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 will be explained to you, and you must be given the chance to ask any questions that you may have. 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.

STUDY INFORMATION

Protocol Title:
Eradicating minimal residual disease using “off the shelf” Natural Killer (NK) cells for advanced nasopharyngeal cancer

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:
A/Prof Lim Chwee Ming
Otorhinolaryngology- Surgery of head and neck
Tel: +65 9824 7996 (mobile)
Institution Mainline: +65 6222 3322

PURPOSE OF THE RESEARCH STUDY

This is a research study. The purpose of this study is to determine how effective NK cell therapy (Study Drug) combined with Chemotherapy and Radiotherapy can help in reducing Nasopharyngeal cancer (NPC) recurrence and determine the highest amount of allogeneic NK cells that is safe and tolerable. The meaning of allogenic means that the NK cells is extracted from another healthy person. Allogenic NK cell therapy has shown to be well-tolerated among cancer patients in the past. However, this method has not been investigated in NPC before.

This is a first-in-man study in Singapore. This means that this is the first time allogenic NK cell therapy is tested in NPC patients in Singapore.

You were selected as a possible participant in this study because you are diagnosed with Nasopharyngeal cancer.

This study targets to recruit a total of 31 participants from Singapore General Hospital, Sengkang General Hospital, Changi General Hospital and National Cancer Centre (NCC) Singapore.

This is a Phase 1 leading to Phase 2 clinical trial. The aim in Phase 1, is to determine the maximum tolerated dose (MTD) of allogenic NK cells that is safe and tolerable in NPC patients. MTD refers to the highest dose that can be administered with minimal side effects. After we have established the MTD, this dose will be used in the Phase 2 portion of the study. If you decide to join the study, the study team will inform you which phase you will be in.

This informed consent form is for Phase 1 of the study only where the MTD has not been established.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

The study involves the following:

Study drug:
Natural Killer (NK) cells are cells that can be found in our immune system which can spot and destroy cancer cells. In this study, the source for NK cells is extracted from the blood of healthy donors. The donated blood will be screened for any potential infectious disease. The samples of blood are tested to ensure that it is safe to be used. The

If you decide to participate, you will be given NK cells infusion for 6 times over the course 12 weeks. Additional 4 doses may be given if your blood test after completion of 6 doses showed persistent minimal residual disease. The expected duration of NK cell infusion each time is approximately 30-60 mins over a slow infusion.

Dosage of NK cells:
Although the dosage between each participant might be different, the 6 infusions that you will receive will be of the same dosage. Even if you tolerate the drug well, the dosage will still be remained the same.

Note: The first 3 patients admitted for the administration of the first dose of NK cells will be monitored overnight. If there are no acute reactions to NK cell infusion for the first 3 patients, subsequent doses to the 3 patients can be treated as outpatient with a monitoring of 4-6 hours following infusion.

Patients who have persistently detectable circulating virus cells after the 6 doses of NK cell infusions will have the option of receiving an additional 4 weekly cycles of NK cells infusion. An additional blood (20ml) and tissue samples will be collected after the additional NK cells infusion. 20ml of blood is about 4 teaspoons.

This study does not require any randomization or blinding.

Medical history:
We will collect information (data) from your medical records. The information will include tobacco consumption and history of treatment for the primary diagnosis, including prior medication and treatment plan.

Biological materials:
The following samples ("biological materials") will be obtained: NPC tumour tissue biopsies and blood. NPC biopsy will be collected at screening period before the trial start and at week 11. Blood (20ml) will be collected 5 different times, at screening period, week 4, week 7, week 9 and week 11. The removal of tissue during screening period will be in excess of samples primarily removed for diagnostic purposes under your standard of care. The removal and collection of tissues at week 11 will be solely for research purpose. An additional blood (20ml) and tissue sample will be collected if additional NK cell infusion is given after the first 6 doses.

We will take blood ("biological materials") from your arm using a syringe and needle during screening period, week 4, week 7, week 9 and week 11. Each time, we will take up to 20ml of blood (About 4 teaspoons). A portion of the blood will be used to check for the virus. The remaining blood will be frozen so that it can be analyzed later on, allowing for further testing or examination. The biological materials collected will not be used in restricted human biomedical research involving human-animal combination.

Your participation in the study will last up to 17 weeks. You will need to visit the doctor up to 9 times in the course of the study. This is not including the standard of care Chemotherapy and/or Radiotherapy throughout the course of the study.

Study Schedule:

Assessment Period	Assessment Procedures	Notes
Screening period	1. Draw Blood (20ml) 2. Tumor Tissue Biopsy 3. EBV assay	
Week 1	1. Radiation Therapy Administration (1 dose daily, 5 doses/week)	
Week 2	1. Radiation Therapy Administration (1 dose daily, 5 doses/week)	
Week 3	1. Radiation Therapy Administration (1 dose daily, 5 doses/week) 2. NK cells infusion	
Week 4	1. Draw Blood (20ml) 2. EBV assay 3. Radiation Therapy Administration (1 dose daily, 5 doses/week)	*Draw blood before Chemo-drug administration *Blood drawing and Chemo-drug administration doesn't have to be on the same day
Week 5	1. Radiation Therapy Administration (1 dose daily, 5 doses/week)	
Week 6	1. Radiation Therapy Administration (1 dose daily, 5 doses/week) 2. NK cells infusion	
Week 7	1. Draw Blood (20ml) 2. EBV assay 3. NK cells infusion	*Draw blood before NK cells infusion *Blood drawing and NK cells infusion doesn't have to be on the same day
Week 8	1. NK cells infusion	
Week 9	1. Draw Blood (20ml) 2. EBV assay 3. NK cells infusion	*Draw blood before NK cells infusion *Blood drawing and NK cells infusion doesn't have to be on the same day

