Deciding About Research when heavy bleeding occurs during Childbirth (DARCi): A Study of Women's Experiences

Interview Schedule

INTRODUCTIONS

The interviewer will thank the woman for attending and will attempt to make them feel as relaxed as possible. The interviews will be held in a place chosen by the participant either in her home or in the antenatal clinic whichever she feels is most convenient, comfortable and non-threatening.

SETTING OF GROUND RULES

- Explain Study
- Explain tape recording & transcription
- Explain study numbers/confidentiality
- Explain names will not be used or changed if appropriate
- Explain can stop at any time
- Explain can refuse to answer question
- Opportunity to ask questions
- Consent
- Check tape

The interview will be semi structured in relation to the three objectives of the study. These questions below are intended to be used as a guide, with the actual direction of the interview respondent led.

Objective 1 To explore women's views of the consent processes utilized during the conduct of The WOMAN Trial.

- Use the patient alert card (that was given to WOMAN Trial participants after discharge from hospital) to re-introduce the woman to the WOMAN Trial. Show woman the card explain its purpose as an aide to jog her memory.
- Ask "Do you recall being part of the WOMAN Research Study?" Explore
- Ask "Do you remember being asked to take part in the study?" Explore

If response Yes

When were you asked to take part e.g. before birth, when bleeding, when recovered?

- Who asked you about it?
- What was your response?
- Was there verbal agreement? Were you asked to sign a form?
- Was anyone else involved in the decision?
- Did you sign a consent form, if yes can you remember when?
- Did anyone explain why your consent was asked for in this way?

<u>If no response</u> Research Midwife will give some explanation of what happened in woman's individual case

TO ALL

- What do you think about the way researchers asked you to take part in the WOMAN research?
- Do you think this way of asking you about the research were acceptable or not?
 Why?
- Can you think of a better way of asking women who are experiencing an emergency about research?

Objective 3

To assess women's acceptability of retrospective consent to research studying treatments for obstetric emergencies

• Do you think it is or is not acceptable for staff to make a decision to involve women in research at the time an emergency is occurring?

Objective 2

To explore the preferred consent method of women involved in research occurring at the time of an obstetric emergency

• Explain different methods that have been used in actual practice i.e. written consent

at time, waiver and retrospective consent after recovery. Ask maternal views on

each and then which option do you think is the best, why?

• Was anyone else involved in the decision to involve you in the research study e.g.

birth partner.

• What do you think about involving other people in the decision to enter you into

research at a time you may be too unwell to decide for yourself

• If you were in a similar situation again what do you think would be the best way to

ask you about whether or not you would be involved in research occurring at that

time?

Is there anything else you would like to say about your experience of participating in the

WOMAN trial?

Would you like to receive a summary of the results of this study?

Thank woman for taking part.