Are you a radiographer involved in obstetric ultrasound?

Researchers at the University of Oxford are recruiting participants for focus group discussions about their experiences providing antenatal scans. Participants will be asked to describe the beneficial and harmful aspects of the current screening system and will receive a payment for their contributions to the project. If you are interested in learning more, visit https://www.npeu.ox.ac.uk/valentia/we-need-your-help or contact Dr. Ashley White at ashley.white@phc.ox.ac.uk

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Valuing the benefits and harms of antenatal and newborn screening programmes (VALENTIA)

Participant Information Sheet

Central University Research Ethics Committee (CUREC) Approval Reference: [Insert]

Thank you for getting in contact with us about our research. My name is Ashley White and I am a researcher working at the Nuffield Department of Primary Care Health Sciences, at the University of Oxford. We are writing to invite you to take part in an interview for a research project based at the University of Oxford. This sheet explains the purpose of the project and what we are inviting you to do. Before you decide if you want to take part or not, we would like to tell you why the research is being done, and what you can expect if you take part. You are under no obligation to take part.

Please read this sheet carefully and feel free to ask any questions.

1. *Why is this research being conducted?*

During pregnancy, women and their partners are offered the choice to participate in a range of screening tests for their unborn baby. These antenatal screening tests are designed to see if there is a higher chance of a genetic or physical condition and allow parents to make informed decisions about what to do next. Additional tests are also offered for newborn babies within the first few weeks of their birth. These screening tests are designed to see if babies have a genetic or physical condition and to try to give babies earlier, potentially more effective treatment.

People think about screening tests in different ways, and there can be both positive and negative aspects to these tests. The purpose of this study is to find out how people think about and use, or do not use, screening tests in the United Kingdom. Findings from this study will be used to develop recommendations for things health care providers should consider about screening programmes.

2. *Why have I been invited to take part?*

You are being asked to take part in this study because you are a health care professional involved in screening programmes. We are conducting a series of online focus groups and individual interviews with health care professionals whose work deals with available antenatal and newborn screening tests. We will be asking you to:

- Share your experiences of providing screening tests.
- Talk about your opinions of screening tests.
- Describe both good and bad experiences you have had administering screening tests.

Up to 20 people will take part in online focus groups or individual interviews this summer. At the moment we are looking for participants who:

- Are involved with screening programmes in a professional capacity
- Live in the United Kingdom
- Are over 18 years old

We are interested in hearing about your experiences with antenatal and newborn screening tests. We seek to hear a broad range of experiences. If you are willing to share your thoughts and experiences with us, then we would like to hear from you.

3. *Do I have to take part?*

No. You can ask questions about the research before deciding whether or not to take part. If you do agree to take part, you may withdraw yourself from the study, without giving a reason, by advising us of this decision. If you wish to leave during the study, you are free to do so. If you want us to, we can make every effort to delete your interview transcript and information for up to six months after the end of the study.

4. *What will happen to me if I take part in the research?*

If you would like to take part, you will be asked to complete and send back the attached screening questionnaire by email or pre-paid envelope in the post. We will contact you to see if you are available for an online focus group or individual interview. You can ask us any questions you may have at this stage. If you do decide to take part, we will give you a consent form to sign before the interview or focus group takes place. If the interview is conducted over the phone or web conference we will also read you a series of statements to confirm that you still wish to participate and to ask if we can record the conversation.

You will be asked to:

- Share your experiences of providing screening tests.
- Talk about your opinions of screening tests.
- Describe both good and bad experiences you have had administering screening tests.

You will be given a fake name to be used for all study-related activity; nobody but the research team will know your identity.

If you are willing to take part in a focus group, you will join 2-4 other healthcare professionals and 2 researchers for a Microsoft Teams web meeting. You will have the option of using video or just audio. The focus group will last approximately 90 minutes and cover topics such as: experiences with screening programmes, the benefits and harms of screening programmes, and opportunities for improvement. Because we want to pick up everything that people say in the interview, we would like to audio record the conversations. The audio recording will be used to create a typed transcript of the conversation. We would also like to take a video recording so that we can capture who said what. The video recording will only be used to check the accuracy of the typed transcript. It will be deleted immediately upon revising the transcript.

If you do not want to discuss their experiences in a focus group, we can arrange an individual interview. Interviews can take place over the phone, over a web conference, or in-person. The researcher will ask a series of questions about your experiences with and opinions about antenatal or newborn screening programmes. Because we want to pick up everything that people say in the interview, we would like to record the conversations. Researchers will analyse what was said to find out what the important issues are for people who are involved with screening tests during pregnancy or after birth. Interviews will last approximately one hour.

5. Are there any potential risks in taking part?

There is a risk that you may become emotionally distressed talking about these experiences. You can take breaks or completely stop participating altogether. We will also provide a list of support resources for you to access. If you decide to take part in the project, you can withdraw at any point before, during, or after the focus group or interview.

There is also a risk of breach of confidentiality, however, we will do our best to ensure that confidentiality is maintained. You will be identified only by a pseudonym on all documents and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be de-identified as soon as it is practical to do so. Whilst confidentiality will be given the utmost priority within this research project, there will be limits to how far this confidentiality can be guaranteed. If disclosures are made within the interview or focus group, which suggest that you are at substantial risk of harm (whether from yourself or someone else), then action will be taken. This action may include contacting relevant health care professionals or agencies (e.g., social care services) as appropriate.

6. Are there any benefits in taking part?

The benefits of taking part are that people often say they have found the experience rewarding. People may be motivated to take part because they want a chance to influence the way screening tests are implemented and offered in the United Kingdom.

7. Expenses and payments

Participants will receive a £20 voucher to say thank you for their time, even if they withdraw during the study.

8. What happens to the data provided?

The information you provide during the study is the **research data**. Any research data from which you can be identified (such as your name, contact details, audio recording) is known as **personal data**. This includes more sensitive categories of personal data such as your racial or ethnic origin, sexual orientation, or data concerning your health.

Personal / sensitive data will be stored on a secure computer server or locked cabinets at the Nuffield Department of Primary Care Health Sciences, University of Oxford. Electronic data will be password protected. Only the research team will have access to the data. We will keep screening questionnaires and audio files from individual interviews until the end of the study in March 2021. We may keep contact details for up to 6 months after the study has finished in case we need to get in touch with participants.

Other research data (including consent forms) will be securely at the University of Oxford for 10 years for future analysis if further research questions arise.

The research team will have access to the research data. Audio recordings of interviews will be given to a typist who will type out everything as it was said the interview. The typist signs an agreement to keep everything they have typed confidential. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research.

9. Will the research be published?

The research may be published in a peer review journal. The researchers will also write a report for the National Institute of Health Research. The researchers may use quotes in their reports but will only use the fake names of participants.

10. Who is funding the research?

The research is funded by the National Institute of Health Research. It is part of a larger study about the potential benefits and harms of antenatal and newborn screening.

11. *Who has reviewed this study?*

This study has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (Reference number: xxx).

12. *Who 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 this study, please contact Dr. Ashley White at ashley.white@phc.ox.ac.uk / 01865 617270 or Dr. Lisa Hinton at lisa.hinton@thisinstitute.cam.ac.uk / 01223 731573, and we will do our best to answer your query. We will acknowledge your concern within 10 working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Chair, **Medical Sciences Inter-Divisional Research Ethics Committee**;

Email: ethics@medsci.ox.ac.uk;

Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD

13. *Data Protection*

The University of Oxford is the data controller with respect to your personal data, and as such will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that is performed in the public interest. Further information about your rights with respect to your personal data is available from http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

14. *Further Information and Contact Details*

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

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