

PARTICIPANT INFORMATION SHEET

1. Study Information

Protocol Title: The Health for Life in Singapore (HELIOS) Study

IRB reference: IRB-2016-11-030

Principal Investigator & Contact Details:

Professor John Chambers, Professor of Cardiovascular Epidemiology, Nanyang Technological University (NTU), Lee Kong Chian School of Medicine (LKC Medicine)

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Study Sponsor: NTU, LKC Medicine

2. Purpose of the Research Study

We are inviting you to participate in the HELIOS research study. It is important that you first take time to read through and understand what this research study involves, including reading the information provided in this information sheet. In addition, we will explain the study to you in person and give you the chance to ask questions. After you are properly satisfied that you understand this study, and that you wish to take part in this study, you must complete and sign the informed consent form accompanying this information sheet. You will be given a copy of both the information sheet and consent form to take home with you.

The HELIOS study aims to find out how lifestyle, environment and genes influence the current and future health of people living in Singapore. The overall purpose of the study is to improve the prevention, diagnosis, and treatment of a range of chronic and acute health conditions, including heart disease, diabetes, cancer, dementia, vision disorders, mental disorders, respiratory disorders and joint problems. We will be collecting a broad range of measurements and biological samples, such as blood, urine and stool from participants, which will enable us to investigate why some individuals develop diseases while others do not.

We will recruit up to 70,000 men and women from the Singapore population. The eligibility criteria are:

Inclusion criteria:

- Singaporean citizen or permanent resident
- Age 21-84 years at the time of visit
- Able to read and write in English, Chinese, Malay or Tamil. You may bring someone to help you.

Exclusion criteria:

- Currently pregnant or breast-feeding. We will carry out a pregnancy test on women aged <55 years old; a positive pregnancy test will exclude participation.
- Current acute illness or recent major surgery (within the last 3 months)
- Age <21 years (including minors)
- Individuals with mental incapacities that prevent them from understanding giving informed consent.

3. What procedures will be followed in this study

If you take part in this study, you will be asked to:

- **Enrolment.** Attend a HELIOS screening centre for about 4 hours. During this visit we will ask you questions about yourself and your family, take some clinical measurements and collect biological samples from you, including blood, urine and stool. The tests carried out are listed in the table below.
- **Research.** Give your consent to use of the data and samples collected from you, for investigation and understanding of the lifestyle, environmental and genetic factors underlying a wide range of health conditions, including (but not limited to) heart disease, diabetes, cancer, dementia, vision disorders, mental disorders, respiratory and joint problems. We also seek your consent to use the data and samples to understand fundamental aspects of human biology.
- **Follow-up.** Consent to have your health and wellbeing followed for many years by the HELIOS study through linkage to disease registers, and to medical, health, social and economic and other records held on you that are relevant to health. This includes records held in electronic and other formats (e.g. paper copy), as well as results of screening or diagnostic tests carried out on you. Linkage relevant to health may

involve (but is not limited to) healthcare providers, organisations involved in health promotion, government agencies, statutory boards and ministries in Singapore (e.g, Ministry of Health, Ministry of Education, and Health Promotion Board).

- **Recontact.** Agree to be re-contacted by the HELIOS study team at some time in the future, so that we can invite you to complete additional health related questions and/or to attend further health assessments or participate in other research studies. This is important to give us a deeper understanding of health in the Singapore population over the longer term.

All women of child-bearing age will be tested for pregnancy using a urine sample. We do this because pregnancy is an exclusion criterion of the study.

Tests carried out in the HELIOS study		
1	Questionnaires	- Health and Lifestyle and Medications - Diet - Memory and Thinking - Skin health questions (optional) - Bowel and cognitive health questions (optional)
2	Clinical measurements	- Weight, height - Waist and hip circumference - Blood pressure - Hand grip strength - Lung function - Electrocardiogram (ECG, heart trace) - Stiffness of the arteries - Ultrasound scan of the arteries in the neck - Eye assessment - Treadmill walking test - Bone density and body composition scan (DXA) - Skin assessment - Hearing assessment (subject to availability) - Liver scan by ultrasound using a Fibroscan device - Physical activity monitoring (subject to availability, for 7 days) - Continuous Glucose Monitoring (CGM, optional and subject to availability)
3	Biological samples	- Blood (up to 70mls, which is roughly 5 tablespoons) - Urine - Skin tape (optional) - Stool and saliva (optional)

