



## **Appx 07: PARTICIPANT INFORMATION SHEET**

### **Giving a Voice to Parents of Children with FASD – Project 3: Experiences of Pregnancy and Raising a child with FASD**

You are being invited to take part in research on your experiences of pregnancy and raising a child with FASD. Stewart McDougall, Research Fellow, at the University of Edinburgh is leading this research. Before you decide whether to take part it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

#### **What is this research about?**

This research aims to understand what it's like for parents during pregnancy and raising a children with FASD. The experiences of biological parents with children who have FASD are not often studied, but it's important to share their voices and experiences to improve services.

#### **Who can participate?**

Biological parents of individuals diagnosed with or suspected of having Fetal Alcohol Spectrum Disorder.

#### **Do I have to participate?**

No – it is entirely up to you. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect your job or healthcare.

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

If you do decide to take part, please keep this Information Sheet. You will be asked to complete an Informed Consent Form to show that you understand your rights in relation to the research, and that you are happy to participate.

You'll be invited to have an interview with a researcher. It can be face-to-face or online, whichever you prefer. You can ask for a male or female interviewer, depending on what makes you most comfortable.

During the interview, we'd like to ask about your pregnancy, what you, and your family and friends, knew about alcohol use during pregnancy, and what others told you. Additionally, we'd like to know about raising a child with FASD. The interview will take about 1 hour. We would like to audio record your responses and will seek your consent for this. The audio recording will be transcribed by a third-party contractor selected among approved UoE providers with your consent, or by a member of the research team.

#### **Are there any benefits?**

You'll receive a £30 Love2Shop ([www.love2shop.com](http://www.love2shop.com)) gift voucher for the interview.

If you come to a face-to-face interview, we'll pay for your transportation (up to the value of £100) and provide refreshments.

This study may also have indirect benefits by improving the understanding the experiences of birth parents with children diagnosed with or suspected of having FASD, so that we can improve policies and support families and individuals better.

#### **Are there any possible risks or disadvantages to taking part?**

There are no significant risks associated with participation. However, we know talking about fetal alcohol spectrum disorder and alcohol use during pregnancy can be tough. This study aims to understand the experiences of birth parents during pregnancy and raising a child with FASD.

If you feel unhappy or distressed during the interview, we'll stop and check if you want to continue. You can choose to take a break, reschedule the interview, or stop participating and not come back. You can also bring a support person like your partner, a trusted friend, or a social worker to the interview if you want. The researcher will attempt to contact you again 24 to 48 hours after the interview to check in.

If you share something during the interview that suggests your safety or others' safety may be at risk (like experiencing family violence), or talk about criminal activity, the researcher may need to report it to the appropriate authorities to address the risk. The researcher will discuss with you how to handle these concerns, involving you and supporting you as needed.

### **Can I change my mind?**

Participating is your choice, and you can leave anytime. If you decide to stop, you can choose whether the things you shared up until that point can be used by the research team or deleted.

### **Will my participation be kept confidential?**

Yes, your participation will be kept confidential. All the information collected during interviews and focus groups will be handled following the General Data Protection Regulations. It will be stored securely in a protected data centre that meets UK standards.

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

We will need to use information from you for this research project.

This information will include your name and contact details. People will use this information to do the research.

We will keep all information about you safe and secure.

We'll use a unique participant number, not your name, to identify your data. Electronic data will be on a password-protected computer, and paper records will be locked in a filing cabinet. Your consent information will be separated from your responses to reduce risk. After the study, we'll keep some data for result verification. We'll make sure no one can tell you took part in the study from the reports. The key linking your identifiable information to your responses will be stored for three months after the transcript has been sent to you, to allow us to identify your data should you wish to withdraw your consent. After this time, your personal information and the key will be permanently deleted.

### **What choices do I have about how my information is used?**

You can stop participating anytime without giving a reason, and you can decide what happens to the data you already provided. We ask that you contact the research team within 3 weeks of receiving your transcript to decide whether you wish to withdraw your data.

### **Where can I learn more about how my information is used?**

You can find more information about how we use your data at <https://www.ed.ac.uk/records-management/privacy-notice-research> or by contacting the research team or the University of Edinburgh Data Protection Officer at [dpo@ed.ac.uk](mailto:dpo@ed.ac.uk).

