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**Detailed information about taking part in the vip study about decision-making during labour**

**Introduction**

Thank you for your interest in taking part in this study. Before you decide, it is important for you to understand why the research is being done and what it will involve. This information sheet tells you about the study. Please read it carefully and discuss it with your family and friends. Please ask us if there is anything that is not clear or if you would like more information.

**What is the purpose of the study?**

The National Health Service (NHS) is committed to involving women in decisions about their care whilst they are in labour. This is important because studies have shown that women often feel more positive about their birth experience when they have been involved in decisions about how things happen. However, there is very little evidence about how midwives and doctors actually involve women in decision-making during labour and birth. The study goal is to provide clear guidelines for midwives and doctors about how to do this well. By taking part in this study, you would be contributing to improving communication between staff and women during labour and we hope this would have a positive impact for women giving birth in the NHS.

**Why have I been invited?**

You have been invited to take part because you are expected to have a routine/normal labour in one of the two maternity units where our study is based. We hope that 50 women (plus their birth partners) will take part in total, in two locations (Sheffield and Calderdale).

**Do I have to take part?**

No, it is entirely up to you. This information sheet should help you to decide whether you want to take part and you will have opportunities to ask any questions you may have. **Even if you decide to take part, you can still leave the study at any time without giving a reason up to six weeks after the recording of your birth**. A decision to take part or leave the study or not to take part will not affect your standard of care.

**What will happen to me if I take part?**

If you take part in this study, your labour and birth will be video or audio recorded (you would decide which option you prefer, although video provides the most accurate information about communication). The camera resembles a drip trolley, so it looks like a piece of hospital equipment (you will be shown what it looks like before you decide to take part), and it is designed not to intrude on your experience of labour. The camera is very simple to operate. It does not require additional people to work it, **so the research team will not be present during your labour**. Instead, the camera will be set up by the ward staff at a time that is convenient to you once you have been admitted to the maternity unit in labour. You will be shown how to stop and start recording when you want to (or you can turn the camera around to face the wall, if you would prefer audio-only).

Apart from the recording, your labour and birth will be no different to what would have happened if you were not taking part in the study. You can, for example, have a water birth and still take part in the study. The purpose of the recording is simply to capture how people **talk and interact** during labour. The recordings will be securely stored and no-one outside of the research team will be able to access them. You will be anonymous (nobody will be able to identify you) when we present our findings. You can choose how we are allowed to use your recordings when we present our findings (e.g. whether we can present anonymous typed-up (text) versions of what was said during labour, anonymous audio clips or anonymous video clips (where we would change voices/hide faces and private body parts).

In addition to recording your labour, we will ask you to complete two questionnaires. The first questionnaire would be sent to you (either online or in the post with a stamped addressed envelope) when you are around 35 weeks pregnant. This will ask you about your expectations for communication and decision-making during the labour and birth. We will send another questionnaire (again either online or by post) about six weeks after the birth that asks you about your satisfaction with the experience. Please note that if you would prefer to receive copies of the questionnaires in a language other than English, we will be able to provide a version in your preferred language.

Please see the timeline of events in Appendix 1 on page 6 for an overview of what will happen and when it will happen if you decide to take part in this study.

**Why are labours and birth being recorded?**

We need to record labour and birth in order to capture the details of what is said and how it is said. It is impossible to do this properly just by observing and making notes or by asking maternity ward staff about their work. We want to know what really happens so that the guidelines we write are based on real-life rather than theory. We would like to video-record in particular because it will help us to know, for example, what is happening during silences in the talk (e.g. did someone nod or smile?). However, we expect that some people who would like to take part may prefer to be audio-recorded. You can therefore choose whether to be audio or video-recorded.

