Study Title: Evaluating Maternity Investigations and Review Tools from the Perspective of Individuals, Resources and Endpoints to Imrpove Outcomes for Mothers and Babies (MATREP)

Participant Information Sheet (PIS) for NHS Staff

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. 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, of the Faculty of Biology, Medicine and Health, 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.

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

In 2018, Healthcare Safety Investigation Branch (HSIB)/Maternity and Newborn Safety Investigation (MNSI) and Perinatal Mortality Review Tool (PMRT) reviews were developed and incentivised to drive improvements in England National Health Service (NHS) maternity safety. To date, there is limited evidence of if and how these interventions have resulted in improvements in maternity safety and the experiences of parents and families, and there has been limited evaluation of the impact and effects of these programmes. This study will examine setup, costs, progress and outcomes of the two programmes from the perspective of NHS programme leads.

The research will provide information for national policy makers, maternity programme leads, frontline staff, and parents and families 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 as you are a senior NHS staff member responsible for the HSIB/MNSI and/or PMRT within your maternity service. We intend to recruit 21 NHS staff members across 7 organisations.

- **Am I suitable to take part?**

If you are an NHS Senior Staff member responsible for the use and monitoring of HSIB/MNSI and/or PMRT reviews within a maternity service, and feel ready to discuss your experiences, you are invited to take part.

If you are currently under warning, suspension, remediation or dismissal procedures by your employers or professional bodies, you will not be able to participate in this study.

- **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?**

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the <<Insert Name of Committee>> Research Ethics Committee.

- **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?**

  Your participation will involve the following:

  You will be asked to read and sign a **consent form**.

  You will then be asked to complete an online survey about the resource and cost implications of the programme. This will take approximately 30 minutes. You will receive reminders at one-week, one-month, and two-months after receiving the link to the survey to complete it.

  You can withdraw from the study at any time, before, during and after completing the survey, without giving a reason. If you decide this, we will delete your survey responses from our records until 01.12.24 (when final data analysis begins).

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

  There is no compensation for taking part.

  However, taking part in this research would contribute to improving maternity investigations and reviews.

➢ **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.

Data Protection and Confidentiality

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

In order to participate in this research project, we will need to collect information that could identify you, called "personal identifiable information".

Specifically, we will need to collect:

- Name
- Contact details
- Your work role and dates of employment in this role.

This information will be collected to send over the link, and details for our survey.

➢ **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.

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:

Name and email contacts of participants will be stored on a password protected Excel sheet on a separate folder on a secure University of Manchester server. They will be retained only for as long as necessary (when the survey questionnaire has been returned or the reminders have been sent). Then the email contact will be deleted. Additionally, the survey questionnaires, that will be returned to the University of Oxford, will be pre-coded by the University of Manchester team. This means that only one research team will retain the code sheet with personal information for identifying participants. Therefore, the sharing of personal information is minimised.

The study team will store your identifying information (name and brief contact details) securely and separately from your study data. 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 01.12.24 (when final data analysis begins). After this date we will destroy the key, so anonymising your data. Some confidential data from participant recruitment (work role or social details such as length of time in employment) will be retained by the study team. Only necessary identifiers will be retained as pseudonymised information.

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 of Manchester premises. Your consent form and anonymised data will be deleted on 31.3.35.

Your personal details will be deleted at the close of the research (31.3.25).

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.

Potential Disclosures

If 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 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.

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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 research team's shared mailbox which is accessed by the Project Manager, and researchers based at the University of Manchester (matrep@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

The research team at matrep@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