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 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:
Surgical and Patient Reported Outcomes in Robotic Mastectomy – A Pilot Study

Principal Investigator:
Dr Mok Chi Wei
Consultant
Department of Surgery
Changi General Hospital
Contact No:

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to whether robotic mastectomy is a safe surgical alternative in comparison to conventional mastectomy. Robotic mastectomy is performed in a few countries/centres worldwide (Taiwan, South Korea, Japan, China, France, Italy), there are no cases performed in Singapore. Dr Mok Chi Wei, Principal Investigator is the first and only trained surgeon in Singapore/South East Asia to perform robotic mastectomy. He was trained in Taiwan in year 2019. We hope to learn whether robotic mastectomy offer better aesthetic outcome, faster recovery time and improve patient's satisfaction.

You were selected as a possible participant in this study because you have been known to have a tumour and will be undergoing mastectomy with or without axillary dissection, implant reconstruction, flap construction as per discussion with your attending surgeon.

This study targets to recruit 20 participants from Changi General Hospital.

What is a Conventional Mastectomy?

A mastectomy is surgery to remove the whole breast.

It is usually performed when you are under general anaesthesia (GA) so that you are made unconscious and should not feel pain during surgery. A cut (incision) is made in the skin and the entire breast is surgically removed. In certain situations, small metal clips may be placed in the area where the cancer had been, to mark the site should you require radiation therapy to the chest wall after surgery.

What is a Robotic Mastectomy?

A robotic mastectomy is a surgical procedure to remove the breast through a small incision with a robotic camera and small instruments attached to a robotic arm that is controlled by the surgeon at a computer console. Similar to conventional mastectomy, you will also be under GA. In robotic mastectomy, a smaller incision is created on the side of the chest wall in comparison to the conventional mastectomy.

What is an Axillary Dissection?

An Axillary Dissection is an operation to surgically remove the majority of the lymph nodes (small bean-shaped gland found throughout the body which act as filters to trap substances such as dirt and germs which maybe harmful to the body) in the axilla. This is to allow for accurate cancer staging so that you may be appropriately advised on further systemic treatment after surgery to reduce the risk of cancer relapse.

What is an Implant Reconstruction?

An implant reconstruction is a surgical procedure where an implant (a breast-shaped prosthesis with an outer shell made of silicone and filled either with salt solution (saline) or silicone), is placed under the skin and/or chest muscle, to recreate the breast mound.

What is a Flap Reconstruction?

A flap reconstruction is a surgical procedure that uses the skin, fat and the latissimus dorsi muscle from your back to cover wounds and/or breast reconstruction. It involves the use of your own tissue and therefore there is no risk of tissue rejection or use of artificial material.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to take part in this study, you will be asked to undergo robotic mastectomy.

Your participation in the study will last till 6 month post-operatively. You will need to visit the doctor's office 3 times in the course of the study (Visit 1-Visit 3).

Schedule of Visit Appointments and Research Study Procedures:

Visit 1 (Screening):

You will be assessed to determine if you are suitable to participate in the study. If you do consent to participate, data will be collected with regards to your demographics, general health, biochemical and radiological tests. This will be done for tests that you may have done before, and data will continue to be collected until your involvement in the study has been completed. You will be required to complete questionnaires to look at your quality of life. This should not take more than 15 minutes.

Visit 2 (Day of Surgery):

You will undergo robotic mastectomy as per planned. There will be virtual/remote supervision from Dr Mok's mentor (from Taiwan) during the surgery. The study will be using the Da Vinci Xi surgical system and Dr Mok's surgical experiences are mainly using the Da Vinci Si surgical system. The difference between Da Vinci Si and Da Vinci Xi is that Da Vinci Xi is an improved

version of Da Vinci Si as the Xi system features smaller, thinner robotic arms with redesigned joints that enable greater range of motion. Potentially this may result in shorter operating time with Da Vinci Xi system due to shorter docking time as well as easier manoeuvrability.

