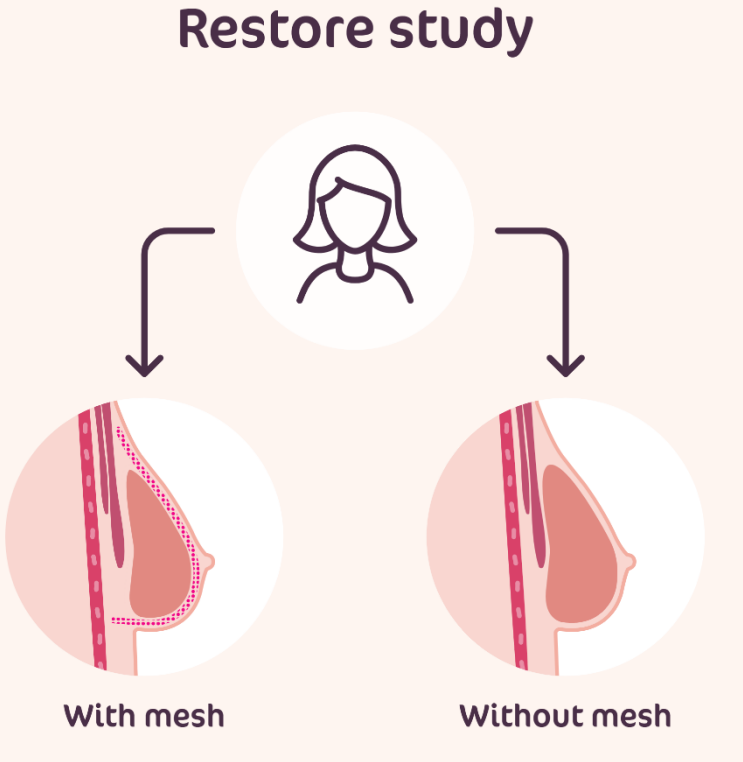
Chief Investigator: Ms Rachel Rolph

<insert local trust logo and contact details>

## PARTICIPANT INFORMATION SHEET: The Restore-B Study

### The Restore-B study: A study evaluating the feasibility of a future research trial comparing implant-based breast reconstruction with and without mesh.

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.



## What is the purpose of the study?

The Restore-B study is looking to understand if it would be possible to run in the future a large research trial for women who are having their breast reconstructed with an implant or expander and a mesh (also referred to as an acellular dermal matrix). Mesh is routinely used in this operation since its introduction to surgeons approximately eight years ago, to provide internal support and coverage to the implant.

Currently, we do not have high quality research evidence to tell us exactly what the benefits or risks to patients are when having this operation with and without the mesh. Some breast surgeons in the NHS perform the same operation without the use of mesh.

This study aims to understand if it is possible to run a future large study where women are randomly chosen to either receive mesh in their implant reconstruction or not. This would help us to understand which surgical technique is better and help women in the future decide which option would be best for them.

