PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Understanding experiences with breast implants
Interview Group (Study 2)
Dr Jill Newby, Chief Investigator

1. **What is the research study about?**
   You are invited to take part in this research study. The research study aims to investigate the experiences of women experiencing negative effects associated with breast implants, including women with Breast Implant Illness. You have been invited because you responded to a recruitment advertisement.

2. **Who is conducting this research?**
   The study is being carried out by the following researchers: Dr Jill Newby, Chief Investigator (School of Psychology, Faculty of Science), Ms Maria Sharrock (St Vincent's Hospital Sydney), and Dr Kate Faasse (School of Psychology, Faculty of Science). **Research Funder:** This research is being funded by the Aesthetic Surgery Education & Research Foundation (ASERF).

3. **Inclusion/Exclusion Criteria**
   Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:
   - Females who have undergone breast implant surgery.
   - Have experienced negative physical or psychological effects of breast implants.
   - Are fluent in English

4. **Do I have to take part in this research study?**
   Participation in this research study is voluntary. If you do not want 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 study at any stage.

   If you decide you want to take part in the research study, you will be asked to:
   - Read the information carefully (ask questions if necessary);
   - Sign and return the consent form if you decide to participate in the study;
   - Take a copy of this form with you to keep.

5. **What does participation in this research require, and are there any risks involved?**

   If you decide to take part in the research study, we will ask you to complete online questionnaires, and a skype interview.

   We will ask you to complete two screening questions to assess whether you are eligible to participate in the study. If your responses indicate that you are eligible to participate, you will be asked to participate in a skype-based interview with a member of the research team. During the interview you will be asked questions about your surgical history with breast implant surgery, and your experiences of physical and psychological symptoms after surgery. It should take approximately 30 minutes to complete.

   To ensure we collect the responses accurately, we seek your permission to digitally record the interview using an audio recording. If you would like to participate but do not wish to be recorded, you will need to discuss the options for your participation with the research team.

At the conclusion of your participation, you will be offered reimbursement of $20AUD per hour for your participation. If the interview or questionnaires take longer than one hour to complete, you will be offered additional recompense at a rate of $20 per hour, calculated pro rata. This means that for every half hour you will receive $10AUD, for example, if you complete 1.5 hours, you will be reimbursed $30AUD in total.

If you experience discomfort or feelings of distress while participating in the research and you require support, you can stop participating at any time. You can also tell a member of the research team and they will provide you with assistance or alternatively a list of support services and their contact details are provided below.

6. What are the possible benefits to participation?

We hope to use information we get from this research study to benefit others who experience unwanted physical and psychological side effects after breast implant surgery. We also hope to learn more about Breast Implant Illness. By participating in this study, you may learn more about psychological research.

7. What will happen to information about me?

By signing the consent form you consent to the research team collecting and using information about you for the research study. Your data will be kept for a minimum of 5 years after the project's completion and publication of study results. We will store information about you in a de-identified format. Paper records will be stored at the School of Psychology, University of New South Wales. Electronic information will be stored in UNSW OneDrive. Please note, we will not provide you with transcriptions to check for accuracy.

Your information will be used for publications, including report of the key findings to the funding agency who provided grant funding for this study, and will be only made available in de-identified format. All information published will be done in a way that will not identify you.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan**.

8. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by including your details in the space provided in the consent form.

9. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively you can ring

the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney, or St Vincent's Hospital..
If you decide to leave the research study, the researchers will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project.

10. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Jill Newby
Position	Senior Lecturer
Telephone	02 9385 3425 or +61293853425 (from overseas)
Email	j.newby@unsw.edu.au

Support Services Contact Details

If at any stage during the study you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	Lifeline
Position	
Telephone	13 11 14
Email	

You will find a list of additional support services below:

- **Lifeline (free 24/7 counselling and support):**
  - USA: call 1800 273 8255
  - Australia: call 13 11 14
  - International: Visit the following website for a list of counselling services in your country: http://www.iasp.info/resources/Crisis_Centres/
- Contact your general practitioner/primary practitioner for support and guidance about your mental health.

What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC190578

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Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I understand that the research team will audio/video record the interviews; I agree to be recorded for this purpose.
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ 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 study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;
  Name: _____

  Address: _____

  Email Address: _____

- ☐ I understand that I can download a copy of this consent form from www.breastimplantstudy.com
- ☐ I agree to be contacted to participate in future studies.

Participant Details

Name of Participant (please type)	
Participant email address (if applicable)	
Date	

I agree, start questionnaire

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Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, St Vincent's Hospital, Sydney or ASERF. In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Dr Jill Newby
Email:	j.newby@unsw.edu.au
Phone:	02 93853425
Postal Address:	Technical Support Unit, Level 1 Mathews Building, UNSW Sydney, NSW, Randwick ,2052