4. What research will be done using my information and samples?

- We will use the information and samples collected from you to investigate the lifestyle, environmental and genetic factors underlying health conditions, and to understand fundamental aspects of human biology. Our research will include determining patterns of genetic variation, profiling of gene regulation and gene transcription, and measurement of protein and metabolite levels, and microbial composition of samples.
- Some of the research and testing on your sample(s) will be genetic in nature as this can be the most powerful way to discover the causes of disease/defects and to treat and deal with these by developing new drugs and treatments. For example, we may try to find variants in genes that protect against or increase the risk of heart attack and stroke. This may include “sequencing” the DNA samples to read all the genetic information in it.
- Our aim is always to work towards the benefit of patients and communities. In doing so, it may be beneficial for us to allow researchers from outside the HELIOS study team to analyse the data independently from us. This may include researchers from universities, hospitals, pharmaceutical, bio-technology and other commercial companies, and may include researchers from organisations in other countries. These researchers may have expertise, technology, and resources unavailable in the HELIOS study team, and which could be helpful in driving research forward to everyone’s benefit. Sharing data and samples collected by the HELIOS study with these external partners aims to enable the best research and maximise

benefit to the community. Any sharing will pay careful attention to your privacy as a participant in the research, as described in section 17 below.

- The data and samples collected during this study may also be used for purposes other than research such as teaching or training future researchers, or development of health policy.

5. Your responsibilities in this study

- We will ask you to visit the HELIOS screening centre to undergo the procedures that are outlined above. We always aim to complete all the tests in a single visit. On some occasions, we may not be able to complete all procedures described (for example, if the machine is undergoing maintenance). If this happens, we may ask you to come for a second visit to complete the procedures. However this will be voluntary, and you would receive an additional token of appreciation. Alternatively, the procedure may be omitted.
- Results from the blood tests will be more accurate if you come fasted. If your appointment is in the morning (before midday), we would like you to come after an overnight fast (water only after midnight). If your appointment is in the afternoon, we would like you to have a light early breakfast (e.g. 6am) on the day of the appointment and to fast (water only) until you are seen. Refreshments will be provided after blood draw.
- We also ask that you bring a list or a photograph of all your medications with you (over-the-counter and medical prescriptions), including oral contraceptives and hormone replacement therapy, and vitamins or supplements. If you are unwell (for example, flu, cough, sore throat etc.) on the day of your appointed visit, please call us to postpone your visit to the study.
- For the physical activity monitoring, we will give you the wearable device and an envelope (self-addressed and stamped) to take home. You will need to wear and return the device by mail according to the instructions provided.
- For the optional skin evaluation, this will include some short additional questionnaires, and collection of non-invasive, painless skin measurements and skin surface samples using a sticky tape.
- For the optional stool and saliva evaluation, this will involve short additional questionnaires, as well as collection of stool and saliva samples. If you are unable to provide the stool sample during the visit day, we will give you a stool collection kit and an envelope (self-addressed and stamped) to take home. You will need to collect, store, and return the stool samples by mail according to the instructions provided.
- For the optional Continuous Glucose Monitoring, you will be fitted with a clinically approved monitoring device (Dexcom) on your forearm. This can be used for 10 days continuously. It has a small, short needle to keep the device secure in the skin of your forearm. The insertion will be performed by the study team. You may experience mild pain and discomfort when the device is inserted but you should not feel any pain or discomfort after that. This device is waterproof, and you do not need to worry about the device affecting your daily activities. You will also be provided with a small, portable Receiver box that collects and records information from the CGM device. We will provide and teach you how to use the CGM device and Receiver box, including how and when to remove the CGM device.

6. What is not standard care or is experimental in this study

There are no treatments or experimental treatments involved in this research. We are carrying out a range of physical and biological measurements to better understand their importance in predicting or diagnosing health and disease. All of the procedures carried out are well established. The clinical significance of the measurements being taken is the focus for the research.