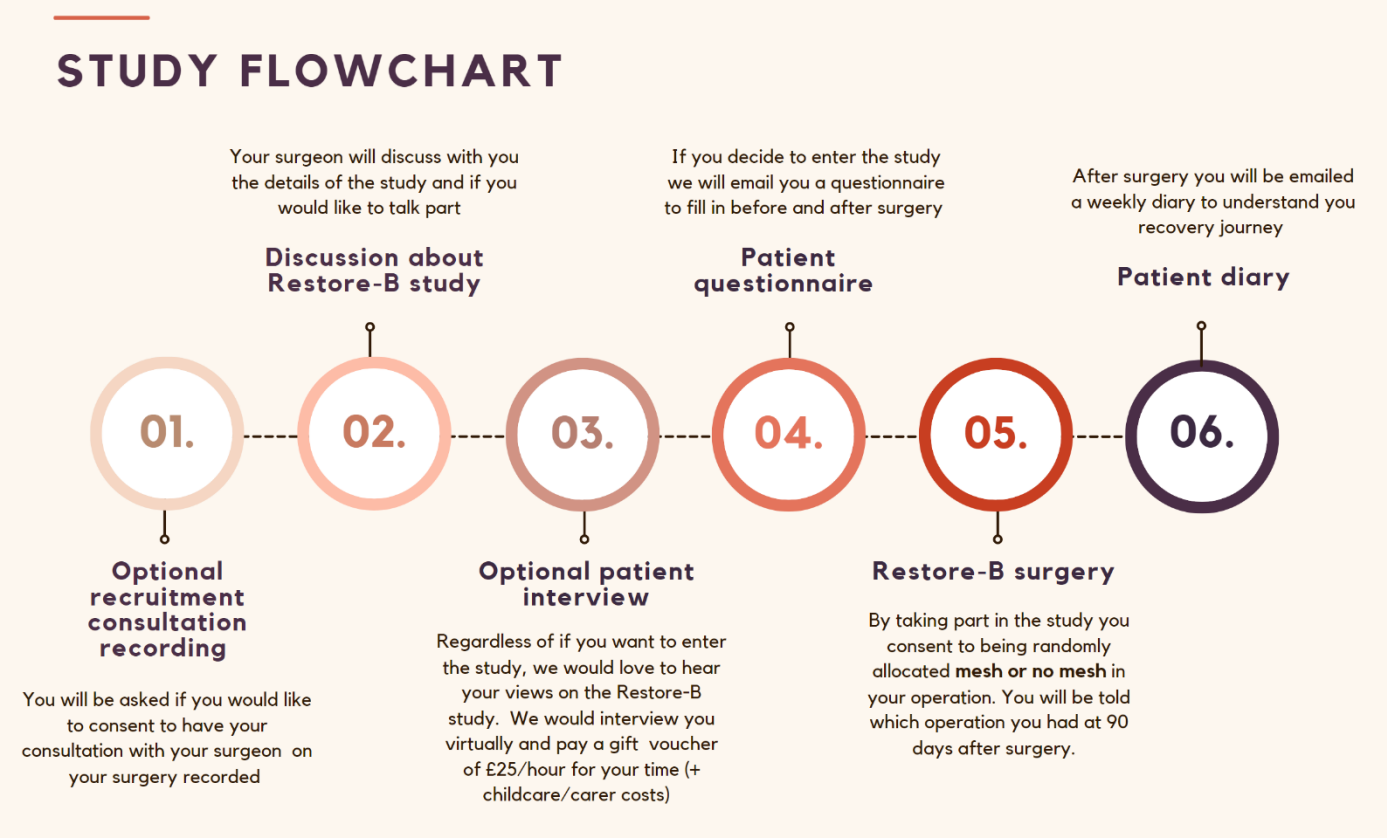
In this study we are inviting women to recruit into a small initial study to understand both your experience of the research study and that of your healthcare team to see if running a larger trial would be possible.


**Important**

Breast cancer patients have been involved in the design of this study to provide the patient viewpoint.

This is a nationally funded study involving multiple hospitals and surgeons in the UK. This study is supported by the University of Oxford and approved by an independent research committee.

## What would you like me to do?



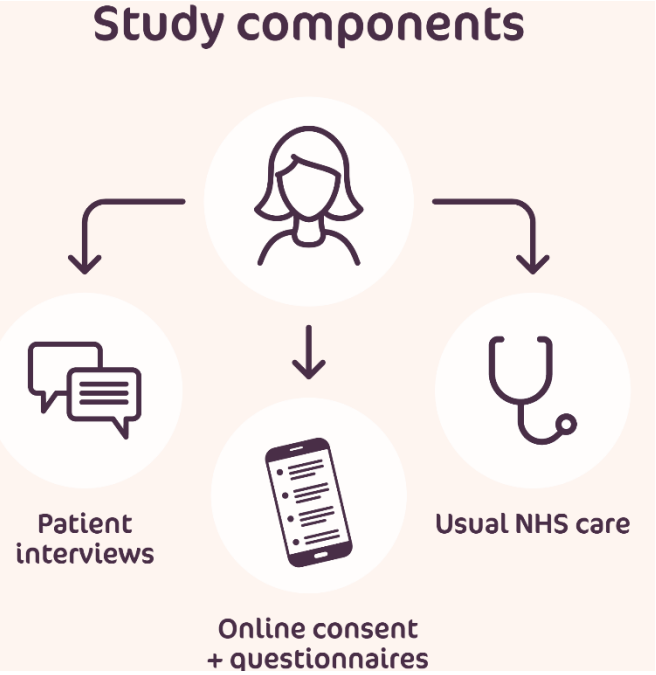

This information sheet is about the plan for your surgery. In your consultation with your surgeon they will discuss with you about immediate breast reconstruction following mastectomy with an implant (or expander) and the use of a mesh (sometimes called an acellular dermal matrix).

The surgical part of the Restore-B study is inviting women having this operation to be randomly assigned to have their operation with or without the use of mesh. In the operation, all the surgical steps will remain the same, apart from using mesh or not. If you are having surgery on both breasts, you will receive the same operative technique in both (either both with mesh or both without mesh).