**If I decide that I would like to take part, what will happen next?**

If you so wish, and if you are happy that you fully understand the study and your role in it and you have had all of your questions answered satisfactorily, you can consent to taking part in the study straight away. This includes agreeing to take part in the study at your 20 week scan appointment. Alternatively, if you would like to take study information away with you to think about and discuss with family and/or friends, then you can do so. In this event a research midwife or our study research associate will contact you by phone approximately a week after you first complete the Expression of Interest form. They will talk through this information sheet with you and see if you have any questions. If you are happy to take part then a research midwife or our study research associate will arrange to meet with you at a time and place convenient to you, when you are about 30 weeks pregnant or before. At this meeting, they will talk through the study consent form, and ask you to sign it to show that you understand what taking part involves. The meeting can take place in one of three ways, depending on your preference:

* Face-to-face at home or at a place of your choosing.
* Face-to-face in an antenatal care setting as part of your usual midwifery care
* Remotely via Skype or telephone (we will then send a copy of the form out for you to sign and return in a stamped addressed envelope).

It is important that anyone who is planning to attend the birth with you is also present at this appointment, so that they have a chance to ask questions and sign their own consent form. For us to use the recording of your labour in the research, **everyone who is present during labour has to agree that this is ok.** In addition to your own information, we have given you an information sheet for your birth partner(s) to read and think about before they give their consent. If someone attends the birth without having consented before the birth, there will be an opportunity for them to consent at a convenient point after the recording. We will ask you (or them) to leave contact details so that our research associate can get in touch to arrange a consenting appointment (preferably to take place in person or via telephone/Skype with consent forms then returned to the University of York via stamped addressed envelope).

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

The information will be used to help improve future health services by understanding the ways maternity staff include women in decision-making. The study may not have any immediate direct benefits for you but it may help maternity services provide better support for women in the future.

**What are the possible issues for me if I take part?**

The study will involve you spending some time to complete the questionnaires. There is a minor risk that you might find some of the questions difficult to answer. You are free not to answer any questions.

You might feel uncomfortable about having your labour and birth recorded. At any time, you would be free to ask for the recording to be stopped or to switch off the recording equipment yourself. You would also be free to switch from video to audio-recording by turning the camera around to face a wall.

You might feel concerned that researchers and/or others viewing anonymised clips could involve a loss of dignity for you. Please be assured that all data will be sensitively managed and reported (e.g. we will hide private body parts as well as faces). Please also note that the research is not intended to judge your personal labour experience. Instead, we are interested in **patterns** in how decisions are communicated between women, birth partners and healthcare practitioners across all 50 births we are recording.

**Will my labour and birth definitely be recorded if I consent to take part?**

We will do everything we can to make sure that anyone who would like to take part is able to do so. However, there may be reasons that we will not be able to record your labour. For example, we will also need your birth partner, midwives and doctors to agree to take part. If, on the day, there are not sufficient numbers of staff willing to be recorded then it will not be possible to record your labour. Also, in the unlikely event that the recording equipment is already in use at the point at which you are admitted, then it will not be possible to record your labour.

**What if something unexpected happens during labour or something goes wrong because of the study?**

We are recording labours and births that are expected to progress routinely under the care of midwives. The camera is setup to record only on the midwifery led unit. If something changes and you require a move to Consultant-led care the ward staff will stop the recording. We would still use the recording up until the point that it was stopped, unless you ask us not to.

It is unlikely that something will go wrong due to taking part in the study because we will not be interfering with the labour and birth. However, if you have any questions, concerns or complaints about the study, you can talk to the Research Midwife or to a member of the research team, and they will do their best to address them. If you would prefer to talk to someone who is not involved in the study, you can also call the Patient Services Team in Sheffield on 0114 2712400 or email [PST@sth.nhs.uk](mailto:PST@sth.nhs.uk).