7. The HELIOS research health report and other Incidental Clinical Findings

- **Health concerns.** The HELIOS assessments are being done for research purposes, and are not a clinical evaluation. If you have health concerns, you should seek guidance from your usual doctor.
- **HELIOS research health report.** After you have completed your enrolment visit study, we would like to send you a structured report comprising clinically relevant results from your health assessments that have been reviewed by the research clinicians on the team. This report will include the following results (where they have been measured):

- Height, weight, body mass index (BMI)
- Blood pressure
- Electrocardiogram (ECG)
- Blood test results: full blood count, lipid panel, blood glucose, kidney function
- Bone density (DXA scan)

- **Incidental Clinical Findings.** In addition to the routine health report above, if the research team do identify an abnormality which they believe might be of clinical significance during the course of your HELIOS assessment, we would feed back the results to you. An example of this would be a severe narrowing in the artery to the neck, or an abnormality at the back of the eye. Please note that we cannot guarantee that we will identify all abnormalities from the HELIOS tests, as this is a research study, not a clinical service.
- **Your choice about your results.** There is a chance that your research health report shows an abnormality, or we find other incidental clinical findings. Such detection has the benefit of starting treatment early which may improve future health outcomes, especially for conditions about which you were unaware. However it may also have implications for your future healthcare, employment and insurance. Receiving the **health report and other incidental clinical findings** is therefore optional, and you may choose whether you want to receive them, when you sign the consent form at the end of this document. However, if the research team do identify an abnormality during the course of your HELIOS assessment, which they believe might be potentially life-threatening, we will still feed back the results to you.
- **What about research results?** The results of most research tests within the HELIOS assessment are not suitable for clinical decision making. Feeding back these research findings could lead to inappropriate anxiety or other indirect harm. Therefore, apart from the situations described above, we will NOT be reporting back the results of any additional tests done on your samples. Specifically, we will NOT be reporting back the results of genetic evaluation, or results generated by analysis of your data or samples in the future, except in setting of possible recontact for future research studies.

8. Possible risks and side effects

- Joining the HELIOS study will involve donating a small sample of your blood. Qualified, experienced nurses or phlebotomists will collect the samples; however, blood sampling can cause some discomfort when the needle is placed in the vein and the blood is drawn. There is also a possibility that a small bruise may develop at the site of blood collection.
- There is a small chance of tripping and falling down when you are performing the **treadmill test**. The risk of this happening is minimised by keeping the test to a walking pace and there will also be an assistant to guide you throughout the procedure. You are also free to stop the test at any point if you feel that you are unable to continue with the procedure.
- The test to measure **bone density** and amount of body fat in the body involves exposure to a very low dose of X-rays. This test is done routinely in hospitals and research institutions and carries minimal risk (it is equivalent to 3 hours of daily X-ray exposure from your normal surroundings).
- Some people (fewer than 1/100) develop itchy skin from wearing the physical activity monitor for a week. This is an allergy, and the itch will be on the skin around where you are wearing the monitor. If you start to get itchy skin, just take off the monitor and let us know. The itch should quickly resolve by itself (1-2 days).
- Continuous Glucose Monitoring (optional). The insertion of the device in the skin may cause slight pain and bleeding. The adhesive tape used to secure the device to the skin, can sometimes cause skin irritation. Contamination of the device may occasionally lead to superficial skin infections. Our study clinicians will be on hand to offer initial advice and assistance if this is needed.

9. Possible benefits from participating in the study

- You will benefit from getting a research health screening through your involvement in this study. The tests undertaken during the screening may reveal potential current and future health risks that you may not be aware of, for example diabetes, high blood cholesterol level, high blood pressure, and heart problems. Such detection has the benefit of starting treatment early, which will help you to avoid future complications.

- The most important health benefits from the HELIOS study will be realised many years from now, and will largely help future generations. The HELIOS study is intended to benefit the general population as a whole in the years to come. It will improve our understanding of the lifestyle, environmental and genetic factors that affect health. It will also provide a resource for future research that will contribute to public health improvement. Results from this study may also contribute to more effective strategies for predicting and preventing future disease.

10. Important information for women

If you are pregnant and/or breastfeeding, we ask that you delay taking part in the study until after the pregnancy and/or breastfeeding is complete. This is because the effects of some measurements in the HELIOS study on a baby's development, such as the DXA scan, are not known. An on-the-spot pregnancy test will be provided at no cost to all women less than 55yrs old, and the results must be negative at study entry.

11. Alternatives to participation

Not applicable.

12. Use of human tissue in restricted biomedical research involving human-animal combination

We confirm that the human biological material collected will not be used in restricted human biomedical research involving human-animal combinations.