Your surgeon will find out which group you are in just before the start of your operation. The mesh and implants will be ordered as usual before your operation if you decide to take part in the study.

At the end of the study you will be told whether you had mesh or not in your breast reconstruction after filling in a patient questionnaire - which will be 90 days after surgery.

Before your surgery, you will be required to have medical photographs, which is a standard step in your pre-operative preparation for this operation. In addition, in this study, we would need you to complete **one questionnaire about your quality of life before surgery** and the outcomes which matter to you the most with this surgery. The photographs and the **questionnaire would also be completed again 3 months after your surgery** to compare the two. The questionnaire usually takes 15 minutes to complete each time.




During the study, your clinical team will collect information on your health in general before the operation, your operation details, and any complications after surgery. You will also be given a way to report any problems you have after surgery which needs you to contact your healthcare team, GP, A&E, so that we know how the surgery is affecting your health for example, if you needed an extra wound dressing by your GP practice nurse. This is in the form of an electronic diary which will be accessible to you on your mobile device or computer device after your surgery. Paper copies are available should you need it. You will need to complete these once a week from the date of your operation until 90 days post-surgery. You will be sent weekly reminders to do this by email.

We would like to ask for your consent to access your routinely collected health records after the end of the study period, this would enable us to understand longer term health outcomes in the women who took part. This would be subject to future research resources, funding and ethical approval.

## Optional parts of the study:

Research discussion:

We would like to discuss with you your thoughts about the study design and mesh in general and you will be offered an opportunity to have a chat with a study researcher (in person or virtually) for 30-60 minutes before and after your surgery and you will be compensated with a £25 voucher per hour of your time.

Breast movements:

There is a further optional part of the study where you can have a specialist scan looking at how your breast movement and shape changes after the surgery compared to before surgery. This is performed at Portsmouth University, and this requires two visits, one before and one 3 months after your surgery. It takes 60 minutes to collect the information and you will be compensated for your travel costs. It is not an invasive procedure and involves placing stickers on the breasts and recording the movement whilst standing and walking. You will be given a bespoke post-operative bra for you based on the data collected about your breast shape if you take part in this part of the study.

You can choose which part(s) of the study you would like to take part in.

## Why have I been invited?

- You have been invited to participate in this study as you are going to have a mastectomy with immediate breast reconstruction using an implant or expander and mesh (acellular dermal matrix) in the pre-pectoral position (over the muscle). We do not include patients who required delay reconstruction as this is a different surgical technique.
- The mastectomy surgery may be for your breast cancer treatment or for reducing your risk of breast cancer in the future (risk-reducing preventative surgery).
- All patients who are eligible to have this operation are being invited to take part in the Restore-B study.

## Do I have to take part?

- The answer is ‘No’: Taking part is entirely voluntary. If you decide not to take part, we will invite you to discuss with a study researcher your reasons for declining the study in a 30-60 minute interview (virtual or in person) as your opinion about the study is important to us. We would compensate you for your time with a £25 gift voucher per hour. Childcare and carer costs will be covered to enable you to have the discussion and reimbursed to you via bank transfer.

- You can withdraw from the study if you later change your mind, without giving a reason.
- Withdrawal from the study will not affect your clinical care.

