

Pregnancy

You are being invited to participate in the Tommy's National Reproductive Health Biobank (TNRHB) Project. It is very important that you understand why we require your participation and what kind of research this could lead to. Please take your time to read this information and discuss it with your friends, family, relatives and members of the hospital staff.

What is the purpose of the TNRHB?

The TNRHB is a project that will help carry out high quality research into pregnancy loss and preterm birth, to develop treatment and help prevention.

TNRHB aims to provide researchers with access to a very large resource of human tissue samples that are vital in helping us to

- Find new ways to diagnose, treat and prevent pregnancy complications.
- Identify causes of poor pregnancy outcomes, by understanding key events that determine a successful outcome of pregnancy.

If you decide to take part, you will be helping researchers investigate and understand why some women suffer pregnancy complications and understand the biology of the process to help develop treatments.

We would like to give you the option to take part in future research studies related to your condition or that are relevant to you. To do this we need to be able to contact you to provide further details of these studies so you can decide if you want to take part. Appropriately trained staff will contact you to explain the study and ask for your permission to share your contact details with the researcher running it. You have the right to say no.

Do I have to take part?

Your participation is entirely voluntary. If you wish to take part we would like you to complete a consent form.

If you decide to take part you are still free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive in the future. We can reassure you that all information you give us and the results we obtain will be confidential and anonymous.

Allowing us to keep your biological samples for research

During your visit to the hospital the care staff will often need to examine you and take samples for tests, to diagnose, monitor and treat you. This may involve the removal of fluids or pieces of tissue (known as biological samples). These biological samples are sent to a laboratory to be tested by doctors or scientists; this can help diagnose your condition.

If you consent to join the TNRHB, samples leftover after routine tests that are usually discarded, e.g. placenta, will be kept for research.

Samples of mouth swabs would not usually be collected from you, however we are asking you to consent to the collection of these samples, as they will allow research in to the bacteria in your mouth, which can provide information about your health and genetics that may contribute to pregnancy complications.

If you are having a sample taken, two or three extra samples maybe taken for research. If you have already had your procedure you can still help us by consenting, we can then ask the laboratory for a small amount of biological samples already used for your diagnosis.

As part of your routine care, your doctor may invite you back for more visits and this may involve taking other biological samples. If, in the future, you have a biological sample taken as part of your care, we may wish to

access these samples too. This will allow researchers to make potentially helpful comparisons with your original samples. If you do not wish to provide further samples, you do not have to.

Allowing samples to be taken from caesarean section procedure

If you have a caesarean section to deliver your baby we may ask if we can take additional samples such as a small samples of fat and/or womb muscle, after the baby is delivered. The surgeon will remove 2 or 3 small pieces of tissue. There are no associated risks in taking these samples during this procedure. If, during your caesarean section the doctor does not feel it is appropriate to take these samples, then they will not be taken. Your care and the care of your baby are of primary concern. You have the right to say no.

Donating Breast Milk for research

A mother's diet during pregnancy is very important and it is known to have effects on fetal development and the health of the child. Breast milk is an important food, which delivers nutrients to the newborn, and studies are needed to investigate the components of this, to understand how they play a part in fetal development. Breastmilk will not be provided to companies or researchers for research into infant milk substitutes.

Allowing samples to be taken from your new born baby

Saliva, buccal swab, urine, meconium and hair would not usually be collected from your baby; however we are asking you to consent for the collection of these samples, as they will help us understand the impact of pregnancy complications on the baby. You have the choice to consent to some, all or none of these samples.

What are the possible disadvantages of taking part?

There are no known health risks or risk of significant harm associated with donating any of the samples.

What are the benefits of taking part for you and your baby?

Taking part in this project will not change your care in any way. You may not benefit personally from any research carried out using the samples and data. However, we hope that women in the future will benefit from your participation. We hope that the findings gained from the donation of your samples will help the care of women suffering from pregnancy complications in the future. You will not gain any financial rewards for your donation.

The samples will not be sold for profit to researchers, but the use of your samples may lead to the development of new drugs, treatments or tests by both academic and commercial organisations.

What will happen to your and your baby's samples?

The samples will be used by researchers based in academic institutions, the NHS or commercial companies worldwide. Researchers will only gain access to your samples and data once the Tissue Access Committee has reviewed their application. This committee will make sure that your samples will be used for high quality scientifically valid research.

What about genetic or stem cell research?

DNA taken from samples of tissues or blood is sometimes used in medical genetic studies to try and better understand the link between genes and disease. Alongside our conventional testing as part of your clinical care, genetic or other analysis of tissue relating to your pregnancy could reveal answers for complications. You and your baby's samples will not be used in any experiments involving cloning designed as a therapy for disease or to assist reproduction. Some scientists may use tissue samples or blood for their research on adult stem cells. For example, blood stem cells can be obtained from cord blood and maybe used in research to understand how blood cell cancers develop, or mechanisms involved in tissue healing. For these types of studies, further ethical approval is required.

Will I receive any results?

The results of these studies will be used to improve treatment and care in the future. Results will be published in scientific papers and updates on research progress will be published on the Tommy's website at Tommy's.org. However if anything that is of direct relevance to your care, is identified we will contact your doctor. You and your baby will not be identified in any publication or through any information on the website.

What will happen to my and my baby's data if I join TNRHB?

Your information is protected under the General Data Protection Act 2018. We have a legal duty to keep your information confidential, secure and hold information only as long as necessary. The Trust collects and stores information about you in order to provide safe and effective healthcare. Your health records are held on paper and on secure computer systems. Your full identifiable medical record will never be seen by researchers.

In order to carry out high quality research and to improve NHS services, your health data may need to be linked to other information about your health or other data that may be relevant to ethically approved research studies. NHS staff will only see the minimum data required to link your records when using identifiable data they will never see other information about you, for example your medical record. After linking your information, the details that could identify you are removed so that researchers using your samples cannot identify you. All your electronic information is linked, stored and transferred using secure, encrypted mechanisms.

If I agree now, can I change my mind later?

Yes. You are free to withdraw and are able to change your mind at any point, even after you have donated samples. If you change your mind, or wish to discuss your or your baby's participation, please contact your local Tommy's team using the details at the end of this information sheet.

We will retain all samples and data until informed otherwise.

If your or your baby's tissue has already been used for research at the time that you withdraw, the data generated by it cannot be destroyed

If you agree to take part then please keep this sheet for your own information

If you have any queries please contact: <local tissue collection/research centre details>

Email: <local tissue collection/research centre details>

Tel: <insert contact number>

Further information about donating tissue for research is available from:

Human Tissue Authority web site: www.hta.gov.uk

The Human Tissue Act: <http://www.legislation.gov.uk/ukpga/2004/30/contents>

More information is available on our website:

<Insert website>