You will be monitored in 23-hour ward as part of the routine clinical management and be discharge on Day 1 if you are well. Data (such as duration, pain medication usage) in relation to your surgery will be collected.

During the robotic mastectomy, the breast is removed through a small incision with a robotic camera and small instruments attached to a robotic arm that is controlled by the surgeon at a computer console. A smaller incision is created on the side of the chest wall in comparison to the conventional mastectomy. Please refer to the figures below for the differences in the incision made for conventional mastectomy versus robotic mastectomy.

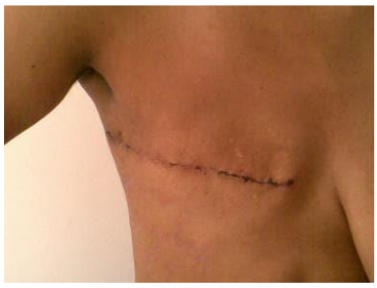

Fig 1: Conventional Mastectomy without Reconstruction

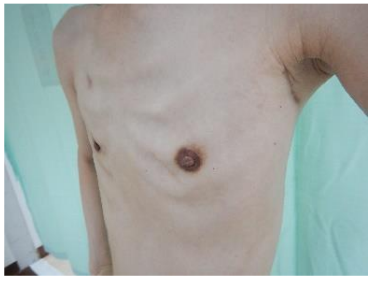

Fig 2: Robotic Mastectomy without Reconstruction

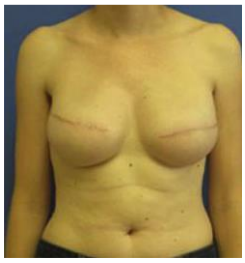

Fig 3: Conventional Mastectomy With Reconstruction

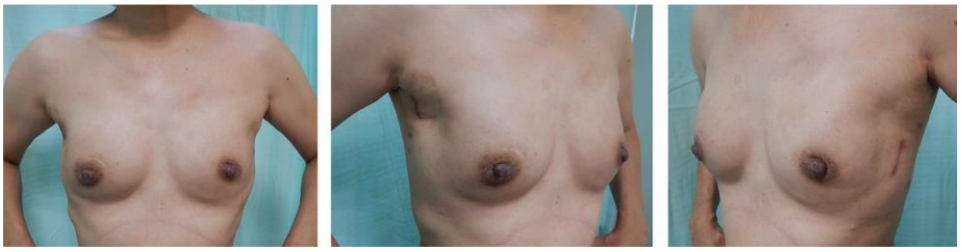

Fig 4: Robotic Mastectomy with Reconstruction

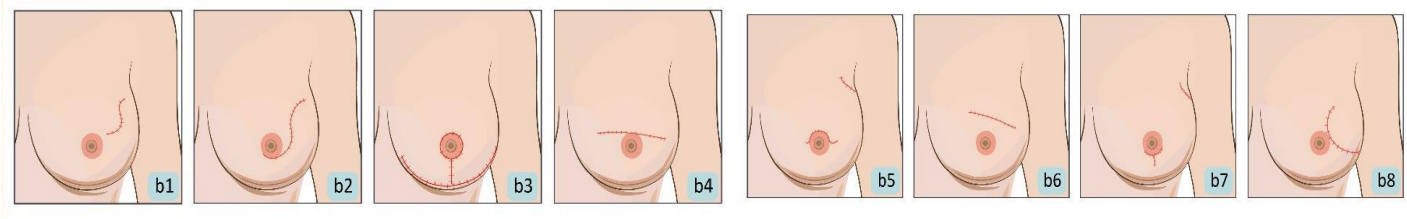

Fig 5: Types of incision used in Conventional Mastectomy

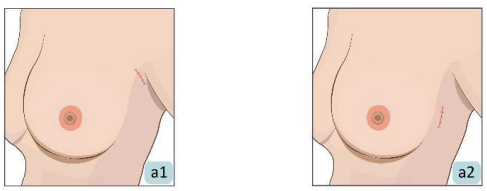

Fig 6: Types of incision used in Robotic Mastectomy

Visit 3 (1 month Post operation follow up):

You will be follow up by your surgeon as part of routine clinical management. You will be required to complete questionnaires, to assess for change in your quality of life. This should not take more than 15 minutes.