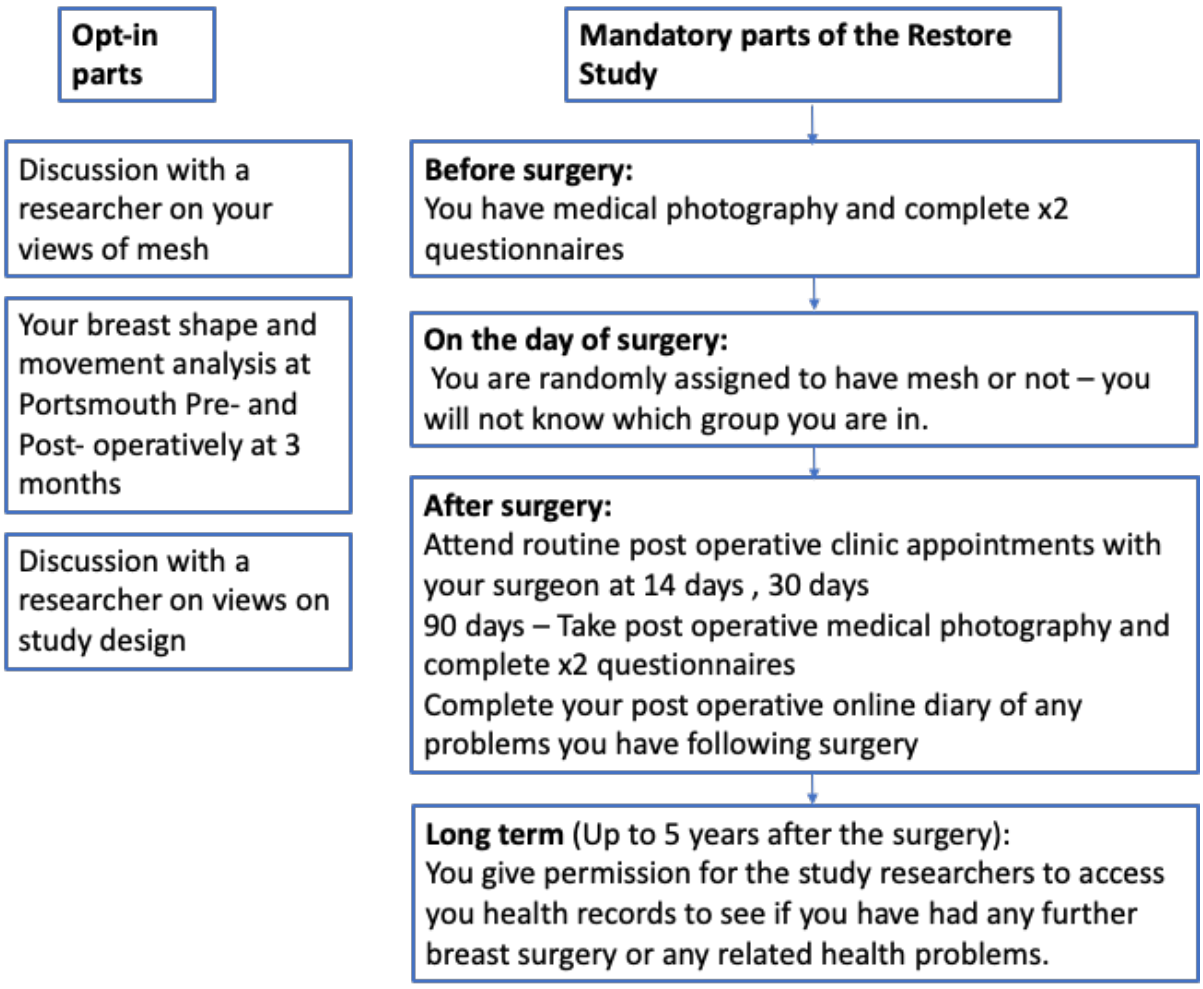
## Where can I find out more information about the study?

We plan to have a trial website which will act as a hub of information for patients and other members of the public. You may also see some videos relating to the study, for example an animation or explainer videos from experts in breast surgery.

## What will happen to me if I decide to take part?

If you decide to take part, you will be given a consent form for you to sign before your consultation.

Here is a summary flow chart of the steps you would take in the surgical part of the study:



## What will happen to me if I decide not to take part?

If you decide not to take part in the study at all, you will be asked if you would mind being contacted by a Restore-B study researcher to talk about your thoughts on the study and mesh in a separate recorded conversation lasting between 30-60 minutes at a time and day that works for you (virtually or in person). This is because we highly value your opinion and perspectives on the study and feedback from you will help to shape the design of a future larger study.

## What should I consider?

- Your personal thoughts and views on taking part in research studies and research in general.
- The potential benefits to taking part
- The potential disadvantages to taking part

## Are there any disadvantages or risks from taking part?

- We know from routine NHS hospital data that not having a mesh in this operation is safe. We do not have any high-level clinical trial evidence to tell us what the role of the mesh is in this operation. Some previous studies have suggested that the mesh may increase complications after surgery. The purpose of this study is to understand if we can run a larger study in the future to understand the role of mesh.
- We do not know if the mesh is helping with the shape of the breast reconstruction. This is why we are collecting photographs before and after surgery in each group to compare the aesthetics in each group.
- We do not know if the mesh is helping to hold the implant in place. This is why we are collecting information up to five years after the surgery to see if one group has more operations than the other group over that time and for what reason.
- We do not know if the mesh is helping with scarring around the implant especially after radiotherapy (called capsular contracture). This is why we are collecting information on whether you have radiotherapy as part of your cancer treatment.

## What are the possible benefits of taking part?

- Access to research hotline telephone and email for additional information and support on your participation in this research.
- Close monitoring of your post-operative journey by the research team.
- Contributing to our knowledge of breast surgery trials and the role of mesh in breast reconstruction.
- Opportunity for a gift voucher for each interview you have with a researcher.
- Opportunity to have a bespoke free post-operative bra if you have breast movement data collected at Portsmouth University.

