Evaluating a new patient-reported outcome questionnaire to assess the outcomes of prolapse, incontinence and mesh complication surgery as part of the APPRAISE Study

APPRAISE

PARTICIPANT INFORMATION SHEET

1. STUDY OVERVIEW

Different surgical treatments are available to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). One of these treatments uses mesh which for some has led to complications requiring further corrective surgery. This research is being carried out to help us develop a new patient-reported outcome questionnaire for women who have had surgery for pelvic organ prolapse (POP), stress urinary incontinence (SUI), and/or mesh complications. This new questionnaire will support women to report the effects of pelvic floor surgery on their quality of life, and will provide a way that surgery outcomes, risks and benefits can be measured and compared.

2. WHY AM I BEING ASKED TO TAKE PART?

You are being asked to take part because you are someone who has undergone pelvic floor surgery for either pelvic organ prolapse, urinary incontinence and/or mesh complications. We are developing a new questionnaire to help us understand patient experiences of pelvic floor surgery and its impacts on quality of life, and we would like to test the first version of this questionnaire to see how well it works. The questions have been developed following interviews with women who have had surgery for POP, SUI and/or mesh complications.

3. WHAT AM I BEING ASKED TO DO?

You are being asked to complete the first version of the new questionnaire which will ask you about your experiences of pelvic floor surgery and the impact that it has had on your quality of life and the symptoms you have experienced. Examples of issues you may be asked about include: pain, discomfort, fatigue, physical functioning, emotional wellbeing, relationships with others, and sexual functioning. The questionnaire will also include some demographic questions (e.g. age, ethnicity). Completing the questionnaire will take **approximately 10-15 minutes**, and you can choose to complete it either **online** or **on paper**.

4. WHAT WILL BE DONE WITH MY INFORMATION?

Once a large number of people have completed the first version of the questionnaire, we will run statistical tests to help us to reduce the number of questions and evaluate its reliability and validity. The findings will help us to refine

the final version of the questionnaire. All the information you provide will be treated securely and confidentially. During the study, the information will be stored securely on password-protected computers, in restricted access folders. We will never use your name or any identifying details. We will give your data an identification number and remove personal information so that no one outside of the research team will be able to identify you from the data. Exceptions to confidentiality will only be made if you tell us something to suggest that you or another person was at significant risk of harm. We will also use the information generated in this study to write research papers, reports and presentations, but this will also not contain any identifiable information and your identity will not be revealed. At the end of the APPRAISE study, we will continue to securely store the information we have collected as part of the study confidentially and securely at Leeds Beckett University for 30 years. We may also make anonymised data collected from the questionnaires publicly available for research, but it will not contain any identifiable information and your identity will not be revealed. If you would like to be sent a summary of the findings when the study is complete, please indicate this on the consent form and provide your preferred contact details to do so. We may also contact you with information about participating in future ethically-approved research related to this study – but you can opt out of this if you wish on the consent form. To understand how we collect, look after and share your data, you should read the data protection information at the end of this document.

5. DO I HAVE TO TAKE PART?

No, you do not have to take part. Taking part is entirely up to you. Your decision not to take part in this study will not affect any care you are receiving. If you do take part, you can skip any questions you'd prefer not to answer. If you do decide to take part in the study, you will be asked to sign a consent form. If there is anything in this Participant Information Sheet that is not clear or you would like more information, please contact the Research Officer or Chief Investigator for the study (contact details can be found at the at the end of this document).

6. WHAT IF I CHANGE MY MIND?

If you decide to take part, you can stop completing the questionnaire at any time. You can also choose to withdraw your data from the study completely up to 2 weeks after completing the questionnaire. We may ask you why you are choosing to withdraw, so that we know how to improve our research in future. However, you do not have to give a reason if you do not wish to. Your decision to withdraw from the study will not affect your medical care in any way. Please contact the Research Officer, Cat Brooke, using the contact details at the bottom of this information sheet if you wish to withdraw your data from the study.

