

# PARTICIPANT INFORMATION SHEET

Project Study Title:

## Phase 3 Design & Prototype of EBP (External Breast Prosthesis) Incorporating 3D Printing Technology

### 1. Invitation to a Project Study



KUPPD® are a new breast prosthesis brand, who are collaborating with researchers in the Manchester Fashion Institute (Manchester Metropolitan University).

You are being invited to take part in an Advisory Group session for a Project Study titled 'Phase 3 Design & Prototype of EBP (External Breast Prosthesis) Incorporating 3D Printing Technology'.

Before you decide to do so, it is important you understand why the study is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything not clear or if you would like more information. Please take your time to decide whether you wish to take part.

We know we are all unique and when treatment for breast cancer changes the body, it can be a challenge to find a breast prosthesis. The study aims to improve breast prosthesis (EBP), wearing experiences and services. The results from this study will inform the development of products and services to better serve the breast cancer community.

### 2. Why have I been invited?

You are invited to take part as you participated in a project study titled '3D Scanning and Questionnaire for Post Mastectomy' in Aug/Sep 2022 and consented for us to keep in touch.

Given that the study has been developed to improve the types of breast prosthesis (EBP) available primarily for those who have undergone treatment in relation to breast cancer, it is important that participants are comfortable with handling breast prosthesis and discussing the prototypes in a supportive manner in a group environment.

We are looking for between 4 and a maximum of 12 participants for the Advisory Group Session.

### 3. Do I have to take part?

Your participation in this study is entirely voluntary and you have the right to contribute as much or as little as you wish. If you do decide to take part, you will be able to keep a copy of this Participant Information Sheet and Informed Consent Form and indicate your agreement on the Informed Consent Form provided.

You can still withdraw. You do not have to give a reason. If this is following the Advisory Group Session you may do so by emailing the MMU contact given later in this document.

#### **4. What will I be asked to do?**

You will be invited to come to a group session hosted at Manchester Metropolitan University, located in the centre of Manchester, Manchester Fashion Institute, Righton Building, Cavendish Street, M15 6BG. You will be met at the location and guided to the room. The session will involve you being in a group of between 4 and 12 ladies who participated in the earlier project, along with the facilitators and a representative of Kuppdd (Sarah Denise Studio Ltd) who commissioned this project.

You will have the opportunity to handle, discuss and we ask for you to give feedback on a small selection of prototypes of 3D Printed External Breast Prosthesis (EBP).

You may also be offered an option to try on one of the prototypes in a private dressing room area (this is subject to EBP availability and if you bring a suitable bra).

Before the start of the session, you will have time to re-read this Participant Information Sheet and Informed Consent Form, and to ask any questions.

Once you have signed the Informed Consent Form and you/the other participants are ready, we will ask you to choose a pseudonym (so that any information you provide will be anonymous).

At the start of the session, you will be introduced to the facilitators and how the session will run.

The session is planned to take approximately 2 hours overall. For your comfort, light refreshments will be provided. The session will include a feedback form to fill in.

#### **5. Are there any risks if I participate?**

We understand that participating in a study can raise sensitive issues. There are some links below for support groups/charities set up to help people affected by breast cancer, these are not affiliated with this study. If you have any concerns at all about any aspect of your breast cancer experience or wearing breast prosthesis, it is always best to start by talking to your GP or breast care team who can advise you on finding the help you need. Some links you may find useful are below:

1. Breast Cancer Care & Breast Cancer Now (Charity) <https://forum.breastcancernow.org>
2. Breast Cancer Haven (Charity) <https://www.breastcancerhaven.org.uk/>
3. Cancer Research UK (Charity) <https://www.cancerresearchuk.org>
4. Flat Friends (Charity) <https://www.flatfriends.org.uk>

Please do not take part if you feel that any element of this project study may not be right for you.

