



THE UNIVERSITY  
of EDINBURGH



Optimal mode of delivery in preterm labour

## CASSAVA STUDY Information Sheet for Women

We are inviting you to take part in a group discussion about a research study we are hoping to do in the future to work out the best way to deliver babies who are born early. Before you decide whether to take part in this group discussion, it is important to understand why it is being done and what your participation would involve. Please read the following information carefully and discuss it with other people if you wish.

### **What is the purpose of the group discussion?**

We are constantly trying to improve the medical care we give to women when they give birth. To improve this care, we sometimes need to do research to work out if one type of treatment is better than another. In the future, we are hoping to do a big research study to find out what is the best way to deliver babies who are born early (before 37 weeks). Before we do this research, we would like to talk to women to get their opinions about the research and whether they think women would be willing to take part in it. We are planning to do around eight discussion groups with women in total; three of these discussion groups will be with Polish, Pakistani and Indian women.

### **Why have I been invited?**

You have been invited because you have had a baby who was born early, are currently pregnant or may be considering getting pregnant in the future.

### **What would taking part involve?**

If you decide to take part, a researcher would contact you to arrange a time for you to take part in a group discussion with around 4 to 7 other women. This group discussion would take around 1½ hours. It would happen in private, at a time and place convenient for everyone. In this discussion, we would tell you about the research we are hoping to do and get your views about it. Your group discussion would be audio recorded.

We would be able to cover any travel and child care expenses, up to the value of £30. In some cases (depending on the venue we book), it may be possible for you to bring a baby along. We would give you a voucher to thank you for your time.

If you attend a discussion group for Polish or Pakistani women, a bi-lingual researcher will be present so that you do not need to speak English.

### **Do I have to take part?**

No, taking part in a group discussion is entirely up to you and if you decide not to take part this will not affect your medical care in any way. You would be also free to withdraw from the group discussion at any point without giving a reason.

### **Are there any benefits to taking part?**

Although taking part in the group discussion will not benefit you directly, we hope that you would find it an interesting experience. We hope to use the findings to inform future research to help us work out what is the best way to deliver babies who are born early.

**Are there any disadvantages to taking part?**

Your group discussion session would take around 1½ hours of your time.

**Will my taking part in the research be kept confidential?**

Yes. All information that we collect about you will be kept strictly confidential and there are strict laws which safeguard your privacy at every stage. Data will only be shared with researchers in the UK or European Economic area. Data will be stored in a locked filing cabinet or on a password-protected computer within a locked office at the University of Edinburgh. Your personal information will not be made available to anyone apart from the research team doing the discussion groups.

With your permission, the recording of the discussion groups will be sent to a professional external company so that it can be typed up. The company will be held to the same level of confidentiality as the researchers and when it is typed up, any names, details or other information that could possibly identify you will be removed or changed.

**What will happen to the information collected?**

The data you provide during the discussion groups will be kept for a minimum of 3 years after the study has finished. If you withdraw from the study, we will keep the information about you that we have already obtained. We will use the minimum of personally-identifiable information as possible. You can find out more about how we use your information in the Data Information Sheet (Version 1 Dated 21st July 2018) given to you, with a copy of your consent form. This information is also available on the on the study website: <https://www.ed.ac.uk/centre-reproductive-health/cassava>.

**Who is managing the study?**

The study is being managed by the University of Edinburgh and is sponsored jointly by the University of Edinburgh and NHS Lothian (ACCORD). Collectively they are the sponsors for this study based in the United Kingdom.

**What will happen to the results of the group discussions?**

The results will be used to inform future research to help work out what is the best way to deliver babies who are born early. Results will also be made available on the study website (<https://www.ed.ac.uk/centre-reproductive-health/cassava>) which is freely accessible.

**Who is funding the group discussions?**

The Study is funded by the NIHR Health Technology Assessment Programme (project number 17/22/02). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the HTA.

**Who has reviewed this work?**

The work has been reviewed by several organisations which include the funders, the sponsors and it has been approved by <<details to be inserted on attaining Research Ethics Committee approval>>.

**If I want to take part, what will happen next?**

If you are willing to take part in a discussion group, please complete and return the opt-in form using the stamped-addressed envelope provided or email it to the discussion group leader whose contact details are below. The discussion group leader will then contact you to answer any questions you might have, and to arrange a time for your group to meet.

**Contacts for further information and to return opt-in forms**

If you would like more information or want to ask any questions about this research, please contact XXXX on XXXX or email: [XXXX@ed.ac.uk](mailto:XXXX@ed.ac.uk)

**Independent Contact:**

If you would like to discuss this study with someone independent to seek general advice about taking part, please contact: Dr Fiona Denison **email:** [fiona.denison@ed.ac.uk](mailto:fiona.denison@ed.ac.uk)

**If you wish to make a complaint** about the study please contact NHS Lothian:

Patient Experience Team

2 – 4 Waterloo Place, Edinburgh, EH1 3EG

Email: [feedback@nhslothian.scot.nhs.uk](mailto:feedback@nhslothian.scot.nhs.uk)

Telephone: 0131 536 3370

**Thank you for taking the time to read this information sheet.**