# STOPPIT-M Study

## Infant hypothalamic-pituitary-adrenal axis responses following antenatal corticosteroids and perinatal outcomes: a mechanism of action of health intervention study

## Study Summary Sheet

You are being given this information as we would like to invite you to take part in a clinical study. Before you decide whether or not to take part, 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 to decide if you wish to take part.

### Why have I been asked to take part?

You have been asked to take part as you are taking part in the STOPPIT-3 trial and planning to give birth to your twins by caesarean section.

### What is the purpose of this study?

STOPPIT-M is the mechanistic part of the STOPPIT-3 trial. The study aims to explore how antenatal corticosteroids (ACS) work and why responses to ACS vary between babies.

The main trial STOPPIT-3 aims to resolve uncertainty about whether ACS given to women with a twin pregnancy reduces breathing complications in twin babies.

In STOPPIT-M, we want to understand why ACS work for some babies, but other babies still develop problems. We know that ACS can directly cross the placenta and reach the baby. We think that ACS may “damp down” the babies own ‘stress response’ systems and that this may be the reason why some babies have problems such as breathing difficulties and low blood sugar levels.

### What will happen if I take part?

An outline of the study is given below.

**Consent:** If you have agreed to participate in the STOPPIT-3 trial and are planning to have a caesarean section you will be asked if you would like to participate. You will be given time to think about this before being asked to sign the study consent form.

**At birth:** At the birth of your babies, we will take blood samples from you and the babies’ cords (about an egg cup full). We will collect some of the fluid that surrounded the babies in the womb and we will take a sample of the placenta. We will use the cord blood samples to measure the levels of the babies’ stress hormone levels. We will also measure the stress hormones and levels of ACS in the other samples to further understand the babies’ stress responses. In a subgroup of babies, we will also collect a small section of the babies’ hair and a saliva sample before and after a routine stressor event. This can include but not

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limited to a physical exam, a blood glucose test or a heel-prick blood test. These samples will allow us to measure the babies 'stress response' and overall stress hormone release.

**What are the possible benefit of taking part?**

We don't know if you and your babies will directly benefit from taking part in this trial. Information we obtain from your participation in the study may help inform on the future healthcare of other people. Taking part may help our understanding of why ACS work for some babies and not others which may help women and babies in future.

**What are the possible disadvantages of taking part?**

We don't think there are any disadvantages for you of taking part. We will collect all the biological samples after you have received your standard antenatal care to ensure the research does not affect your birth experience.

**Who should I speak to if I am interested in taking part?**

If you are interested in participating in STOPPIT-M please speak to your midwife/obstetrician. You can also visit our website (www.stoppitstudy.co.uk) to obtain further information.

Additional detailed information about the research will be given further on in your pregnancy. Please tell your midwife, or a member of the clinical care team, if you don't wish to receive any further information about this trial.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

**Thank you for taking the time to read this information leaflet and considering to take part in the study.**

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