

Evaluation of Maternity Investigations and Review Tools

Participant Information Sheet (PIS) for National Programme Leads

You are being invited to take part in a research study evaluating maternity investigations and review tools. 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.

If you find the interview distressing in any way, please do contact our research team (details at the end of this information sheet). Our research team will forward details of support available to you should you feel that you require this.

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 and Dr Oliver Rivero-Arias and Dr Ramon Luego-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 will examine if the Healthcare Safety Investigation Branch (HSIB)/ Maternity and Newborn Safety investigation (MNSI) investigations and the national Perinatal Mortality Review Tool (PMRT) reviews have met their objectives, resulting in maternity safety improvements and in improved outcomes for parents and families.

The research will provide information for national policy makers on the progress of these programmes and identify what is required for HSIB/MNSI investigations and PMRT reviews to meet their objectives.

You have been chosen for this study because you have had a leadership position in the Maternity and Newborn Safety investigation (MNSI) programme or in PMRT review development and/or implementation. We will be interviewing between 8 and 10 national programme leads.

Am I suitable to take part?

If you have led the development and implementation of HSIB/MNSI investigations or PMRT tools or you are involved in implementing them, 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 the impact of the Maternity and Newborn Safety investigation (MNSI) Programme or the Perinatal Mortality Review Tool reviews on: the quality of investigation and review processes; quality improvement activities arising from the reviews and/or investigations; parent and family involvement; and the work of clinical teams.

We will also ask you about the impact of the pandemic on these reviews and investigations and on parent and family experience of them.

The interview can be conducted by telephone, Zoom or Teams. The time and date of the interview can be scheduled at your convenience.

You will be asked to read, sign and return a written consent form before the interview. Please feel free to contact the research team with any questions or concerns that you have about the interview or the research study before or after you give written consent. They will address these before your interview.

The interview will be audio-recorded verbatim by the named researcher and will last up to 60 minutes.

Also, if you are an investigator we are asking you to complete a short questionnaire on the resourcing and costs of investigations. The questionnaire will take you about 30 minutes to complete.

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).

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

➤ **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’. This will be your work role and dates of employment in this role.

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 on 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 others. You may, however, share your interview transcript with others.

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.

The returned questionnaires will be anonymised, with all personal and organisational identifiers removed, on their return to the University of Oxford. These anonymised questionnaires will be stored at the University of Oxford for data analysis. The anonymised questionnaires will be deleted on 31.5.35.

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 by NHS staff 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 Ms. Ramsha Ali (project manager) at Ramsha.Ali@manchester.ac.uk or Professor Alexander Heazell at 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