#### **Are there any advantages if I participate?**

Your participation will contribute towards understanding effective creation of EBP, methods and services utilising 3D technologies. It is hoped that this work will have a beneficial impact on the choices and wearing experiences of those who choose to wear a prosthesis following treatment.

## **FAQ's**

### ***Will I be compensated?***

*KUPPD@ are offering travel expenses reimbursed for your participation. Contact [sarah@kuppd.com](mailto:sarah@kuppd.com) for details, she will also be available on the day of the Advisory Group. Manchester Metropolitan University are not administering this as part of the study.*

### ***What is an Advisory Group?***

*The Advisory Group is where we ask you as a part of a group of people who participated in the earlier project, to come together to see, handle and take part in discussion and give feedback on the 3D Printed EBP prototypes.*

### ***Will you take any photos/recordings of the session?***

*No, we will not be taking photos or recording the session, the facilitators will be taking written/typed/drawn notes from observing your discussion, how you interact and handle (and wear where applicable) the EBP. We will be prompting/asking questions related to themes which arose during the previous project and during the session and facilitate it to keep on track for timing for your convenience.*

### ***Where will the scanning take place?***

*Participants will need to be able to travel to Manchester Fashion Institute at Manchester Metropolitan University, Righton Building, Cavendish Street, Manchester M15 6BG. KUPPD@ may be able to help securing travel and can be arranged by contacting [sarah@kuppd.com](mailto:sarah@kuppd.com). Travel and parking options can be discussed during booking with [j.mechan@mmu.ac.uk](mailto:j.mechan@mmu.ac.uk) (0161 247 2670).*

### ***What should I wear?***

*If you wish to have the option to try on one of the EBP (where available), it is important that you wear a bra that has a pocket for a breast prosthesis or something where the prosthesis would not sit against bare skin.*

*You may find it easier to wear something comfortable and a separate top from bottoms.*

### ***Will I be able to take a prototype home?***

*At this stage, no, as the prototypes are for feedback at the advisory group event only.*

### ***Who will be in the room with me?***

*The Advisory Group session will be facilitated by a minimum of two members of the study team including Sarah from KuppD. Please note that the study team may not identify as the same gender identity as you. If you are not comfortable with this, the study may not be right for you.*

### ***What if I come along with someone who isn't participating?***

*There is a general student open seating area close to the room (the refurbishment is complete!) if you arrive early or if you have someone with you and they are welcome to sit in this area whilst you participate.*

### ***Who is supporting this project?***

*The Project Study is a collaboration involving Sarah Cordery of Sarah Denise Studio Ltd (KUPPD®), Manchester Fashion Institute and PrintCity at Manchester Metropolitan University, and is part funded by European Regional Development Fund through Health Innovation Manchester, and partly through the founders' business, Sarah Denise Studio Ltd (KUPPD® founder).*

## **Informed Consent**

You can ask questions on initial contact, during and following the Advisory Group Session.

A copy of the Participant Information Sheet and Participant Informed Consent Form will be sent via email to volunteer participants prior to attending the Advisory Group Session. This will allow you to digest the information to see if the study is of interest and whether you will be willing to take part.

- You will be provided with the opportunity to ask questions via email/phone prior to attending.
- The Advisory Group feedback is gathered using the pseudonym you provide and may be used as research outputs which may be published in journals or conferences at a later date and used by Sarah Denise Studio Ltd (KuppD®) for the purposes of designing and marketing breast prosthesis/mastectomy bras, products and services.

## **What information about me will you collect and why?**

- a) We will use your name, age group, location, gender identity, ethnic group that you provided and consented in the earlier project including contact email to book you in for the Advisory Group session, to keep you up to date with the study and invite you to potential future project phases or research. We will ask your ethnicity to ensure the study is representative of the general UK population. This information is known as Recruitment Data.
  
- b) All feedback during the Advisory Group session will be anonymous.