13. Costs & payments if participating in the study

If you take part in this study, all the procedures listed in Section 3 (above) will be performed at no charge to you. You will receive \$75.00 on completion of the HELIOS study as a token of appreciation, if this is done on one day. If we need to break the assessment over more than one day, we will give you an additional S\$50 for each day that you attend. Participants who complete the optional assessments will receive an additional \$50 token of appreciation for each of the three optional components signed up to (i. skin evaluation, ii. stool and saliva evaluation, and iii. Continuous Glucose Monitoring).

14. Voluntary participation and withdrawal

- Your participation in this study is voluntary. We will describe the study and go through this information sheet, a copy of which will be yours to keep. If you agree to take part, we will ask you to sign the consent form at the end of this information sheet.
- You are free to withdraw from the study at any time, and without giving a reason. You can initiate the process of withdrawal by calling **+65 6904 7077** or by writing an email to helios@ntu.edu.sg. You will then be sent a withdrawal form to complete and sign. This will be overseen by the HELIOS study research team and you will receive a letter to confirm your withdrawal. Your decision not to take part in this study or to stop your participation will not affect your medical care or any benefits to which you are entitled.
- In the event that you withdraw from the study, we will not include your data or samples in any future research or analyses. Please note that it will not be possible to remove your data from research work that has already been done before your withdrawal. You may also ask the Principal Investigator to discard or destroy any remaining samples that have been collected from you. However, this can only be done for samples that have not been anonymized and that can still be traced to you.
- Your doctor, the Investigator and/or the Sponsor of this study may stop your participation in the study at any time if they decide that it is in your best interests. They may also do this if you do not follow instructions required to complete the study adequately. If you have other medical problems or side effects, the doctor and/or nurse will decide if you may continue in the research study.

15. Compensation for injury

- In the unlikely event that something untoward happens during the course of the study, you can contact us for advice by phone (**+65 6904 7077**) or by email (HELIOS@ntu.edu.sg).
- LKCMedicine, without legal commitment, will compensate you for the injuries arising from your participation in the study without you having to prove that LKCMedicine is at fault. There are, however,

conditions and limitations to the extent of compensation provided. You may wish to discuss this with your Principal Investigator.

- By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence.

16. Storage and ownership of data and samples

- The data and biological specimens collected from you during the course of this study will be stored long term (at least 20 years). Your data will be held in secure databases. Biological samples will be stored in a secure facility, which meets relevant international security and safety standards. They will only be accessible to authorised researchers and regulatory authorities.
- The data and samples collected will be deemed to be gifted to the HELIOS study. Lee Kong Chian School of Medicine, Nanyang Technological University will act as the custodian of the data and samples.
- The role of an individual sample/set of information in any commercial project is likely to be minimal and impossible to quantify. Therefore, it is not possible to trace back any benefit to individual donors and you should regard participation in the project as being for the benefit of the community at large. No financial benefits from exploiting the results of the study will come back to you.

17. Confidentiality and sharing of data and samples

In this consent form, we are asking your permission to store your name, date of birth, NRIC, address, phone number and other contact details long term, so that we can monitor your health and study other factors that affect health in the long term by linking to relevant records. We may also recontact you in the future to participate in other studies or inform you of clinically relevant incidental findings if appropriate.

We take confidentiality very seriously and will take all reasonable measures to ensure that the information collected from and about you is kept confidential. Your personal identifiable individual records, to the extent of the applicable laws and regulations, will not be made publicly available. In order to keep your information confidential, numerous safeguards are in place. In particular, we will:

- Keep your personal identifiers (name, date of birth, NRIC, address, phone number and other contact details) separate from your research data and samples.
- Remove your personal identifiers from the research data and samples, and replace your identity with a unique anonymous 'code number'.
- Ensure that your personal identifiers, and the 'code number' that links you to the research data and samples, can only be accessed by a small number of personnel, directly authorised by the Principal Investigators.
- Use stringent security measures to protect all the data collected, and to prevent unauthorized use, including: strict access controls, computer security and data encryption techniques, confidentiality agreements and staff training.

Use of the research data and samples will be regulated by the HELIOS Study "Scientific and Data Access Committee". This Committee includes senior management, clinicians and researchers from the LKCMedicine and National Healthcare Group. Permission to use the data will be evaluated based on written applications, according to scientific merit. Applications must be for specific research purposes, within the remit of the HELIOS research program approved by the IRB, and will provide time-limited access to the data needed to complete the research.