Visit 4 (6 Months Post operation follow up):

You will be required to complete questionnaires, to assess for change in your quality of life. This may be done remotely via phone. This should not take more than 15 minutes.

There will not be any additional study visits or blood investigations required. Data will only be collected from the medical records. Details of scheduled are as per tabulated below.

	Visit 1 (Screening)	Visit 2 (Day of Surgery)	Visit 3 (+/-2 weeks) (30^{th} POD)	Visit 4 (+/-2 Weeks) (6 months POD)
Consent taking	X			
Eligibility Check	X			
Adverse Event Assessment		X	X	X
Clinical Assessment	X		X	
Collection of medical information	X	X	X	X

As part of standard care, you will be followed up as per conventional surgery. This includes twice weekly review of wound by the breast surgeon/ breast care nurses, with the earliest visit scheduled on post-operative day 4 and to continue until wound(s) have completely healed.

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 robotic mastectomy is not yet proven to be a standard surgical treatment in patients with breast cancer / tumours. We hope that your participation will help us to determine whether robotic mastectomy is equal or superior to existing conventional mastectomy.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

Personal privacy and confidentiality:

This study uses health information that may affect your privacy. To protect your confidentiality, only a unique code number will be used to identify data 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.
Risks as informed below, are similar between standard of care surgery and robotic mastectomy

Post-surgical Pain (13-21%):

- When the anaesthesia wears off, you may experience some pain at the wound site. In anticipation of this, analgesia (pain medication) will be made available should you require it. The pain is usually more severe immediately after surgery and during the first few days post-surgery.
- You are encouraged to move the arm that is on the same side of the operation immediately after surgery, within the limits of your pain tolerance.
- This is to facilitate your shoulder movement and minimise shoulder tightness and stiffness.

Post-surgical Bleeding / Haematoma (2.5 -5%):

- This usually occurs because small blood vessels may reopen after surgery, or because the blood did not clot fast enough. This complication is more common in elderly patients, patients with bleeding tendencies or patients who are taking certain medications such as blood thinners.
- It may present as skin bruising or an accumulation of blood clot (haematoma) in the wound.
- In most cases, it is self-limiting and will resolve on its own. However, in some cases of more serious bleeding, surgery may be necessary to stop the bleeding and wash out the blood clot. A blood transfusion may also be necessary. Your doctor will assess and advise you accordingly.

Wound Infection / Abscess (5-8.1%)

- As with most surgeries, the risk of wound infection will be present, although all precautions will be taken to minimise it. The risk of wound infection is higher for patients who are elderly, have diabetes, smoke or are taking certain medications such as steroids.
- After discharge, you will be monitored for wound infection.
- In mild cases of infection, cleaning the wound and / or antibiotics may be required.
- In severe cases of infection, pus may accumulate in the wound (abscess), which may require removal by needle aspiration or surgery.
- Your doctor will assess and advise you accordingly.

Wound Breakdown and / or Necrosis (0.5-7.2%)

- The surgical wound may heal poorly, exhibit gaping or breakdown and/or the wound edge may turn black due to a lack of blood supply.
- Patients who are elderly, have diabetes, smoke or are taking certain medications such as steroids, may be more prone to wound breakdown and necrosis.

- In mild cases, it may be managed by daily dressing. In more severe cases, a special type of dressing called Vacuum-Assisted Closure (VAC) dressing may be required. In certain cases, surgery may be needed to remove the unhealthy skin.
- Your doctor will assess and advise you accordingly.

