Participant Information Sheet (PIS)

The Tommy's National Rainbow Clinic Study:

A specialist antenatal service for women and families following a stillbirth or neonatal death

We are approaching you to ask if you would like to take part in this study because you are attending a clinic which specialises in care in pregnancy after stillbirth or neonatal death.

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

About the research

Who will conduct the research?

This research is being led by Professor Alexander Heazell from the School of Medical Sciences, Faculty of Biology Medicine and Health, University of Manchester alongside Research and Rainbow Clinic Specialist Midwives Emilie Bailey and Rebecca Barron. The study is being undertaken at sites throughout the UK who have set up Rainbow Clinics.

What is the purpose of the research?

The majority of women who have experienced the loss of a baby will embark on another pregnancy, usually within a year. Previous studies suggest that parents should receive specialist support from doctors and midwives in a future pregnancy to reduce the risk of pregnancy complications and to provide the care and support they need. The Rainbow Clinic aims to provide specialist care and support to families who have experienced the death of a baby during pregnancy or shortly afterwards. The first established clinic has witnessed improvements in the pregnancy outcomes and patient experience. As this is a new clinical service in most hospitals we would like to evaluate the care provided in the clinics across the United Kingdom, to look at where care can be improved; your experiences will help to do this.

What are the advantages of taking part?

The study may not benefit you directly but the information we get from this study may help to improve the care of all parents and families who have experienced a stillbirth or neonatal death.

What are the possible disadvantages of taking part?

There are no direct disadvantages to taking part in the study as participating in the study will not affect your care. The research team recognise that participation may bring up difficult and distressing memories for some of the participants. The study team are trained and experienced in supporting patients for whom this occurs, and can refer you to specialist services where needed.

In the event that there is something that goes wrong with the research and you are harmed during the research you may have grounds for a legal action or compensation against the University of Manchester or your local NHS trust (Manchester University Foundation Trust) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will the outcomes of the research be published?

Some of the anonymised research data will be used for educational purposes. The results will be presented at clinical and scientific research meetings and will be published in journals read by doctors, midwives and scientists. You will not be identified in any of our results. We can share the overall study results with you if you consent to us keeping your email address at the time you enter the study.

Who has reviewed the research project?

This study has been reviewed and given a favourable opinion by South Central - Hampshire B Research Ethics Committee.

Who is funding the research project?

This research is being carried out by the Maternal and Fetal Health Research Centre, University of Manchester and St Mary's Hospital is organising the research which is being funded by Tommy's Charity.

<u>What would my involvement be?</u>

- **What will I be asked to do if I took part?**

  If you agree to take part in the study, we will collect information about you and your current pregnancy after we have received informed written consent from yourself.

1. The midwife will collect information about you (e.g. ethnicity, marital status, occupation) and your medical and obstetric history, this pregnancy (e.g. investigation results, admissions, emergency attendances, complications) and your baby (e.g. place of birth, onset of labour, use of medication, length of labour, type of birth, birthweight) from your medical notes. The data will be collected at several points during the study (following consent, following birth, following discharge) but not beyond the end of the study.

2. You will be asked to complete three short questionnaires about your levels of anxiety and current psychological state at your first clinic visit which is usually at approximately 23 weeks gestation and last clinic visit which is usually at 36 weeks gestation. However, Rainbow Clinic is a service which offers a tailored, individualised care to meet your needs. The questionnaires are standard questions and your answers are recorded by ticking a box. They take approximately 10 minutes to complete in total.
3. You will be asked to complete a patient experience questionnaire following your final Clinic appointment usually at 36 weeks' gestation, prior to you giving birth. The questionnaire will be CODED (meaning that the people looking after you will not be able to identify your response) and will measure patient experience based on your responses. These can be completed whilst attending a routine appointment at the clinic or can be posted to you, to be completed in the comfort of your own home. This is expected to take no longer than 10 minutes on each occasion. We may use anonymised quotes from people who have completed the questionnaire to illustrate our study findings.

- **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 withdraw from the study at any time if you wish, without giving a reason and without your medical care being affected, by contacting the study team at your site. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. 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 about you, this includes:

  - Name, contact details, demographic data (e.g ethnicity, marital status, occupation)
  - medical details about you (medical and obstetric history)
  - the current pregnancy (e.g. investigations, admissions, emergency attendance, complications) and your baby (e.g. place of birth, onset of labour, use of medication, length of labour, type of birth, birthweight) from your medical notes.
  - The data will be collected at several points during the study (following consent, during labour & birth, following discharge) but not beyond the end of the study.

- **Under what legal basis are you collecting this information?**

  We are collecting and storing this personal identifiable information in accordance with 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 http://documents.manchester.ac.uk/display.aspx?DocID=37095

- **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:

  Only the study team at the hospital where you are being looked after and The University of Manchester will have access to your personal information, but they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a study ID number. Only the research team will have access to the key that links this ID number to your personal information. Your consent form and contact details will be retained for 5 years in the hospital where you have been looked after.

  Study ID numbers will be used and no personal identifiable data will be accessed by anyone outside the study team. In the rare event that information emerges that you are a danger either to yourself or others, it would be necessary to breach confidentiality and forward your details to agencies that can help you.

  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.

  When you agree to take part in a research study, the information about you may be provided to researchers running other research studies in this organisation only This is limited to the anonymised data collected for the purpose of this study. The future research will be of a similar nature to this research project and will concern stillbirth or neonatal death. Your information will only be used by this organisation and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. Your contact details will not be shared for the purpose of recruitment for other studies.

What if I have a complaint?

Minor complaints

If you have a minor complaint then you need to contact the researchers in the first instance. For St Mary's Rainbow Clinic Manchester please contact Emilie Bailey Research Midwife, 0161 701 6965, emilie.bailey@mft.nhs.uk.

For Royal Berkshire Hospital Rainbow Clinic Reading please contact Anna Campbell or Lola Okungade Research Midwives, 0118 322 8652, child.research@royalberkshire.nhs.uk.

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact;

The Research Governance and Integrity Officer, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674.

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 org.uk/make-a-complaint/

https://ico.org.uk/make-a-complaint/

Tel 0303 123 1113

The normal National Health Service complaints mechanisms will still be available to you, this can be accessed via PALS (Patient Advice and Liaison Service) on 0118 322 8338 or PALS@royalberkshire.nhs.uk.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact **The Rainbow Team: Jocelyn Hudson, Juliette Ward and Louise Lane, 07500 835 264 rbft.rainbowcare@nhs.net**

Or

The Research Team: Anna Campbell or Lola Okungade Research Midwives, 0118 322 8652 child.research@royalberkshire.nhs.uk

If you would like any further information please contact Professor Alexander Heazell, Professor of Obstetrics on 0161 276 6484.

Thank you for taking the time to read this information sheet. You will be given a copy to keep.