

Participant information sheet for HCPs

Recording



Hospital Trust logos here



INFORMATION FOR HEALTHCARE PRACTITIONERS ABOUT THE VIP STUDY

Dear Health Care Provider,

We are informing you about our research project on decision-making during labour and birth and your potential involvement. The research is funded by the National Institute for Health Research (NIHR) and is being undertaken by a research team of Consultant Midwives at (*two hospitals named*), researchers from the University of York, and a service representative. The research has been considered and approved by the South Yorkshire Research Ethics Committee.

This information sheet tells you about the project and what is involved. It is up to you whether you want to take part in the study, and it is important that you have time to consider your decision. Please ask if anything is not clear, or if you would like more information. Thank you for taking the time to read this.

What is the study about?

This study aims to use video/audio recordings to understand the range of interactions which take place between women, birth partners and health professionals during labour. It is in no way intended to judge your clinical practice. Instead, we are interested in the different ways in which decisions are communicated between women, birth partners and healthcare practitioners. We hope to be filming 50 labours and births and will be looking for patterns of communication **across** all of these, rather than at the practice of individuals.

Research has shown that women in labour are more likely to have a positive experience if they are involved in decisions about their care and treatment. We know that what is said during labour can impact on how women look back on their birth. However, research and policy recommendations to staff about how to communicate with women in labour are not based on evidence about what **actually happens** in birth. This is because most existing research is based on interviews or surveys with women some weeks **after** birth, so the details of what was said in labour are lost. Thus systematic research is needed which provides details of **actual talk** about decisions during labour between healthcare practitioners, women, and their birth partners.

To achieve this, we will:

- Video (or audio record if preferred) the labours of 50 women who have given consent to be part of the study, who are low-risk, at full-term.
- We will transcribe (type up) what was said and how it was said and analyse how decisions during labour are discussed using Conversation Analysis, which is the leading research method for understanding how talk works.
- Ask women to complete questionnaires before birth about their expectations and to complete them after birth to ask about their experiences and current wellbeing.
- Look at associations between how women felt about their experience and the kinds of talk that happened during birth.
- Conduct one-to-one interviews with a sample of midwives and doctors to better understand the contexts in which they work.

Will I be filmed?

We are inviting 50 women (between two NHS Trusts), 25 of which will be receiving care in the Birth Centre at (*name supplied*), to be filmed or audio recorded during their labour. They, and their birth partners, will be given detailed information about the study and asked to consent to have their labour / birth either video or audio recorded. Women will have the option to stop filming or withdraw from the study at any point. The camera and microphone are mounted on a drip stand-like pole, which is discrete and unobtrusive. Women and their birth partners will be shown how to operate the cameras so that they remain in control of recording at all times. In the event of a

medical emergency, a move to Consultant Led Care or at the client's request, recording will be stopped.

The recording is for research purposes only. The original footage will be seen only by members of the research team and neither you, nor anyone else who is recorded (e.g. women/birth partners) will be personally identified in the analysis or dissemination of findings.

Insofar as is possible, we want to give staff the option of deciding whether they would like to be included in the study in advance of filming. We are therefore inviting all staff to read this information leaflet and, if they are happy to be recorded, to complete the attached consent form. The consent form enables you to choose the ways in which the research team are allowed to use footage that includes you 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). Please return this consent form to the person who gave you this information sheet or, alternatively, to (*contact details supplied*).

If a woman who has consented to be filmed is admitted to the Birth Centre then recording would be initiated only if midwives who have previously consented to recording are available to provide care. The format of the recording (i.e. audio or video) would be determined by the woman in labour and her birth partner.

All women in the Birth Centre receive care from a range of staff. Once a recording is in progress it is possible that, regardless of whether you have previously agreed to take part in the study, you may be called upon to provide care to a woman in labour who is participating. If recording is in progress, this will be clearly indicated via a sign on the door. You cannot decline to provide care, if required, but you will still be able to decide what happens to any footage that is taken which includes you via a consent form. Consent forms will be made available in rooms where recording is taking place, or can be requested from a member of the research team. **We would not use any footage which includes you without your written consent.**

What are the possible advantages and disadvantages of being included?

Information from the study will be used to help improve future health services by understanding the ways in which decisions are communicated during birth. Participation in the film/audio may not

have any immediate direct benefits for you, but it will ultimately help maternity services better support women in the future.

You might have concerns around anonymity and confidentiality. Please be assured that you will not be identifiable to anyone beyond the research team. You might feel concerned that researchers and/or others viewing anonymised clips could involve a loss of dignity for women in labour. Please be assured that all data will be sensitively managed and reported (e.g. we will hide private body parts as well as faces).

What if something goes wrong?

