



## **PARTICIPANT INFORMATION SHEET**

### **Fear of childbirth: Improving identification in maternity services (FOCUS 2)**

You are invited to take part in a research project. Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. Please read the following information carefully.

#### **What is the purpose of the study?**

How women and birthing people feel about birth when they are pregnant is very varied. Some women may be quite fearful and this can be distressing during pregnancy. Identifying fear of childbirth early in pregnancy is important, as it can help people to access the appropriate support.

At the moment there are no acceptable and accurate questionnaires to measure this. A new measure, the Fear of Childbirth Questionnaire, has been recently developed specifically for women in the UK. We want to check how we can use this to identify women and birthing people with mild and more severe levels of fear by comparing scores with a brief interview. We also want to check if it gives results that are the same over several weeks during pregnancy. The findings from this study aim to improve our ability to identify fear of childbirth and help women and birthing people get support where needed.

#### **Why have I been invited to take part?**

You have been invited to participate because you are aged 18 years or above and are not more than 16 weeks pregnant. You will also need to have a good understanding of the English language.

#### **Do I have to take part?**

No. It is up to you to decide whether or not you are willing to be involved. If you are willing, you will be asked to complete a consent form. You may withdraw from the study at any time, without giving any reason, before submitting the survey responses. If a participant loses capacity, data which is not identifiable to the research team may be retained.

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

Taking part in this study involves two steps.

Step 1) You will be asked to complete an online survey. This will ask questions about you, your pregnancy and any previous experience of birth (if relevant). There will be some questions about how you feel about giving birth, the Fear of Childbirth Questionnaire, and other measures relating to general feelings of anxiety and depression. This survey will take around 15 minutes to complete.

Step 2) 60 participants will be randomly selected to complete the study questionnaire again. Otherwise, you will be contacted by a member of the research team to take part in a telephone interview at a time that is suitable for you. This telephone interview will include some questions about how you feel about childbirth, in particular, if there are any elements of birth that you are worried about. The interview will take around 20 minutes to complete.

For some participants, there may be a change of circumstances between completing the first survey which might mean that you are no longer able to complete the second part of the study. If this is the case, we will apologise for contacting you and we can signpost support services to you as required.

**Are there any potential risks in taking part?**

Some of the questions in the survey touch on sensitive topics relating to mental health, pregnancy and childbirth. There may be potential for some of these questions to highlight existing stress. You do not have to answer questions that you feel uncomfortable with, and you do not need to explain why a question has not been answered.

If you feel distressed during a telephone interview, you will be asked whether you would like to pause the interview, move on to another question, or complete the interview at a different time. We can also contact a friend or family member on your behalf for support. The researcher can signpost you to relevant support services if you feel like you would benefit from additional support. You will be advised to contact your midwife for onward referral if we have concerns regarding your mental well-being.

**Are there any benefits to taking part?**

Although there are no direct benefits for you in taking part, we hope that by exploring this new tool for fear of childbirth we can improve our ability to identify individuals who may benefit from further support throughout their pregnancy.

**Are there any payments, reimbursements of expenses or any other benefit or incentive for taking part?**

Participants who complete the telephone interview will receive a £10 voucher as reimbursement for their time.

**How will we use information about you?**

We will need to use information from you. This information will include your name, email address and telephone number. We will use this information to do the research. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data 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.

**What are your choices about how your information is used?**

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. 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.

**Where can you find out more about how your information is used?**

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

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- by asking one of the research team
- by sending an email to UWE Bristol's research governance manager ([researchgovernance@uwe.ac.uk](mailto:researchgovernance@uwe.ac.uk)).

Personal data will be deleted after the completion of Step 2. If you participate in a telephone interview, this will be audio recorded. Following the telephone interview, this recording will be transferred onto a secure University drive and then deleted from the recording device. Recordings transferred onto the secure University drive will be destroyed after 5 years. Any

personally identifiable information will be removed from interviews. Anonymised data generated from this research needs to be kept for a minimum of 5 years.

**Where will the results of the research study be published?**

A report will be written containing our research findings. This report may include direct quotes in an anonymised format. This report will be available on the University of the West of England's open-access Research Repository and provided to our research finder. No individual will be identifiable in any output. Findings will be published in peer-reviewed scientific journals and presented at conferences. A summary of findings will be available for all research participants if you would like to see it.

**Who is organising and who is funding the study?**

This study is organised by the University of the West of England (UWE) Bristol, University of Liverpool and Liverpool Women's Hospital. The study is funded by a National Institute for Health and Care Research (NIHR) Research for Patient Benefit grant (NIHR203154).

**Who has ethically approved this research?**

This project has been reviewed and approved by an NHS Research Ethics Committee (23/SW/0015). It is sponsored by the University of the West of England (315121).

**Whom do I contact if I have a concern about the study or I wish to complain?**

If you have a concern about any aspect of the study, please contact the Lead Researcher, Rebecca, or Research Midwife, Maya. If you remain unhappy or wish to make a formal complaint, please contact the Chief Investigator Dr Kayleigh Sheen. You can also contact UWE Bristol's research governance manager ([researchgovernance@uwe.ac.uk](mailto:researchgovernance@uwe.ac.uk)).