7. WHAT ARE THE BENEFITS AND RISKS?

There are no direct benefits to participating in the research. However, by taking part, you might help improve the care of people who may have to undergo surgery for pelvic floor conditions such as prolapse and incontinence, or for mesh complications. The new questionnaire will provide a way that patient outcomes, risks and benefits of the different surgical treatments for POP, SUI and mesh complications can be measured and compared. The findings will also help inform and support healthcare professionals and policy makers to improve health services.

Completing the questionnaire is not expected to cause distress. However, if you do find answering some of the questions upsetting, you can take a break or choose to stop taking part in the study. If any safeguarding issues arise that cause concern for your safety or that of someone else, the Leeds Beckett Nominated Safeguarding Officer may be consulted.

8. WHO HAS APPROVED THIS RESEARCH?

The study has been checked and reviewed by the NHS Research Ethics committee and Leeds Beckett University ethics committee too. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Leicester South Research Ethics Committee.

9. WHAT IF I NEED MORE INFORMATION OR THERE IS A PROBLEM?

If you need more information before making a decision, please get in touch with members of the study team using the contact details below. If you have any complaints, please contact the independent representative at Leeds Beckett University, Dr Lauren Smith at L.M.Smith@leedsbeckett.ac.uk.

If you have any questions or concerns, please speak to one of the research team.

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If you require any further support, you can access advice or support at:

- **The MASIC Foundation:** https://masic.org.uk/ | phone: 0115 937 5934 | admin@masic.org.uk
- **Bladder and Bowel:** https://www.bbuk.org.uk/ |phone: 0161 214 4591

If you have specific questions about your healthcare or treatment, please contact the clinical nurse specialist or the named contact at the hospital where you received treatment.

10. HOW DO I TAKE PART?

You can choose to complete the questionnaires either **online** or **on paper.**

If you would like to complete the questionnaire online, please go to the below link on your device (computer, phone or tablet) **or** scan the QR code. You will, again, be shown this Information Sheet, before being asked to complete the Consent Form. After providing your consent to take part in the study, you will be directed to the questionnaire to complete.

For the online version of the questionnaire, follow the below link:
https://leedsbeckettpsych.eu.qualtrics.com/jfe/form/SV_6umU3N3vkfFFpBQ

Or, scan the QR code:

If you would prefer to complete the questionnaire on paper, please complete **both** the printed Consent Form and the questionnaire included within this information pack, and return them to our research team in the post using the return envelope and stamp provided. If you'd prefer, you can also choose to return these (sealed in the envelope) directly to the health care professional who told you about this study. They will then return them to our team.

DATA PROTECTION

How will we use information about you?

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.' Leeds Beckett University is the data controller and is responsible for looking after your information and using it properly. For further information in how they use and process your data please visit the University Privacy Notice.

We will need to use information from you in order to undertake this research study. This will include the information you provide on the consent form (e.g., your name, email address, postal address, and phone number) and on the questionnaire. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will use the minimum personally-identifiable information possible. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique identification number instead. We will keep all information about you safe and secure.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have (unless you contact us to ask us to withdraw your data). You can withdraw from the study up to

2 weeks after completing the questionnaire. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Once we have finished the study, we will store the information you have provided securely at Leeds Beckett University for 30 years so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We may also make fully anonymous information collected from the questionnaires publicly available for research, but it will not contain any identifiable information and your identity will not be revealed. This data will be deposited securely on the Thesis and Research Data Repository at Leeds Beckett University indefinitely.

You can find out more about how we use your information:

1. At www.hra.nhs.uk/information-about-patients/

2. Our leaflet available from www.hra.nhs.uk/patientdataandresearch

3. By asking the project officer or Professor Georgina Jones (see contact details above)

4. By emailing the Leeds Beckett University Data Protection Officer at DPO@leedsbeckett.ac.uk