# Northern Sydney Local Health District

# Participant Information Sheet/Consent Form

**Non-Interventional Study** - *Adult providing own consent*

*Royal North Shore Hospital*

| | |
|---|---|
| **Title** | Outcomes of pre-pectoral and sub-pectoral breast reconstruction: a prospective multi-centre cohort study from Sydney, Australia |
| **Short Title** | PRASE Study |
| **Project Sponsor** | None |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Isobel Yeap, Professor Andrew Spillane |
| **Associate Investigator(s)** | Dr Railya Mousina, Dr Kylie Snook, Dr Samriti Sood, Associate Professor Sanjay Warrier, Dr Cindy Mak, Dr Belinda Chan, Associate Professor James French, Associate Professor Elisabeth Elder, Dr Farid Meybodi, Dr Jeremy Hsu, Dr Kathy Flitcroft |
| **Location(s)** | Royal North Shore Hospital, the Mater Hospital, Westmead Hospital, Chris O'Brien Lifehouse Hospital, Royal Prince Alfred Hospital |

## Part 1 What does my participation involve?

### 1 Introduction

You are invited to take part in this research project, the PRASE Study because you have attended the rooms and/or one of the clinics of the co-investigators (Professor Andrew Spillane, Dr Kylie Snook, Dr Samriti Sood, Associate Professor Sanjay Warrier, Dr Cindy Mak, Dr Belinda Chan, Associate Professor James French, Associate Professor Elisabeth Elder, Dr Farid Meybodi and Dr Jeremy Hsu) and are considering undergoing implant-based breast reconstruction as part of your treatment for breast cancer or as prophylaxis since you have been identified to be at high risk of breast cancer.

The research project is aiming to compare clinical and quality-of-life outcomes for two different approaches to implant-based breast reconstruction: the pre-pectoral approach vs. the sub-pectoral approach.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

## 2 What is the purpose of this research?

You are invited to take part in a research study comparing outcomes for two different methods of implant-based breast reconstruction. These two methods are: the pre-pectoral method, where the implant is placed underneath the pectoralis major muscle, and the sub-pectoral method, where the implant is placed superficial to the pectoralis major muscle. The sub-pectoral method is relatively new, and this is the first prospective multi-centre observational study to take place in Australia. Through this study, we are hoping to understand more about the clinical and quality of life outcomes related to these two methods. In particular, we are interested in whether the pre-pectoral method leads to a better quality of life for these patients, without an increase in the rate of short and medium-term medical or surgical complications.

The study is being carried out by the following researchers:

- Professor Andrew Spillane, Professor of Surgical Oncology at The University of Sydney, Northern Clinical School and Consultant Breast Surgeon at Mater Hospital, Sydney, North Shore Private Hospital and Royal North Shore Hospital
- Dr Kylie Snook, Consultant Breast Surgeon at Mater Hospital, Sydney and North Shore Private Hospital
- Dr Samriti Sood, Consultant Breast Surgeon at Mater Hospital, Sydney, Royal North Shore Hospital and Northern Beaches Hospital
- Associate Professor Sanjay Warrier, Associate Professor of Breast Surgery at the University of Sydney, Royal Prince Alfred Academic Institute, Consultant Breast Surgeon at Chris O'Brien Lifehouse and Royal Prince Alfred Hospital
- Dr Cindy Mak, Consultant Breast Surgeon at Chris O'Brien Lifehouse, Royal Prince Alfred Hospital and Mater Hospital, Sydney.
- Dr Belinda Chan, Consultant Breast Surgeon at Chris O'Brien Lifehouse
- Associate Professor James French, Clinical Associate Professor at The University of Sydney, Westmead Clinical School and Consultant Breast Surgeon at Westmead Hospital

- Associate Professor Elisabeth Elder, Clinical Associate Professor at the University of Sydney, Westmead Clinical School and Consultant Brest Surgeon at Westmead Hospital
- Dr Farid Meybodi, Consultant Breast Surgeon at Westmead Hospital
- Dr Jeremy Hsu, Clinical Senior Lecturer of Surgery at The University of Sydney, Westmead Clinical school and Consultant Breast Surgeon at Westmead Hospital
- Dr Railya Mousina, Breast Fellow at Westmead Hospital
- Dr Kathy Flitcroft, Research Manager, Breast and Surgical Oncology at the Poche Centre, North Sydney

Dr Isobel Yeap is conducting this study as the basis for the degree of Masters of Surgery (Plastic and Reconstructive Surgery) at The University of Sydney. This will take place under the supervision of Professor Andrew Spillane.

We have no funding to declare and no conflicts of interest. There exist no financial benefits to the researchers or institutions that might arise from the conduct of this research.