## Will my General Practitioner/family doctor (GP) be informed of my participation?

- Your GP will be notified if you decide to take part in the surgical part of the Restore-B study after your consultation with your surgeon. Your GP will not know which group (mesh or no mesh) you are allocated to.

## Will my taking part in the study be kept confidential?

Information from your consultation is kept secure and there will be no identifiable data stored with the recordings. Once the recordings have been transcribed and analysed by the research team, the recording will be destroyed. Once the recording has been taken, as it is de-identified, it would not be possible for you to withdraw your recording as we would not know which recording is yours.

Responsible members of the University of Oxford and your NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

## Will I be reimbursed for taking part?

- If you decide to talk with a Restore-B study researcher about your views on the study and mesh in a separate recorded conversation (virtually or in person) you will be sent a gift voucher to compensate you for your time. Childcare and carer costs will also be reimbursed as required.

## What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

All data will be stored and used in compliance with the relevant, current data protection laws (Data Protection Act 2018; United Kingdom General Data Protection Regulation (UK GDPR)). Further information is provided below, and you will need to indicate on the consent forms that you understand this.

We will be using information from you and your medical records to undertake this study and will use the minimum personally-identifiable information possible.

We will store any research documents with personal information, such as consent forms, securely at the University of Oxford. We will keep identifiable information about you for 5 years after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 20 years after the end of the study, as part of the research record.

Your local hospital will use your name, NHS number, home address, and contact details to give to the research team to contact you about the research study. They will keep identifiable information about you from this study for 12 months after the study has finished. The research team may use your personal data during the study to contact you to remind you to fill in your online (or paper) questionnaires or post-operative diary. In rare circumstances we may do questionnaires over the telephone. This will be held up to 12 months after the end of the study. A copy of your consent form from this study will be kept in your medical records for as long as those records are retained.

If you are being compensated for your time being involved in the study, we will be required to collect your bank details in order to make payment(s). Your bank details will be stored for 7 years in accordance with University of Oxford financial policy.

We would like to ask for your consent to access your nationally held patient records for up to 5 years after the end of the study to see how you have recovered long-term from your surgery. This may include the General Register, eDRIS, NHS England/NHS Central Register, NHS Spine/ISD Scotland, the Health and Social Care Information Centre, the national registries and other cancer related datasets (if relevant) and databases for data collection, for purposes directly linked to this research study

This research would be subject to future research resources, funding and ethical approval. We will do the follow up from your electronic patient notes and nationally held data, so you will not have to do anything.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research study and as explained in this information sheet for example text messaging service providers/companies to send study-related text messages to you. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at : https://compliance.web.ox.ac.uk/individual-rights. You can find out more about how we use your information by contacting Ms Rachel Rolph [CI or study team email]

## What will happen if I don't want to carry on with the study?

Participation is voluntary and you may change your mind at a later stage. Withdrawal will not affect the care you receive from your healthcare team.

## What happens at the end of the study?

You will not be identified personally in any report or publication placed in the public domain because of this research. The findings from this research may be shared with others in the following ways: published in a research journal, presented at a professional conference and summarised on the study website. If you would like to be informed of the research findings please let the research team know and they will add your email or address to the study newsletter distribution list. Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis.

What if there is a problem?

- The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.
- If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Ms Rachel Rolph <contact details (phone number & email)> or you may contact the University of Oxford Research Governance, Ethics & Assurance (RGEA) on 01865 616480, or the director of RGEA at rgea.complaints@admin.ox.ac.uk.
- The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact them via your local hospital switchboard and website.

## How have patients and the public been involved in this study?

Breast reconstruction patients have helped to develop the Restore-B study and what research questions should be asked.

## Who is organising and funding the study?

This research study has been funded by the National Institute for Health Research (NIHR) UK, a government organisation which funds research to improve peoples' health and wellbeing. The research is sponsored by the University of Oxford and forms part of Ms Rachel Rolph's doctoral thesis at the University of Oxford.

## Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by _____Research Ethics Committee.

## Participation in future research

We would like to ask you whether you would be happy to be contacted about taking part in other research in the future.

All contact will come from the research team of this study. If you agree to be contacted, this does not oblige you to take part in future research.

Your contact details will be held securely on a contact register, separately from the Restore-B study on a password protected computer in the Nuffield Department of Surgical Sciences at the University of Oxford. It will only be accessed by authorised individuals working on this study.

You can be removed from this contact register any time you wish.

Further information and contact details:
Please contact < > by < >(telephone, e-mail, in writing)

**Thank you for considering taking part.**