We are recording labours and births that are expected to progress routinely under the care of midwives. The camera is set up to record only on the midwifery led unit/birth centre. If something changes and the woman requires a move to Consultant-led care the recording would be stopped. Recordings made prior to this point would be retained and used in the study, unless the woman asks us not to do this.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time **before** the recording of a labour and birth. If you wish to withdraw, please contact a member of the research team. Be assured that when you contact us, we will not try to change your mind. You will also be able to withdraw your consent for your video/audio recording to be used up to 6 weeks post birth. Where practicable you will be edited out of the recording. Where this is not possible your video/audio recording will be destroyed. You can also choose to opt out of further participation in the study in subsequent women's labours. If you wish to do this, please contact a member of the research team. We would ask you **not** to turn the video/audio off **without** the woman's consent (unless there is a medical emergency, or the woman loses her low risk status and is moved to another unit). This is so that the woman and her birth partner do not experience undue stress and anxiety over the care they are receiving.

What will be done with the information that is collected from the recording?

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 anonymised findings will be published in scientific journals and presented at conferences and in teaching and training workshops.

The research team will make sure that you have the opportunity to hear about the results of the study by presenting the findings at staff meetings. 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?

We have legal and ethical obligations to protect your anonymity and confidentiality (please see Appendix 1 on page 5-7 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 a woman's 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 names and places) on the video and/or audio so that you cannot be recognised. We may use direct quotes from the labour and birth in papers, presentations, classes and workshops. However, the quotes will be **anonymous** and your name will never be included in any paper or presentation.

We would like, with your permission, to offer the anonymous typed up (text) version of your recording to the UK Data Archive. This is so that other researchers can also use the data in the future for different projects, which will mean that the maximum benefit is gained from this study. The UK Data Archive is carefully managed. Researchers have to register with the archive, and they have to sign agreements which strictly regulate the ways in which they can use data held in the archive. You can still take part in the study even if you do not want us to put your data in the archive. You will have a choice about this on the consent form

Can I have a copy of the 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 the recording (e.g. you, your colleagues, the woman giving birth and her birth partner), we will **not** be able to provide you with a personal copy.

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 (*two hospitals named*), five researchers from the University of York and a lay representative.

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. (*Contact details supplied*)

Many thanks for your time in reading this leaflet and considering taking part.

Appendix 1 Legal and Ethical Obligations

The University of York is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

On what basis will you process my data?

Under the General Data Protection Regulation (GDPR), the University has to identify a legal basis for processing personal data and, where appropriate, an additional condition for processing special category data.

In line with our charter which states that we advance learning and knowledge by teaching and research, the University processes personal data for research purposes under Article 6 (1) (e) of the GDPR:

Processing is necessary for the performance of a task carried out in the public interest

Special category data is processed under Article 9 (2) (j):

Processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes

Research will only be undertaken where ethical approval has been obtained, where there is a clear public interest and where appropriate safeguards have been put in place to protect data.

In line with ethical expectations and in order to comply with common law duty of confidentiality, we will seek your consent to participate. This consent will not, however, be our legal basis for processing your data under the GDPR.

How will you keep my data secure?

The University will put in place appropriate technical and organisational measures to protect your personal data and/or special category data. For the purposes of this project, the following measures are in place:

- Code numbers or pseudonyms ('made-up' names) will be used in place of names of people who have given us information so that all information collected for the study can be kept strictly confidential.
- Consent forms and a database containing participants' real names and contact details will be stored securely by the University of York and by the hospital in which the birth takes place. Your name and personal details will not be provided to any other parties. 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.
- Access to the recordings 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 a woman does not speak English during her 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.
- 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).

All research material irrespective of its nature could potentially be used if requested to corroborate a complaint. In these circumstances, it would not be possible to maintain confidentiality. Additionally, you should be aware that, in the highly unlikely event that we observe poor practice on the recordings, the research team would have an ethical and legal obligation to follow institutional procedures for reporting this. However, if care is given according to usual best practice standards, then accurate recording would be an advantage if care were to be subsequently questioned.

Will you transfer my data internationally?

Possibly. The University's cloud storage solution is provided by Google which means that data can be located at any of Google's globally spread data centres. The University has data protection compliant arrangements in place with this provider. For further information see, <https://www.york.ac.uk/it-services/google/policy/privacy/>.

What rights do I have in relation to my data?

Under the GDPR, you have a general right of access to your data, a right to rectification, erasure, restriction, objection or portability. You also have a right to withdrawal. Please note, not all rights apply where data is processed purely for research purposes. For further information see, <https://www.york.ac.uk/records-management/generaldataprotectionregulation/individualsrights/>.

As outlined previously, you can withdraw from the study at any time before, during or up to six weeks after a birth takes place. 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, we will **not** be able to provide you with a copy to take home.

Questions or concerns

If you have any questions about this information or concerns about how your data is being processed, please contact Professor Ellen Annandale (ellen.annandale@york.ac.uk) in the first instance. If you are still dissatisfied, please contact the University's Data Protection Officer at dataprotection@york.ac.uk.