When data are shared with researchers, service providers, regulators or third parties, this will typically be done in one of the following ways:

- **Anonymised.** Here, not only will we remove your personal identifiers, but we will also remove the code number that links the research data/samples to your identity. As a result it should not be possible to use traditional approaches to identify you from the data shared. This will be the typical approach that we will use to carry out research on completed datasets, or for publishing results of the study.

- **Coded.** Here a unique code number is shared that identifies the data and samples collected from you (but not your personal identity). This is typically done when the research will lead to generation of new information that we need to link back to existing data (for example running laboratory tests on the stored samples). This is also sometimes called “De-identification”.
- **Identifiable.** Here we will share one or more of your personal identifiers (such as NRIC) with another researcher or organisation. This will be only done in a small number of specific circumstances, typically when we want to identify your health outcomes from hospital and national datasets. No alternate mechanism currently exists to make this link possible. In this situation we will use the highest degree of security possible to transfer the identifiable information (e.g. high-level data encryption). Transfers of identifiable information will only be done where necessary for the research, and with the guidance and supervision of information governance experts.

We plan to publish the results of the research based on the HELIOS Study in medical journals. You will not be identified in any publication. The results of the research may also be shared through open access (public) scientific databases, including internet databases (www.internationalgenome.org is an example of such an approach). This will enable other researchers to use the data to investigate other important research questions. In publications and open databases, the results will be fully anonymised by removing all traditional identifying information (e.g. name, address, date of birth), as well as any code number linking your identity to the data.

The relevant Institutional Review Board and Ministry of Health may also access your original medical records and research data for audit, research and/or regulatory purpose (for example, to check study procedures have been followed correctly), without making any of your information public.

By signing the Informed Consent Form attached, you (*or your legally acceptable representative, if relevant*) are authorizing (i) collection, access to, use and storage of your “Personal Data”, and (ii) disclosure to authorised service providers and relevant third parties.

18. Consent for ‘Future Research’

- Because medical healthcare, health related databases and records, technology and analysis tools develop all the time, it isn’t possible to give you an exact list of everything that might be done with your samples or information over the years ahead (‘in the future’).
- If the proposed ‘future research’ goes beyond what is described in this consent form, we shall seek approval from the ethics committee, who may approve the research if they agree it is ethical, scientifically justifiable and in the public interest.
- We will not usually contact you directly about individual ‘future research’ studies done using your stored data and samples, as this would be impractical given the number of people participating in the research.

19. Consent to be recontacted

- We would also like permission to recontact you in case we need to obtain new consent (“**reconsent**”) for a specific component of the research. We will contact you for reconsent if the IRB recommends this.
- We would also like to invite you to take part in further research studies, including research directly relevant to the HELIOS study. We may provide you with letters of invitation to additional studies on the day that you attend, or as part of your research health report, or at some point in the future.
- You will be free to decide whether or not to “reconsent” or to accept any invitation to take part in further research. Your decision will not affect your medical care or any benefits to which you are entitled.

20. Who To Contact if You Have Questions

If you have questions about this research study, you may contact the Principal Investigator, Professor John Chambers, or the HELIOS study team at

Email: HELIOS@ntu.edu.sg

Phone: +65 6904 7077 (Monday-Friday 8am to 5pm)

Address: Professor John Chambers, HELIOS Study, Level 18, Clinical Sciences Building, Lee Kong Chian School of Medicine, 11 Mandalay Road, Singapore 308232.

The study has been reviewed by the NTU Institutional Review Board for ethics approval. If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research participant, you may contact the NTU Institutional Review Board:

Email: irb@ntu.edu.sg

Tel: +65 6592 2495

Address: NTU-Institutional Review Board, Research Integrity and Ethics Office, Blk N1.2, B1-02A, 62 Nanyang Drive, Singapore 637459

