into research databases. These databases store information from many other research studies. Researchers can then study the combined information to learn even more about human health and diseases, to advance medical research.
    - We may deposit the data into one or more open-access (public scientific database) and/or controlled-access research databases. Anyone on the Internet can access publicly accessible database. Only researchers (including private companies involved in publicly-funded research) who apply and are granted approval can access controlled-access databases.
- You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.
- We may also use the data and biological materials for purposes other than research such as teaching, or training future researchers, development of health policy, quality control, validation testing.

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

- Any information that could identify you will be removed (de-identified) before this de-identified data and biological materials are used and/or shared with other researchers and/or deposited into research data repository.
- The open-access and controlled-access research data repositories have robust procedures in place to protect confidentiality of the stored data. Although these repositories do not have your identifying information, it may be possible to identify you based on information in the databases when combined with information from

other public sources (including information you tell people or post about yourself). We believe the chance of this happening is currently very low.

- If you decide at a later time that you do not want the data and biological materials to be used for Future Research, you can contact the Principal Investigator or study team at any time. All the stored data and biological materials that have not been used or shared with other researchers will be removed from the storage facility and/or destroyed, unless this information is already deposited into the research data repository or included in analyses or used in publications.

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

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

CONSENT FORM FOR FUTURE RESEARCH

This component is optional. You do not have to agree to it in order to participate in the research study.

Please indicate your choice using the relevant checkbox.

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

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

Disclosure of incidental findings arising from Future Research

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

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

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

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

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

To be completed by translator, if required

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

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

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

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

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

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

Investigator's Statement

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

Name of Investigator/ Person obtaining consent	Signature	Date