**What will happen if I don’t want to carry on taking part in the study?**

You can withdraw from the study at any time before, during or up to six weeks after your labour and birth. You can also change your mind after the birth about the ways in which you want us to use the recording. If you withdraw, your standard of care will not be affected in any way. Any information collected during the time that you took part, and that you no longer wish us to use, will be destroyed and your anonymity and confidentiality will continue to be protected. Be assured that when you contact us, we will not try to change your mind. If you would like to remain in the study but your birth partner changes their mind, we will edit your birth partner out of the recording where practicable. Where this is not practical the recording will be destroyed. If you decide to withdraw but your birth partner wishes to remain in the study, we will destroy any data you do not wish us to use.

**What will be done with the information collected in this study?**

We are interested in communications where decisions about care get made (e.g. pain relief and use of monitoring), so we will not be using your personal or private discussions in our research. Instead, members of the research team will watch or listen to the recordings and type up the moments where decisions were made. Then these moments will be analysed alongside questionnaire responses to find out whether the way decisions are made during labour fits with women’s expectations and whether this helps explain how women feel about their experience of birth afterwards. The findings will be published in scientific journals and presented at conferences and in teaching and training workshops.

We will also publish summaries of the findings on the study website so you can find out the results. The website is <https://www.york.ac.uk/sociology/research/current-research/vip/>

**How will you protect my anonymity and confidentiality?**

You may be concerned that because this study involves recording you that your anonymity and confidentiality will be at risk. However, we have legal and ethical obligations to protect your anonymity and confidentiality (please see Appendix 2 on page 7 for further details). The camera records onto an encrypted hard drive which will be kept in a separate, locked room in the hospital. This means that the recording of your labour is **physically separate** from the camera and it is completely secure. Only members of the research team will be able to access the raw footage. We will digitally alter any identifying features (e.g. your face, your voice, and all mention of identifying names/places) on the video and/or audio so that you cannot be recognised. We may use direct quotes from your labour and birth and from your questionnaire responses in papers, presentations, classes and workshops. However, the quotes will be **anonymous** and **your name will never be included in any paper or presentation.**

**Can I have a copy of my recording?**

You will be able to review the recording with a member of the research team, should you wish to do so. However, in order to maintain the anonymity and confidentiality of **all the people** who appear in your recording (e.g. you, your birth partner, and the healthcare practitioners), we will **not** be able to provide you with a copy to take home.

**Who is organising and funding the study?**

The research is funded by the National Institute for Health Research. It is being carried out by Consultant Midwives at the Sheffield Royal Hallamshire Hospital and at the Calderdale Royal Hospital, five researchers from the University of York and a lay representative. The research has been considered and approved by the South Yorkshire Research Ethics Committee.

**Who should I contact with questions?**

If you have questions about the study at any stage (before, during or after taking part) that you would like to discuss, please don’t hesitate to contact one of the following members of the research team:

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| **Sheffield Royal Hallamshire Hospital** | |
| **Research Midwives:**  **Hilary Rosser**  **Hilary.rosser@sth.nhs.uk**  **Sarah Senbento**  [**Sarah.senbento@sth.nhs.uk**](mailto:Sarah.senbento@sth.nhs.uk)  **Siobhan Gillespie**  [**Siobhan.gillespie@sth.nhs.uk**](mailto:Siobhan.gillespie@sth.nhs.uk)  **Tel: 0114 226 8514**  **Mobile: 07880 182 882** | **Helen Baston** (Consultant Midwife)  **Alison Brodrick** (Consultant Midwife)  Jessop Wing  Royal Hallamshire Hospital  Tree Root Walk  Sheffield  S10 2SF  Tel: (HB) 0114 22 68160  (AB) 0114 22 61003  Email: [Helen.Baston@sth.nhs.uk](mailto:Helen.Baston@sth.nhs.uk)  Alison.Brodrick@sth.nhs.uk |
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| **Dr Victoria Land** (Researcher)  Department of Sociology  The University of York  Heslington, York  YO10 5DD  Tel:  Email: [victoria.land@york.ac.uk](mailto:victoria.land@york.ac.uk) | **Dr Clare Jackson** (Researcher)  Department of Sociology  The University of York  Heslington, York  YO10 5DD  Tel:  Email: [clare.jackson@york.ac.uk](mailto:clare.jackson@york.ac.uk) |
| **Lay Representative** | |
| **Laura Cook**  **Email: laura.cook@york.ac.uk** | |