Week 10	1. NK cells infusion	
Week 11	1. Draw Blood (20ml) 2. Tumor Tissue Biopsy 3. EBV assay	
Week 12 (Optional)	1. NK cells infusion	
Week 13 (Optional)	1. NK cells infusion	
Week 14 (Optional)	1. NK cells infusion	
Week 15 (Optional)	1. NK cells infusion	
Week 16 (Optional)	1. Draw Blood (20ml) 2. Tumor Tissue Biopsy 3. EBV assay	

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

The study is being conducted because administration of NK cells is not yet proven to be a standard treatment in patients with nasopharyngeal cancer. We hope that your participation will help us to determine whether this treatment is equal or superior to existing treatments.

In this study, the collection of blood and tissue biopsies for research and NK cells infusion are being performed for the purposes of the research and are not part of your routine care.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

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. *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.*

Side effects of NK cells infusion:
Allogeneic NK cells are generally safe to administer with minimal toxicities reported. The study is designed where the dosage of NK cells infused will be slowly increased to reach the Maximum Tolerated Dose (MTD).

Some of the short-term side effects includes fever, chills, headache, or mild low blood pressure during infusion.. The risk percentage of having these side effects is less than 5%.

Some of the major potential side effects of NK cell therapy (less than 5%) in the long run includes:

1. Graft versus host disease (GVHD) - where new cells don't recognize your body and start fighting it. This may cause side effects like rashes and upset stomach. Although small, there is still a possibility that these NK cells causing too many harmful side effects. In this case, we may switch to using NK cells from your family members (called haplo-identified NK cells) or even your own NK cells (autologous NK cells) to continue the treatment.

2. Auto-immune disease – where your immune system starts attacking your own cells. (patients with active auto-immune disease are excluded from this study)
3. Excessive/chronic pro-inflammatory response – This is where your body send wrong signals to fight off virus which are not there leading to ongoing inflammation that can harm your body instead of protecting them.

Induce Miscarriage – Loss of baby if pregnant (hence pregnancy is an exclusion criterion for the trial)

Note: The expected risk percentage for these side effects is less than 5%.

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 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

There is no assurance you will benefit from this study. However, your participation may add to the medical knowledge about the use of this NK cells infusion as treatment for Nasopharyngeal cancer.

IMPORTANT INFORMATION FOR FEMALE PARTICIPANTS

The effect of NK cells 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 NK cells infusion and 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

A $30 travel allowance will be reimbursed to you for each trip to SGH for study procedures that are not part of your regular routine treatment visit. The listed cost will also be borne by the study:

- The NK cell and related treatment/manufacturing cost.
- The administration cost for collection of blood and tissue biopsies for research

- Inpatient stay for monitoring (if required)

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

INCIDENTAL FINDINGS

During the course of the study, incidental findings are unlikely but there is a possibility that we might unintentionally come to know of new information about your health condition from tests that 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. 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.

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 your medical care being affected. If you decide to stop taking part in this study, you should tell the Principal Investigator.

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 unless you give consent at the time of withdrawal for your archival tissue samples to be used for correlative analyses with those who have completed the trial.

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:

- Documented disease progression
- Death (Due to the nature of the disease)
- Development of an unacceptable toxicity
- Non-compliance with protocol medications/administrations and/or required follow-up as judged by the PI
- Unable to receive the study infusion due to development of a significant health disorder
- Pregnancy

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 or study 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.

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 collected in this study are the property of SingHealth. The data will be used for the purpose of this research study only, unless you give permission for your data to be made available for future use in other research studies. For this purpose, consent for future research will be sought from you.*

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

WHO HAS REVIEWED THE STUDY

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

Protocol Title:
Eradicating minimal residual disease using “off the shelf” Natural Killer (NK) cells for advanced nasopharyngeal cancer

Declaration by Research Participant

(i) 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.

(ii) 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.

(iii) 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.

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

Consent to be Re-identified and Notified in the case of an Incidental Finding
There may be potential incidental findings arising from this research. Please indicate whether you consent to re-identification and notification about the incidental finding:

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

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

- In exceptional situations such as discovery of life-threatening incidental findings with available treatment options, I will be contacted to confirm my decision whether to learn more about the incidental findings.
- In rare situations where the incidental findings have public health implications and as required by the law (e.g. under the Infectious Diseases Act), I will be contacted and informed of the incidental findings.

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

To be completed by 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 (biopsy tissue and blood) 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.
    - Where required, researchers may request that the research data be combined or linked with data from other sources, including but not limited to healthcare billing information, government administrative and/or research data such as health, and health-related data, social data, education data, birth and death data, economic and housing data, data from disease registries and databases, whether by itself of with the assistance of a data intermediary. This will enrich their data analysis and provide valuable information for policy and research into health and wellbeing of the population (public interest). The data intermediary will use strict privacy preserving policies, protocols and procedures to ensure security of the data and confidentiality of the individuals the records relate to.
- You should not expect to get personal test results from Future Research. However, it may be possible that incidental findings will be detected in the course of conducting Future Research. If this happens, we may contact you to find out if you would like to learn more. Only medically actionable incidental findings (where medical treatment is available) will be disclosed. You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.

- We may also use the data and biological materials for purposes other than research such as teaching, or training future researchers, development of health policy, quality control, validation testing.

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.

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