Thank you very much for taking the time to read this information

INFORMED CONSENT FORM

Protocol Title: The Health for Life in Singapore (HELIOS) Study

Components that are **REQUIRED** for participation in the HELIOS study

I agree

1. I confirm that I have read and understood the informed sheet **version 7.0**, dated 29/05/2025 for the Health for Life in Singapore (HELIOS) study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the study, and these questions have been answered to my satisfaction. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, with no obligations and penalty, and without my medical care or legal rights being affected. ☐
3. I know how to contact the research team if I need to. ☐
4. I agree to the research team taking the health-related and clinical and physical measurements described in information sheet **version 7.0**, dated 29/05/2025. ☐
5. I agree to the collection of blood and urine samples. ☐
6. I understand that I will be asked for stool, skin and saliva samples with short additional questionnaires, but these are optional. ☐
7. I understand that I will NOT necessarily receive feedback on any tests or analyses done on my samples or data that are carried out purely for research, including the results of any genetic studies. ☐
8. I confirm that any data and samples I give will be treated as a donation to Lee Kong Chian School of Medicine, Nanyang Technological University, and I will relinquish any commercial rights in the data and samples once donated. ☐
9. I understand that my personal details (including NRIC), data collected about me and any samples I provide will be stored long-term (20 or more years) for research. ☐
10. I agree that the samples I have donated and the information gathered about me can be stored and used for research studies aimed at identifying and understanding health, wellbeing, and the causes, natural history, prevention, prediction, diagnosis, and treatment of diseases. ☐
11. I agree to genetic studies being conducted on my samples, including determining the entire genetic code. I understand that I will not be contacted directly for further permission for these genetic studies. ☐
12. I agree to laboratory analyses being conducted on my samples for research purposes that may cover a range of biological measures and processes, including gene regulation, protein and metabolite levels, and microbial composition. I understand that I will not be contacted directly for further permission. ☐
13. I agree that HELIOS study investigation may have access to records about me that are relevant to my health and wellbeing, and that are held by healthcare providers, health promotion organisations, statutory boards, government agencies and ministries in Singapore, even if I can no longer make decision for myself, or after my death. ☐
14. I agree that my data and samples may be made available to other research and healthcare groups in the public and private sector, as well as to commercial entities involved in biomedical research subject to prevalent regulations, in Singapore or other countries. I understand that anonymized research data and other results of the research may be shared through open-access (public) scientific database on the internet. ☐
15. I agree that no compensation will be given to me, nor will funds be forthcoming to me due to any invention(s) resulting from research and development and commercialisation using my data and samples. ☐
16. Having agreed to **all** of the points above, I agree to join the HELIOS study. ☐

Components that are OPTIONAL for participation in the HELIOS study
YES NO

17. **Health report.** I would like to receive the HELIOS research health report that summarized the clinically relevant health-related results from my baseline HELIOS screening assessment, as described in **Section 7**.

☐ YES ☐ NO

18. **Incidental clinical findings.** I would like to be informed of findings that may be of clinical significance that are identified by the research team, during the course of the HELIOS assessment, as described in **Section 7**.

☐ YES ☐ NO

* Please note that if an abnormality is identified which the research team think potentially life-threatening, they will still pass on this information.

19. **Saliva and Stool.** I agree to collection of saliva and stool samples, and to being asked additional bowel related questions

☐ YES ☐ NO

20. **Skin research.** I agree to collection of skin samples (by skin tape) and to being asked additional skin related questionnaires

☐ YES ☐ NO

21. **Glucose monitoring.** I agree wearing a Continuous Glucose Monitor for 10 days and to return the device once the 10-day monitoring is complete.

☐ YES ☐ NO

22. **Future research using my data and samples.** I agree to my data and samples being used for future research for public benefit that is approved by the IRB. I understand I will not be contacted again personally.

☐ YES ☐ NO

23. **Recontact.** I agree that I may be re-contacted in the future to be invited to participate in research, or for reconsent. However, I understand that I will be free to decide whether or not to take part in this additional research or to give this reconsent. My decision will not affect my medical care or any benefits to which I am entitled.

☐ YES ☐ NO

I agree to be contacted by

☐ Phone ☐ Email ☐ Mail ☐ Others _____

Name of Participant

Signature

Date

Translator Information

The study has been explained to the participant / legally acceptable representative in _____ <insert language> by _____ <insert name of translator>

Witness Statement

I, the undersigned, certify that: **i.** I am 21 years of age or older; **ii.** To the best of my knowledge, the participant/ the participant's legally acceptable representative signing this informed consent form has the study fully explained in a language understood by him/ her and clearly understands the nature, risks, and benefits of his/ her participation in the study; **iii.** I have taken reasonable steps to ascertain the identity of the participant/ the participant's legally acceptable representative giving the consent; and **iv.** I have taken steps to ascertain that consent has been given voluntarily without any coercion or intimidation.

Name of Witness

Signature

Date

Participant ID

**Attach sticky
label**

Investigator Statement

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

Name of Investigator /
Person administering consent

Signature

Date