The University of Edinburgh is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Edinburgh will keep the anonymised information for 5 years after the study has finished and, with your consent, the data may also be used in future ethically-approved studies. A digital copy of your consent form will be stored for 5 years, with no means of linking this with your de-identified interview transcript.

**What happens after the study?**

Once the study is done, the researchers will write a report summarising the findings. You won't be identifiable in any report or publication. The report may be published in a scientific journal or presented at conferences. We'll talk to the group about other ways to share the research, like with the Scottish Government and third sector organizations. You can request a copy of the study summary or access it on our webpage, likely in Spring 2025. Should you wish to receive a copy of the study findings directly, we will ask you to provide an email or postal address for us to send this to. We will delete this information upon sending the summary to you.

**Who's organizing and funding the research?**

The Fetal Alcohol Advisory, Support, and Training team organized this study, sponsored by the University of Edinburgh, and funded by the Scottish Government.

**Who has reviewed the study?**

This project has been approved by the Ethics Review Committee at School of Health in Social Science at the University of Edinburgh.

If you would like further information, please contact the Chief Investigator:

Dr. Stewart McDougall, University of Edinburgh at [smcdouga@ed.ac.uk](mailto:smcdouga@ed.ac.uk)

If you would like to discuss the project with someone independent of the study, please contact:

Dr. Angus MacBeth, University of Edinburgh at [angus.macbeth@ed.ac.uk](mailto:angus.macbeth@ed.ac.uk)

If you would like to make a complaint about the study, please contact:

Professor Matthias Schwannauer at [headofschool.health@ed.ac.uk](mailto:headofschool.health@ed.ac.uk)

**You can also visit the study's webpage here:**

<https://www.faast.ed.ac.uk/our-services/research/research-opportunity-giving-a-voice-to-parents-of-children-with-fetal-alcohol-spectrum-disorder/>

### Participant Consent Form (Administered via Qualtrics)

**Title of Study:** Giving a Voice to Parents of Children with FASD – Project 3: Experiences of Pregnancy and Raising a child with FASD

If online: Please indicate that you have read and agree to each statement by ticking the box. If you do not wish to participate, please decline participation by clicking on the "disagree" button, which will redirect you to the debrief page or exit the survey by closing your browser.

If in person: Please indicate that you have read and agree to each statement by initialling the box and signing where indicated below.

- |    |  |                          |
|----|--|--------------------------|
| 1. | I confirm that I read and understand the information sheet (version 5, dated 5 <sup>th</sup> October 2023) for this study.   | <input type="checkbox"/> |
| 2. | I have been given the opportunity to consider the information provided, ask questions and have had these questions answered to my satisfaction.  | <input type="checkbox"/> |
| 3. | I understand that my participation is voluntary and that I can withdraw from the study at any time without giving a reason and without my job or healthcare being affected.  | <input type="checkbox"/> |
| 4. | I understand that I have three weeks from receiving my transcript to request my data be withdrawn.   | <input type="checkbox"/> |
| 5. | I understand that my anonymised data will be stored for 5 years and may be used in future ethically approved research.   | <input type="checkbox"/> |
| 6. | I understand that the key linking my responses to identifiable information will be stored for three months, after which this will be deleted   | <input type="checkbox"/> |
| 7. | I agree to my interview being audio recorded.  | <input type="checkbox"/> |
| 8. | I agree to my audio recorded interview being transcribed by a third party contractor. <i>If you do not consent, the interview will be transcribed by a member of the research team.</i>  | <input type="checkbox"/> |
| 9. | I understand that relevant sections of my data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh) where it is relevant to my participation in this research. I give permission for these individuals to access my data. | <input type="checkbox"/> |

I agree to the above points and agree to participate in the above research study.

Agree

Disagree

If consent is online: If you do not wish to participate, please decline participation by clicking on the "disagree" button, which will redirect you to the debrief page or exit the survey by closing your browser.

(The below signature spaces can be replaced by the above tick box, if Consent is online)

Name of person giving consent

Date

Signature

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Name of person taking consent

Date

Signature

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

(Remove the following instructions if Consent is online: 1x original – into Site File; 1x copy – to Participant)