## 3 What does participation in this research involve?

A consent form will be signed prior to any study assessments being performed. If you agree to participate in the study, the study will involve you attending all your usual clinic appointments with your consulting surgeon. This study is observational only in nature. It will not affect the type of surgical reconstruction (pre-pectoral or sub-pectoral) that you choose. The type of surgical reconstruction is a decision that will be made between you and your surgeon. Once you have chosen the type of reconstruction, we will collect relevant medical data from your treating surgeon, such as your BMI, whether or not you smoke, the stage and type of your breast cancer and whether or not you have had chemotherapy or radiotherapy and what type.

If you choose to remain in the study, further information will be collected as your surgical journey progresses. For example, we will collect data regarding surgical complications, such as post-operative infections or collections, or a need for a repeat operation. This data will be collected at your first post-operative follow up assessment, usually around one month after your operation. It will also be collected at later follow up assessments, one year and two years after your initial operation.

If you consent to participating in this study during your pre-operative consultation, you will be asked to fill out a quality-of-life questionnaire called the BREAST-Q questionnaire. This will approximately 15 minutes to complete. At your one-year follow-up appointment, you will be asked to fill out two questionnaires: the BREAST-Q post-operative questionnaire and the Kroll Score. This will take approximately 30 minutes. Your treating surgeon will also be asked to complete two questionnaires regarding how satisfied he or she is with your surgical outcome.

The data collected both in relation to your surgery and your questionnaire responses will be de-identified and stored on an encrypted, password-protected database known as REDCap. The de-identified data will be accessible only to members of the study group. Once the data has been aggregated and analysed, it may be presented at scientific conferences or in scientific journals.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

## 4 What do I have to do?

Participating in this study will not require you to attend any more appointments than you normally would when undertaking surgery for breast reconstruction. However, it will require that you show up to your three follow-up appointments (an appointment one month after your surgery, an appointment one year after your surgery and an appointment two years after your surgery). It will also require an extra 15 minutes of your time at your pre-operative assessment appointment and an extra 30 minutes of your time at the one year post-operative appointment for the filling out of questionnaires.

If you do not have time to complete these questionnaires during your appointment, we can arrange for an online copy to be emailed to you and you can complete it at home. Please let your treating surgeon know if this is the case.

## 5 Other relevant information about the research project

The PRASE Study is a multi-institutional trial run across five hospitals in Sydney: Royal North Shore Hospital, The Mater Hospital, Westmead Hospital, Chris O'Brien Lifehouse and Royal Prince Alfred Hospital. We will be recruiting patients for two years (2021-2022) and each patient will be followed up for two years. By 2022, we are hoping to have recruited 150-200 patients with pre-pectoral reconstruction and 200-300 patients with subpectoral reconstruction.

## 6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Royal North Shore Hospital.

## 7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you choose not to participate in the study, your clinical data will not be shared with the study team and you will not be asked to complete the any quality-of-life questionnaires.

## 8 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. However, we hope that the results of the PRASE study will be used to better inform future patients regarding the outcomes of breast-implant based reconstruction.

## 9 What are the possible risks and disadvantages of taking part?

The PRASE Study is strictly observational in nature. Therefore, your medical and surgical treatment and their associated risks will not be altered based on whether you choose to participate or not. The main difference with participating in the PRASE Study is that you will be asked to complete

quality of life questionnaires at your pre-operative assessment and one year routine follow-up appointments.

These questionnaires are validated and have been extensively used in previous research studies to evaluate quality-of-life outcomes. However, if you find the process of completing the questionnaire distressing, you should let your study doctor know. We will then arrange for a member of the PRASE Study group to call you the following day to ensure that you are not experiencing ongoing distress.

Patients who make a joint decision with their treating surgeon to have pre-pectoral implant reconstruction will be made aware of the risks of the procedure in the PISCF document. As per "Pre-pectoral implant-based breast reconstruction: a joint consensus guide from UK, European and USA breast and plastic reconstructive surgeons", patients will be told that pre-pectoral reconstruction is a relatively new procedure with a paucity of studies on long-term outcomes. In particular, they should be warned of rippling, which is more common in pre-pectoral reconstruction.

All patients will be informed of the risks of implant reconstruction in general, such as the likelihood of further revision for capsule formation, asymmetry, implant rupture or rotation, infection and pain. They will be informed of the risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) which has been estimated at 1 in 28 000 for textured implants. All patients will be registered with the Australian Breast Device Registry – a national registry designed to track patient health outcomes and monitor the long-term safety of breast devices.

## 10 What will happen to my test samples?

Agreeing to participate in the PRASE study does not require you to provide any additional test samples. If you agree to participate, you will be allowing members of the study to access your clinical data, such as blood tests results relating to your reconstructive surgery, operation reports, histopathology reports and data on whether or not you experience any medical or surgical complications.

## 11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

## 12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

These medications will consist of those medications routinely stopped in the pre-operative period, such as blood-thinning medication that may increase your risk of bleeding during surgery. Some vitamins, such as fish and krill oil are known to increase your risk of bleeding, so you may be asked to stop these too. These medications can be resumed in the post-operative period.

