THE UNIVERSITY of EDINBURGH

CASSAVA
Optimal mode of delivery in preterm labour

CASSAVA STUDY Health Care Professional Information Sheet

Health professional information sheet
We are inviting you to take part in an interview study in which we are seeking health professionals' views about a trial to determine the optimal mode of delivery in women presenting in preterm labour. Before deciding whether you would like to take part, please read the following information carefully and discuss it with others if you wish.

What is the purpose of the research?
The purpose of the study is to see if it is possible to carry out a randomised trial of different modes of delivery for women in preterm labour (or with a planned preterm delivery). We've already undertaken a survey and a Delphi consensus with Clinicians and women in order to identify the research priorities for pre-term birth and have used this information to design a trial. We now wish to speak to health professionals to get their views about whether they and their colleagues would, in principle, be willing to recruit and randomise women to this trial; we will also be seeking women's views via focus groups.

Why have you been invited to take part in the research?
You have been invited because you completed an earlier survey in which indicated that you would be interested in taking part in an interview or because one of your colleagues has suggested you would be a good person to speak to.

What would taking part in the interview involve?
If you would like to take part, you would be contacted by a researcher from the University of Edinburgh who would arrange a convenient time to interview you over the phone. Before this interview, you would be sent a brief description of the trial (a summary protocol) which would take no more than a couple of minutes of your time to read. In your interview, the interviewer would ask you to share your thoughts about the about the proposed trial, whether you would be willing to recruit and randomise women (and why or why not) and what training and support you think health professionals would need to deliver the trial. Your interview would take around 20 minutes of your time and would be audio-recorded.

Do I have to take part in the interview?
It is up to you to decide whether you would like to take part. If you do take part, you would be free to withdraw at any time without giving a reason.

Are there any benefits to taking part?
Although the research will not benefit you directly, taking part in an interview will provide you with an opportunity to share your opinion about the proposed trial.

Are there any disadvantages to taking part in the research?
Your interview may take about 20 minutes 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 interviews. With your permission, the recording of your interview will be sent to a professional external company, so that it can be typed up. The company will be held to the same levels of confidentiality as the researchers and when the interview is typed up, any names, details or other information that could possibly identify you used during the interview will be removed or changed. When findings from the study are also written up any information, which could identify you, will be removed.

What will happen to the information collected?
The data you provide 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?
This 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 interviews?
The results will be used in publications, conferences and presentations, which will help, inform decisions about whether a randomised trial should be funded. If a trial is funded in the future, the findings may also be used to inform the training and support given to staff delivering the trial. 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 study?
The study is funded by the NIHR Health Technology Assessment Programme (project number 17/22/02). Any views expressed will be those of the researcher(s) and not necessarily those of the NHS, the NIHR or the HTA.

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

What do I need to do next?
If you are willing to take part in an interview, please complete and return the opt-in form using the stamped-addressed envelope provided or email it to the researches at Edinburgh University (contact details below).

Contacts for further information and for returning the opt-in form
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

Independent Contact:

THE UNIVERSITY of EDINBURGH *To be inserted Study Logo*

If you would like to discuss this study with someone independent to seek general advice about taking part, please contact: Professor Fiona Denison **email**: 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
Telephone: 0131 536 3370

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