## **How will my information be stored and how will you look after it?**

The MMU Project Study Team will store your Recruitment Data, and Advisory Group feedback data on a secure MMU Project Specific Research Data Storage Area.

The MMU Project Study team will be responsible for this and give access to Sarah Cordery of Sarah Denise Studio Ltd (KuppD®) who will be the owner of the recruitment, anonymised Advisory Group data.

## How will you use my information?

The results of this study will inform future research, teaching, designs, prototypes, and services.

The findings and analysis may also be published in academic journals, presented at relevant conferences or events.

If you would like to be informed of the outcomes of this Project Study or other related future opportunities in relation to the study and have given us your informed consent, we may use your provided contact information to contact you later to invite your further participation.

## Will my data be sent anywhere else, or shared with other people or organisations?

Your contact information (known as recruitment data) and anonymised Advisory Group feedback will be made available to Sarah Cordery of Sarah Denise Studio Ltd (Kuppd®).

## When will you destroy my information?

Data will be kept for the duration of the project and up to 10 years following the project completion. At this point the data will be archived following MMU Data Regulations and Guidelines.

## Data Protection Law

Data protection legislation 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.' If we use more sensitive information about you, such as information about your health, religion, or ethnicity (called 'special category' information), our basis lies in research in the public interest. Manchester Metropolitan is the Controller for this information and is responsible for looking after your data and using it in line with the requirements of the data protection legislation applicable in the UK.

You have the right to make choices about your information under the data protection legislation, such as the right of access and the right to object, although in some circumstances these rights are not absolute. If you have any questions, or would like to exercise these rights, please contact the researcher or the University Data Protection Officer using the details below.

You can stop being a part of the study at any time, without giving a reason. You can ask us to delete your data at any time, but it might not always be possible. If you ask us to delete body scan information up to 2 weeks from attending the body scanning data gathering, we will make sure this is done. If you ask us to delete data after this point, we might not be able to. If your data is anonymous, we may not be able to withdraw it, because we will not know which data is yours – this applies to the questionnaire data.

## What will happen to the results of the Project Study?

MMU Project Study team will store and give access to the results of the Project Study to Sarah Cordery of Sarah Denise Studio Ltd (Kuppd®) for the purposes of developing 3D printed breast prosthetic prototypes, and related products and services.

Anonymous and anonymised results, findings and analysis may be published in relevant peer reviewed journals and may be used for teaching purposes and future opportunities for research.

### Who has reviewed this Project Study?

Manchester Metropolitan University (MMU) Ethics Committee.

### Who do I contact if I have concerns about this study or I wish to complain?

MMU Principal Investigator (Research Lead) Jayne Mechan, Senior Lecturer Fashion Technology, Manchester Fashion Institute. [J.mechan@mmu.ac.uk](mailto:J.mechan@mmu.ac.uk) 0161 247 2670

MMU Barbara Shepherd (Project Commercial Lead/Client Liaison) Manchester Fashion Institute. [B.shepherd@mmu.ac.uk](mailto:B.shepherd@mmu.ac.uk) 0161 247 4618

MMU Arts & Humanities Ethics Department. [artsandhumanitiesethics@mmu.ac.uk](mailto:artsandhumanitiesethics@mmu.ac.uk)

Collaborator Sarah Cordery of Sarah Denise Studio Ltd (KUPPD®) [sarah@sarahdenisestudio.com](mailto:sarah@sarahdenisestudio.com), [sarah@kuppd.com](mailto:sarah@kuppd.com)

**Manchester Metropolitan Data Protection Officer** [dataprotection@mmu.ac.uk](mailto:dataprotection@mmu.ac.uk)

Tel: 0161 247 3331 Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH

### UK Information Commissioner's Office

You have the right to complain directly to the Information Commissioner's Office if you would like to complain about how we process your personal data:

<https://ico.org.uk/global/contact-us/>

**THANK YOU FOR CONSIDERING PARTICIPATING IN THIS PROJECT**