Scar and Keloid formation (1-3.8%)

- The incision will heal with the formation of a scar. In most patients, the scar will become less obvious with time.
- However, some patients are prone to keloid formation (raised scars). This is largely dependent on the patient's personal healing capacity.
- If you are prone to keloids, there is a cream which may be applied to the wound once it has healed to minimise the keloid formation. Please let your doctor know if you are prone to keloids.

Seroma (Build-up of body fluid) (2.5-51%)

- In most cases, the drain used to collect the seroma may be removed after 1-2 weeks. However, some patients may require the drain to be kept in longer.
- You may experience some discomfort at the site of the drain.
- Seroma may also accumulate after the drain has been removed.
- If the amount is small, your body will re-absorb the fluid naturally.
- If the volume is large, a needle aspiration (insertion of a needle into the fluid collection to draw out the fluid) may be required.
- However, the fluid may re-accumulate and repeated needle aspiration of the fluid may be required.
- A seroma may also get infected. Antibiotics, needle aspirations and surgery may then be needed.
- Your doctor will assess and advise you accordingly.

Shoulder Stiffness (2-11%)

- You may experience some stiffness and/or tightness in the shoulder on the side of your surgery.
- This is usually due to the pain and swelling which may occur after surgery.
- Early movement and stretching of the shoulder will help to minimise and possibly avoid future shoulder stiffness and restricted movement.
- Moving the arm on the side of the surgery will not cause injury to the wound and therefore, you are encouraged to start moving your arm as soon as possible after the surgery, within the limits of your pain tolerance.

Numbness (11-28%)

- The skin over the chest will be numb after a mastectomy as the nerves to the skin over the breast have been cut during the mastectomy.
- The numbness may lessen with time, but full recovery of sensation is unlikely to occur.

For participants undergoing reconstruction, the following may applies:

Size discrepancy (2-20%)

- Although implants are available in a variety of shapes and sizes, it is not customized to you. Hence it may not be an exact match of your breast shape and/or size.
- Moreover, as the implant shape and size is fixed, it will not increase or decrease in size should there be subsequent weight loss or weight gain after the surgery.
- Your doctor will assess your condition and advise you accordingly.

Asymmetry (1-20%)

- During surgery, the implant is placed in the position to match your other breast when you are wearing a bra.
- The implant will not droop like the other breast.
- Therefore, symmetry may only be achieved when you are wearing a bra.

Implant migration (2-7%)

- The position of the implant may shift / move (migration). If it is minimal and not noticeable, it can be left alone.
- However, if the position is unacceptable, surgery may be required to re-position it.

Implant rupture (1.1 -17.7%)

- With time, the implant may break, especially if a large force is exerted on it.
- Should this happen, the implant may need to be removed surgically.

Capsule formation and contracture (5-10.6%)

- Your body will react to the implant by forming a fibrous layer around the implant, wrapping it in a “capsule” (capsule formation).
- This helps to protect the implant from infection and migration.
- Should there be a break in the implant (rupture), the capsule also keeps the material of the implant contained.
- However, in some individuals, the capsule may thicken and harden (contracture) with time, causing distortion and discomfort. This may then require surgery to release the capsule.
- Should this happen, your doctor will assess your condition and advise you accordingly.

Prolonged anaesthesia

- As the robotic surgery will be estimated to be 0.5-1.5hour than conventional mastectomy, you will be placed under GA for a longer period.
- The side effect of prolonged anaesthesia includes but is not limited to nausea and vomiting, sore throat or hoarseness, difficulty with urination, post-operative infection etc. You will be monitored for side effect during your stay.

Failure in robotic mastectomy (2-5%)

- In the event robotic mastectomy is not successful, the surgery may be completed using conventional/ endoscopic surgery. The risks of conversion is between 2-5% based on current reported series in the literatures.

The possible risks, discomfort or inconveniences of endoscopic mastectomy are similar to conventional mastectomy and robotic mastectomy.

