

Evaluation of Maternity Investigations and Review Tools

Participant Information Sheet (PIS) for Parents and Families

You are being invited to take part in a research study that will look at if reviews and investigations into serious harm in maternity care have worked from the point of view of parents and families and for making improvements in safety. This research has been commissioned by national policy makers. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➤ **Who will conduct the research?**

The research will be conducted by Professor Alexander Heazell, Dr Mary Adams and Dr Anja Wittkowski, at the Division of Developmental Biology and Medicine, University of Manchester; and by Professors Marian Knight and Jennifer Kurinczuk, Dr Oliver Rivero-Arias and Dr Ramon Luengo-Fernandez at the Department of National Perinatal Epidemiology, University of Oxford. Patient and Public Involvement leadership is by Charlotte Bevan and Antonia Moses.

➤ **What is the purpose of the research?**

The research is to see if the main approaches to understanding what happened to a baby or mother when there has been serious harm in NHS maternity care are working.

These approaches are the Healthcare Safety Investigation Branch (HSIB)/ Maternity and Newborn Safety investigations (MNSI) and the national Perinatal Mortality Review Tool (PMRT) reviews.

We want to understand if these are working from the point of view of parents and families; if and how they contribute to improvements in safety in maternity care, and what resources are needed for them to run properly.

The research will provide information for national policy makers on the progress of the approaches and identify what is work well and what isn't working well, and what improvements are needed.

You have been chosen for this study because you have experienced serious harm during your maternity care and this has been/is being reviewed or investigated during and since January 2019.

We will be interviewing about 20 parents or families from various social and ethnic backgrounds.

Am I suitable to take part?

If you have experienced serious harm during your maternity care (such as that resulting in the death of your baby or serious brain-injury to your baby); if you know that this has been/is being reviewed or investigated, and if you feel ready to discuss what had happened to you, you are invited to take part.

Will the outcomes of the research be published?

The outcomes of the research will be reported to the Policy Research Team, at the National Institute of Health Research and at public and professional conferences. We will also publish our findings in journals and on social media. You will not be identified in the research outcomes.

Disclosure and Barring Service (DBS) Check

Researchers will have undergone appropriate levels of DBS checks prior to conducting the interview.

➤ **Who has reviewed the research project?**

This study has been reviewed by The University of Manchester Research Ethics Committee [application number 18320]

Who is funding the research project?

The National Institute of Health Research Policy Research Programme (Reference number NIHR204248)

What would my involvement be?

➤ **What would I be asked to do if I took part?**

Have a one-to-one interview with a named researcher who will ask you about your experiences of the HSIB/MNSI investigation and/or PMRT review that was undertaken for your baby or family member.

The interview can be conducted by telephone, Zoom or Teams or, if possible, in-person at a quiet, public location of your choice. The time and date of the interview can be scheduled at your convenience. You can invite a family member or a friend to be present during interview.

You will be asked to read and sign a written consent form before the interview. About a day before the interview the named researcher will check again that the interview is happening at a suitable time for you and will ask you if you have any concerns or questions about the interview or the study and will reply to these. The interview will be audio-recorded by the named researcher.

You can withdraw from the study at any time, before, during and after interview, without giving a reason. If you decide this, we will delete your interview from our records until 1.12.24 (when final data analysis begins).

The interview will last approximately 60 minutes.

You can stop or interrupt the interview at any time, without giving a reason.

You may find the interview distressing. The researcher will be aware that you are being asked about difficult things, and you will be able to determine your own pace of things, before and during the interview. At the close of the interview the interviewer will check on your wellbeing and, if you would like, give you a call the day after. If it would help, they will forward you information on forms of support a few days later.

➤ **Will I be compensated for taking part?**

There is no compensation for taking part in the interview.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. You can inform us of your decision by email or telephone contact with our project administrator or lead researcher (whose contact details are on the back of this information sheet). If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form to take part in the study.

If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, we are unable to remove your interview data from the project after 1.12.24 (when final data analysis begins). This does not affect your data protection rights.

If you decide not to take part you do not need to do anything further.

Data Protection and Confidentiality

➤ **What information will you collect about me?**

At the start of the interview we will need to collect some information called 'personally identifiable information'. We are collecting this information to understand if these things could have affected your investigation or review. We will collect information on your:

-age

-gender

-ethnicity

-any other social factors that you think might have affected your investigation/review.

During the interview we will record only your voice (no photography will be used).

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for

collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, that is, the audio recording.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#).

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The audio-recording of your interview will be made on a password protected recorder that encrypts the recording. Immediately after the interview, the audio-recording will be sent by password-protected folder to a University of Manchester-approved transcription company, that has a signed confidentiality agreement between their organisation and the University of Manchester.

The interview content will be anonymised at transcription. This means that any information identifying you will be removed from the transcript. The transcript will be returned to the research team in a password protected folder and stored on a pass-word protected University of Manchester server. The research team will then delete the audio-recording. Only the research team will have access to the transcripts.

The study team will store your identifying information (name and brief contact details) securely and separately from your study data. Your transcript will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the research team. This link means that you can request the withdrawal of your data until 1.12.24 (when final data analysis begins). After this date we will destroy the key, so anonymising your data.

Your anonymised data will be stored for 10 years for the research team conduct any further analysis of the data. Your consent form (including your name and signature) will be retained separately for 5 years after the end of the study. At the end of the study on-line consent forms will be stored in separate password-protected folder and hard copies will be stored in a locked filing cabinet on University premises. Your consent form and anonymised data will be deleted on 31.3.35.

Your personal contact details will be kept only for arranging the interview and for interview follow-up, if required. Your personal details will be deleted at the close of the research (1.12.24).

Given the sensitivity of your interview data, it will not be retained in a data repository and so will not be available to other people. You may share your interview with others if you choose.

If you decide to have your interview over Zoom or Skype, then your personal data will be processed by [Microsoft/Zoom]. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third-party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

Potential Disclosures

If, during the interview, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.

You might also discuss with us malpractice or negligence of those involved in your care. If this occurs, we will encourage you to report these to the relevant bodies, and assist you with this process if necessary.

You might also reveal information that means you may be at risk of harming yourself or others. Then we will be required to break confidentiality in order to put you in touch with the correct support. This may involve signposting you to relevant support services or calling emergency services.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

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What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact the study manager (Ramsha.Ali@manchester.ac.uk) or the study lead (Alexander.Heazell@manchester.ac.uk)

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researcher in the first instance then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building,

The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](#) Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact

Ms. Ramsha Ali (project manager) at Ramsha.Ali@manchester.ac.uk

Dr. Mary Adams (interview research lead) at Mary.Adams@manchester.ac.uk or

Professor Alexander Heazell (study lead) at Alexander.Heazell@manchester.ac.uk