**Appendix 1: VIP Study Timeline of Events**

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| **Event** | **When it happens** |
| Research Midwife provides information about the study and asks you to complete an ‘Expression of Interest’ Form. Please return this form to the Research Midwife.  If you express an interest in finding out more information, you will progress to the next stage. You may, if you wish, consent to taking part in the study straight away, at your 20 week scan appointment. If you indicate no further interest in the study, then no further contact will be made. | When you are around **20 weeks pregnant**, at your scan appointment. |
| If you wish to go away and think about taking part in the study after your 20 week scan appointment, the Research Midwife will give you information about the study to pass on to anyone who is planning to be there during your labour. If you are interested in taking part, please share the study information with your birth partner(s) and discuss it with them. | At your scan appointment. |
| A Research Midwife or the study Research Associate will contact you to ask whether you are still interested in taking part in the study. This will also be an opportunity for you to ask questions.    If you are not interested in taking part, no further contact will be made. | This will happen about one-two weeks after you were first approached in the clinic. |
| An appointment with a Research Midwife or our study Research Associate who will ask you and your birth partner(s) for your written consent to take part in the study (or just your birth partner, if you have already given consent).  Please note that you can withdraw from the study at any point, even after consenting. | Between **20 and** **30 weeks pregnant**. |
| Complete the antenatal questionnaire (online or hard copy) | When you are around **35 weeks pregnant**. |
| When you ring the hospital in labour, please tell them you are part of the VIP study. We will also give you a notice to place in your hand-held maternity notes that says you are part of the study. Please present this to staff when you arrive at the hospital. | Full-term, **on admission to hospital in labour**. |
| Ward staff will show you how to use the camera and your labour and birth will be recorded. | Full term, **at a point that is convenient to you following admission.** |
| Complete the postnatal questionnaire (online or hard copy). | About s**ix weeks following the birth**. |

**Appendix 2 Legal and Ethical Obligations**

1. We are required to comply with the Data Protection Act 1998 in terms of handling, processing, storage and destruction of the information that we collect from you.
2. Code numbers or pseudonyms (‘made-up’ names) will be used in place of names of people who have given us information on all questionnaires and transcripts so that all information collected for the study can be kept strictly confidential.
3. Consent forms and a database containing participants’ real names and contact details will be stored securely by the University of York and the hospital in which you are giving birth. Your name and personal details will not be provided to any other parties. Questionnaires and recordings will be labelled with a unique code (no real names will be used) and stored on secure servers (all of which will be password-protected) at the University of York. Transfer of recordings will be managed using a portable hard drive and encryption software to ensure that your recordings cannot be accessed by unauthorised people.
4. Access to the recordings and questionnaires will be restricted to the research team. In addition, we will extract the sound from the video recordings and the audio-only versions of the recordings will be sent to a professional transcribing team (the transcribers will not have access to video). Where we need to involve translators (e.g. because you do not speak English during your labour), we will also provide professional translators with audio-only versions. All members of the research, transcribing and translating teams have a duty to protect your anonymity and confidentiality. Nothing that could reveal your identity will be disclosed beyond these teams.
5. Questionnaires and original recordings will be kept for 10 years for the purposes of writing up the study’s findings for publication/training and for possible use in follow-up studies (subject to your consent). After 10 years, the questionnaires and the original recordings will be destroyed (although the anonymised versions will be archived).
6. The only reason that we might have to break confidentiality is if anything you told us suggested that you or another person was at risk of harm. Depending on the circumstance, health researchers are required by law to co-operate with designated authorities to prevent or minimise harm in line with legislation or guidance (especially to children – Children Act 1989). This might mean informing someone else about our concerns, **after discussing this with you first**.