POTENTIAL BENEFITS

If you participate in this study, you may reasonably expect to benefit from the robotic surgery in the following way:

- Smaller incision which may translate to lesser pain and faster recovery
- Improved satisfaction due to lesser pain and faster recovery
- Better aesthetic outcome

ALTERNATIVE PROCEDURES/ TREATMENTS IF YOU DO NOT PARTICIPATE IN THE STUDY

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution, this would be conventional or endoscopic mastectomy.

The advantage of standard care or endoscopic mastectomy would be a shorter duration of surgery (approximately 0.5-1.5hr shorter). The disadvantage would include a longer and scar, longer recovery period (approximately 1-2 weeks longer) and pain as a result of the longer incision required.

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:

- Instruments and consumables associated with the robotic surgery and the cost of the longer surgery due to the robotic surgery. These costs will be borne by Changi General Hospital.

The cost of your usual medical care (pre-operation blood tests, medications and doctor visits), the conventional mastectomy surgery cost and follow up post surgery will continue to be billed to you.

You will be reimbursed for your time, inconvenience and transportation costs as follows:

- You will receive $50 per study visit from Visit 1 – Visit 3 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.

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.

If you withdraw from the study,

- You will still be required to follow up as per routine clinical practice.

However, any of your data that has been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

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
- 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 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. Your study records and medical records, to the extent required by the applicable laws and regulations, will not be made publicly available. Only the study team will have access to the personal data being collected from you. In the event of any publication regarding this study, your identity will remain confidential.
However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records and study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Changi General Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above.

Any information containing your Personal Data that is collected for the purposes of this research will be stored in Singapore. To protect your identity, your Personal Data will be labelled with a unique code number. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code number to your Personal Data. This will be kept in a safe place with restricted access.

All data collected in this study are the property of Changi General Hospital. 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:

Principal Investigator

Dr Mok Chi Wei
Consultant
Department of Surgery
Changi General Hospital
HP:

Or Study Coordinator:

Name: Ms Alva Chew
HP:

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:
Surgical and Patient Reported Outcomes in Robotic Mastectomy – A Pilot Study

Principal Investigator:
Dr Mok Chi Wei
Department of Surgery, Changi General Hospital

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

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

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

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

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

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for _____ (Name of Participant) to participate in the research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

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

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

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

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

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

_____	_____	_____
Name of Investigator/ Person obtaining consent	Signature	Date

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 your data for future research. The data will be kept in Changi General Hospital. Except if you withdraw your consent or there are limits imposed by law, there is no limit on the length of time we will store your data. Researchers will use your data for research long into the future.

This is what will be done with your stored data:

- We may use the data to answer additional research questions in other research studies. This is outside the scope of the research study but still related to breast cancer and breast tumours.
- We may share the data with other researchers within Singapore public health institutions and with researchers outside of Singapore such as Taiwan, Australia etc.
- The stored data will be labelled with a code instead of information that directly identifies you (e.g. your name, NRIC, date of birth, etc.). We will keep a separate file (key) that links your code to your identifiable information.
- When we share your data with other researchers, it will be in a coded manner. They will not be able to identify you from the coded data.
- If you decide at a later time that you do not want your data to be used for future research, you can contact the Principal Investigator or study team at any time. All your stored data that has not been used or shared with other researchers will be removed and discontinued from further use, unless this information is already included in analyses or used in publications.

CONSENT FORM FOR FUTURE RESEARCH

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

Please indicate your choice using the relevant checkbox.

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

☐ I agree to have my data stored for future use in other research studies.

I understand the purpose and nature of this optional component (storage of data for future use in other research studies). 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

Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The optional component (storage of data for future use in other research studies) has been explained to the participant/ participant's legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this Information & Consent Form for Future Research had the optional component fully explained to him/her in a language understood by him/ her and clearly understands the purpose and the nature of 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 for future use in other research studies) 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