Ethox Centre
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Full title of research: Non-invasive prenatal genetics and genomics in England, France and Germany - Exploring practical ethical issues 'on the ground'

Short title of research: NIPT France-England-Germany

Central University Research Ethics Committee (CUREC) Approval Reference: R64800/RE001

PARTICIPANT INFORMATION SHEET FOR PROFESSIONALS

1. Why is this research being conducted?

This project explores the ethical issues arising from the introduction of non-invasive prenatal testing (NIPT) into routine antenatal care. Some European countries such as England, France and Germany, have decided to offer the test free of charge to women at risk of common chromosomal anomalies. Offering NIPT as part of routine clinical service carries benefits, but also raises ethical questions about the scope of public health interventions and reproductive choice, as well as the meaning of health, illness and disability.

The aim of this project is to better understand these issues by exploring professionals' (healthcare professionals, laboratory staff, geneticists, policymakers, scientists) and women's views and experiences with NIPT. We compare countries that have adopted similar policies (England, France and Germany) in order to better understand the socio-cultural contexts in which ethical issues arise. We hope that our findings will help develop models of good practice. The present study focuses on the views and experiences of professionals in England/France/Germany, who are involved in the development, implementation and/or offer of NIPT as part of NHS routine care. We will conduct up to 40 interviews with professionals in England/France/Germany.

2. Why have I been invited to take part?

You have been invited to participate in an interview because your professional area is related to the development, implementation and/or offer of non-invasive prenatal tests (NIPT). Also, you fulfil the study's recruitment criteria of being over 18 and under 65 years of age.

3. Do I have to take part?

No. We hope that this information sheet will provide you with sufficient information for you to decide whether or not you would like to be involved in the study. If you would like to discuss this further please do contact us.

If you do decide to take part in online interviews, we will ask you for your consent. For this, we will complete a paper form by ticking the boxes as we ask you each question on the form. We will then sign the document, scan it and email a copy to you for your records and store our copy electronically.
You are free to change your mind after you have signed the consent form and may withdraw from the research at any time without giving any reason. You can withdraw up to three months after the interview, when we will start data analysis and prepare academic publications. If you withdraw, any information you provided will be destroyed, including recording/transcription. After the interview, you will be given the option to view the interview transcript but not to alter the transcript. During the study you can tell us any time if there is anything that you do not want included in the project and we will not publish it.

4. What will happen to me if I take part in the research?
You will be contacted by Dr Adeline Perrot or Dr Ruth Horn to arrange a date for an online interview, using Microsoft Teams, a video conferencing App that is approved by the University (yet, if preferred by the participant Zoom, Skype or telephone).. We will introduce you to the study procedures and give you the opportunity to ask questions about the participation information sheet (PIS). If you are still willing to participate in the study, you will be asked to give your consent. The interview questions will be open to allow for an open discussion and your point of view to emerge. The interviews aim to better understand your experiences with NIPT. We would like to how and when you offer the test to women, what you communicate and what your general views on NIPT are.
The interview should last about 45-60 minutes. During the interview, you may ask for a break, interrupt or end the interview at any time. With your consent, we would like to audio-record and transcribe our interview, in order to accurately record what you say and avoid misinterpretations of your thoughts. If you do not want the interview to be recorded, for scientific purposes, we prefer to cancel the interview as we will not be able to accurately transcribe and analyse the data.

5. Are there any potential risks in taking part?
The interviews involve potential breaches of confidentiality. To reduce any potential risks of identification, your name, city of residence, and profession will be removed or changed. Although unlikely, it might be possible that the interview could lead to consideration of some sensitive, emotionally charged topics concerning your experience with NIPT. If you find yourself in any way uncomfortable at any point, then you can take a break or end your participation in the study. If the interviewer has any concerns about practice that may be putting patients at risk, we would follow local procedures for reporting this.

6. Are there any benefits in taking part?
Taking part in this study will enable you to make your voice heard, be listened to, take active influence on our research and the issues we will address, and to feed into policy debate. This international study about NIPT will demonstrate new ways to address ethical issues and inform professional guidelines and public health policies that are of benefit to women, couples and professionals when using NIPT.

7. 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 (name, city of residence, profession, age, contact details) is known as personal data.
Personal data and other research data (interview transcripts, audio records, consent forms/records) will be password protected and stored on secure encrypted computers within the University network or, in case of written consent, filed in a locked cabinet in the University. Personal data such as your names, consent forms and identifiers will be kept for at least three years after publication or public dissemination and then will be destroyed. Audio recordings and de-identified transcriptions will be deposited in the UK Data Archive so that it may be used and shared with other researchers if they request access.
The research team in England, France and Germany will have access to the transcriptions (de-identified by removing direct identifiers, reducing the precision of geo-referenced data or age, profession, or generalising the meaning of specific personal information that could directly identify you). The transcription service will receive the audio files via an encrypted data exchange programme. Your identifiers and names will not be communicated to the transcription service. Furthermore, responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the research. We would like your permission to use anonymised direct quotations in research results.

When storing audio recordings on the University's secure platform (OneDrive Business) and depositing it in the UK Data Archive, for practical reasons and to prevent risk of data loss, the recordings will not be anonymised but access and use will be controlled.
All data will be treated confidentially and access to, and use of, the data will be controlled in order to prevent potential breaches of confidentiality.

8. Will the research be published?
We plan to publish the research findings in international open access peer-reviewed journals and present at national and international workshops and conferences. We will run a series of dialogue events that allow us to share our findings and have conversation with a broad range of pregnant women/couples and health professionals. All research data (anonymised transcriptions and audio recorded interviews) will be shared in the UK Data Archive (UKDA).

9. Who is funding the research?
The research is funded by the Economic and Social Research Council (grant number: ES/T00908X/1). ESRC is part of UK Research and Innovation (UKRI). UK Research and Innovation is a non-departmental public body funded by a grant-in-aid from the UK government.

10. 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 (R64800/RE001).

11. Who do I contact if I have a concern about the study or I wish to complain?
If you take part, we very much hope that you will find this a positive experience and will value the opportunity to share your experiences and give your opinion. However, if you have a concern about any aspect of the study, or you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Ruth Horn, Principal Investigator and supervisor of the research (Ethox Centre, NDPH, University of Oxford, ruth.horn@ethox.ox.ac.uk, +44 (0)1865 287888). She will do her best to answer your query. She 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

12. 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/.

13. 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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