This applies if you elect for the pre-pectoral reconstruction method and if you elect for the sub-pectoral reconstruction method. It will also apply if you choose not to be part of the study, since it is routine pre-operative management.

### 13 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

### 14 Could this research project be stopped unexpectedly?

It is not anticipated that this research project will be stopped unexpectedly.

### 15 What happens when the research project ends?

After the project ends, the collected data will be analysed by the study group. It may be presented at scientific conferences or published in scientific journals. We will provide you with a summary of the results of the project at its completion via email.

## Part 2 How is the research project being conducted?

### 16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential.

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. This information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

The types of information that will be collected about you and used in the study may be seen in the data collection sheet (attached at the end of this document). Only the two study coordinators, Dr Isobel Yeap and Dr Railya Mousina, will have access to the data in its identified form. This data will be stored on REDCap and will be encrypted and password protected. Dr Isobel Yeap and Dr Railya Mousina will then de-identify the data. The de-identified data will also be stored on REDCap. All members of the study group will have access to the de-identified data. The de-identified data may also be sent off for statistical analysis to a third party.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be de-identified. It may then be aggregated and analysed and presented at a scientific meeting or in a scientific journal. Study findings may be published, but you will not be individually identifiable in these publications.

Your information will be stored securely and your identity and information will be kept strictly confidential, except as required by law. Your de-identified data will be stored for five years on a protected Sydney University storage network.

In accordance with relevant Australian and NSW privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## 17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

## 18 Who is organising and funding the research?

This research project is being conducted by Dr Isobel Yeap as part of her Master of Surgery (Plastic and Reconstructive Surgery), supervised by Professor Andrew Spillane.

## 19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Sydney University, as well as the HREC of Northern Sydney Local Health District.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

## 20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor or any of the following people:

**Clinical contact person**

| | |
|---|---|
| Name | Isobel Yeap |
| Position | Principal Investigator |
| Telephone | Work number: 0406 549 239 |
| Email | iyea4625@uni.sydney.edu.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

| | |
|---|---|
| Name | Northern Sydney Local Health District Research Ethics Office |
| Position | General Enquiries, quite the HREC reference number [***] |
| Telephone | 02 9926 4590 |
| Email | NSLHD-Research@health.nsw.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

| | |
|---|---|
| Name | Northern Sydney Local Health District Research Ethics Office |
| Position | General Enquiries, quote the HREC reference number [***] |
| Telephone | 02 9926 4590 |
| Email | NSLHD-Research@health.nsw.gov.au |

**Reviewing HREC approving this research and HREC Executive Officer details**

| | |
|---|---|
| Name | Ethics Administration, Sydney University |
| Position | The Manager, quote the HREC reference number [***] |
| Telephone | 02 8627 8176 |
| Email | human.ethics@sydney.edu.au |

# Consent Form - *Adult providing own consent*

| | |
|---|---|
| **Title** | Outcomes of pre-pectoral and sub-pectoral breast reconstruction: a prospective multi-centre cohort study from Sydney, Australia |
| **Short Title** | PRASE Study |
| **Project Sponsor** | None |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Isobel Yeap, Professor Andrew Spillane |
| **Associate Investigator(s)** | Dr Railya Mousina, Dr Kylie Snook, Dr Samriti Sood, Associate Professor Sanjay Warrier, Dr Cindy Mak, Dr Belinda Chan, Associate Professor James French, Associate Professor Elisabeth Elder, Dr Farid Meybodi, Dr Jeremy Hsu, Dr Kathy Flitcroft |
| **Location(s)** | Royal North Shore Hospital, the Mater Hospital, Westmead Hospital, Chris O'Brien Lifehouse Hospital, Royal Prince Alfred Hospital |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Royal North Shore Hospital concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that, if I decide to discontinue the research project treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date _____

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

| | |
|---|---|
| Name of Study Doctor/ Senior Researcher† (please print) | _____ |
| Signature _____ | Date _____ |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

# Form for Withdrawal of Participation - *Adult providing own consent*

| | |
|---|---|
| **Title** | Outcomes of pre-pectoral and sub-pectoral breast reconstruction: a prospective multi-centre cohort study from Sydney, Australia |
| **Short Title** | PRASE Study |
| **Project Sponsor** | None |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Isobel Yeap, Professor Andrew Spillane |
| **Associate Investigator(s)** | Dr Railya Mousina, Dr Kylie Snook, Dr Samriti Sood, Associate Professor Sanjay Warrier, Dr Cindy Mak, Dr Belinda Chan, Associate Professor James French, Associate Professor Elisabeth Elder, Dr Farid Meybodi, Dr Jeremy Hsu, Dr Kathy Flitcroft |
| **Location(s)** | Royal North Shore Hospital, the Mater Hospital, Westmead Hospital, Chris O'Brien Lifehouse Hospital, Royal Prince Alfred Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Royal North Shore Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.