**Data Protection:**

The University of the West of England (UWE), Bristol, University of Liverpool, and Liverpool Women's Hospital are joint data controllers for your personal data.

**Contact details:**

Chief Investigator: Dr Kayleigh Sheen  
Email address: [kayleigh.sheen@uwe.ac.uk](mailto:kayleigh.sheen@uwe.ac.uk)

Research Midwife: Maya Sacks  
Email address: [maya.sacks@lwh.nhs.uk](mailto:maya.sacks@lwh.nhs.uk)

Lead Researcher/Research Associate: Dr Rebecca Hunter  
Email address: [rebecca.hunter@liverpool.ac.uk](mailto:rebecca.hunter@liverpool.ac.uk)

## **Privacy Notice for Research Participants – Fear of childbirth: Improving identification in maternity services (FOCUS 2)**

### **Purpose of the Privacy Notice**

This privacy notice explains how the University of the West of England, Bristol (UWE Bristol) collects, manages and uses your personal data before, during and after you participate in **FOCUS 2**. 'Personal data' means any information relating to an identified or identifiable natural person (the data subject).

This privacy notice adheres to the General Data Protection Regulation (GDPR) principle of transparency. This means it gives information about:

- How and why your data will be used for the research;
- What your rights are under GDPR; and
- How to contact UWE Bristol and the project lead in relation to questions, concerns or exercising your rights regarding the use of your personal data.

This Privacy Notice should be read in conjunction with the Participant Information Sheet and Ethical Consent Form provided to you before you agree to take part in the research.

### **Why are we processing your personal data?**

UWE Bristol undertakes research under its public function to provide research for the benefit of society. As a data controller we are committed to protecting the privacy and security of your personal data in accordance with the (EU) 2016/679 the General Data Protection Regulation (GDPR), the Data Protection Act 2018 (or any successor legislation) and any other legislation directly relating to privacy laws that apply (together "the Data Protection Legislation"). General information on Data Protection law is available from the Information Commissioner's Office (<https://ico.org.uk/>).

### **How do we use your personal data?**

We will only process your personal data when the law allows us to. In addition, we will always comply with UWE Bristol's policies and procedures in processing your personal data. Our lawful basis for using your personal data for research purposes is fulfilling tasks in the public interest, and for archiving purposes in the public interest, for scientific or historical research purposes. Our lawful basis for using your special category personal data for research purposes is Article 9 (j) Archiving, research and statistics (with a basis in law) by virtue of paragraph 4 of Schedule 1 of the DPA 2018.

You can find out more information about lawful bases at the following webpage:

<https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/>

We will always tell you about the information we wish to collect from you and how we will use it. We will not use your personal data for automated decision making about you or for profiling purposes.

The research team adhere to the principles of the General Data Protection Regulation (GDPR).

### **What data do we collect?**

The data we collect will vary from project to project. Researchers will only collect data that is essential for their project. The specific categories of personal data processed are described in the Participant Information Sheet provided to you with this Privacy Notice.

### **Who do we share your data with?**

IRAS ID: 315121

Research Ethics Committee Reference Number: 23/SW/0015

We will only share your personal data in accordance with the attached Participant Information Sheet.

### **How do we keep your data secure?**

We take a robust approach to protecting your information with secure electronic and physical storage areas for research data with controlled access. Access to your personal data is strictly controlled on a need to know basis and data is stored and transmitted securely using methods such as encryption and access controls for physical records where appropriate.

Alongside these technical measures, there are comprehensive and effective policies and processes in place to ensure that those who process your personal information (such as researchers, relevant University administrators and/or third-party processors) are aware of their obligations and responsibilities for the data they have access to.

By default, people are only granted access to the information they require to perform their duties. Mandatory data protection and information security training is provided to staff and expert advice is available if needed.

### **How long do we keep your data for?**

Your personal data will only be retained for as long as is necessary to fulfil the cited purpose of the research. The length of time we keep your personal data will depend on several factors including the significance of the data, funder requirements, and the nature of the study. Specific details are provided in the attached Participant Information Sheet.

Anonymised data that falls outside the scope of data protection legislation as it contains no identifying or identifiable information may be stored in UWE Bristol's research data archive or another carefully selected appropriate data archive.

### **Your Rights and how to exercise them**

Under the Data Protection legislation, you have the following **qualified** rights:

- (1) The right to access your personal data held by or on behalf of the University;
- (2) The right to rectification if the information is inaccurate or incomplete;
- (3) The right to restrict processing and/or erasure of your personal data;
- (4) The right to data portability;
- (5) The right to object to processing;
- (6) The right to object to automated decision making and profiling;
- (7) The right to [complain](#) to the Information Commissioner's Office (ICO).

We will always respond to concerns or queries you may have. If you wish to exercise your rights or have any other general data protection queries, please contact UWE Bristol's Data Protection Officer ([dataprotection@uwe.ac.uk](mailto:dataprotection@uwe.ac.uk)).

If you have any complaints or queries relating to the research in which you are taking part please contact either the research project lead, whose details are in the attached Participant Information Sheet or UWE Bristol's research governance manager ([researchgovernance@uwe.ac.uk](mailto:researchgovernance@uwe.ac.uk)).