Right to complain

If you are unhappy with the way in which the University has handled your personal data, you have a right to complain to the Information Commissioner's Office. For information on reporting a concern to the Information Commissioner's Office, see www.ico.org.uk/concerns

PIS for HCP interviews



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INFORMATION FOR HEALTHCARE PRACTITIONERS ABOUT BEING INTERVIEWED FOR THE VIP STUDY

We are contacting you to ask if you would consider taking part in an interview as part of our research project on decision-making during labour and birth. The research is funded by the National Institute for Health Research (NIHR) and is being undertaken by a research team of Consultant Midwives at (*two hospitals named*), researchers from the University of York, and a service representative. The research has been considered and approved by the Yorkshire and Humber – South Yorkshire Research Ethics Committee.

This information sheet tells you about the project and what is involved. It is up to you whether you want to take part in the study, and it is important that you have time to consider your decision. Please ask if anything is not clear, or if you would like more information. Thank you for taking the time to read this.

What is the study about?

The study is about the communication that takes place between healthcare practitioners, women, and their birth partners during labour and birth. We are doing this because research shows that when women in labour are involved in decisions about their care (e.g. decisions about pain relief, fetal monitoring and birth position) they are more likely to feel positively about their experience than when they are not. Our main aim is to find out how decisions are reached and communicated through the 'talk' that happens between staff, women in labour and their birth partners when giving birth in maternity units. We also want to understand healthcare professionals' *experiences* of discussing decisions during labour, as well as how such discussions are shaped by the organisational contexts in which they work. It is in order to address this aspect of the study that we are inviting healthcare practitioners to take part in research interviews.

Collectively, the information generated by the study will be used to identify how woman-centred decision-making can be facilitated and to inform health care professionals' undergraduate and continued professional development, as well as the development of policy concerning communication during maternity care.

To achieve this, we will:

- Video (or audio record if preferred) the labours of 50 women who have given consent to be part of the study, who are low-risk, at full-term.
- We will transcribe in full what was said and how it was said and analyse how decisions during labour are discussed using Conversation Analysis, which is the leading research method for understanding how talk works.
- Ask women to complete questionnaires before birth about their expectations and to complete them after birth to ask about their experiences and current wellbeing.
- Look for associations between how women felt about their experience and the kinds of talk that happened during birth.
- Conduct one-to-one interviews with a sample of midwives and doctors to better understand the contexts in which they work.

Why have I been invited to take part in an interview?

We are interviewing a sample of approximately 4 doctors and 6 midwives in each of the two Trusts (around 20 interviews in total) to get their views and feedback on

- What is helpful and unhelpful in giving women choice and involving them in decisions.
- The organisational factors that may facilitate or constrain decision-making during labour e.g. busyness, local protocols, fluctuation in demand, staff skill mix.
- Our broader study, and the way in which it is being implemented (i.e. are there issues you want to draw to our attention?).

This information will assist us in interpreting the data on how decisions are made by providing important information about the contexts in which this takes place.

What will happen if I decide to take part?

If you would like to take part, please contact [*contact details supplied*]. A member of the research team will then contact you to arrange an interview which will be:

- Conversational in style, as we are interested in your experiences and perceptions (you may decline to answer any questions should you wish and halt the interview at any point).
- Approximately 45 minutes, at a time and location convenient to yourself.
- Audio-recorded (for accuracy) and transcribed (typed up) for analysis.
- Confidential and anonymous. Nothing you say will be reported in a way that might identify you.

What are the possible advantages and disadvantages of taking part?

Information from the study will be used to help improve future health services by understanding the ways in which decisions are communicated during birth. Participation in the interview may not have any immediate direct benefits for you, but it will be an opportunity for you to express your views and will we hope that it will ultimately help maternity services better support women in the future.

You might have concerns around anonymity and confidentiality. Please be assured that you will not be identifiable to anyone beyond the research team.

What will happen to the information collected from the interviews?

The interviews will be transcribed (typed up) by a professional transcriber who has signed a confidentiality agreement. Members of the research team will examine the transcripts to explore the issues which healthcare professionals describe as central to decision-making during labour. This information will be used to provide a background context in which to understand our recordings of the interactions that take place between healthcare professionals, women and birth partners during labour. Collectively, the information generated by the study will be used to identify how woman-centred decision-making can be facilitated. The anonymised findings will be published in scientific journals and presented at conferences and in teaching and training workshops.

The research team will make sure that you have the opportunity to hear about the results of the study by presenting the findings at staff meetings. We will also publish summaries of the findings

on the study website so you can find out the results. The website is

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How will you protect my anonymity and confidentiality?

We have legal and ethical obligations to protect your anonymity and confidentiality (please see Appendix 1 on page 4-5 for further details). We may use direct quotes from your interview in papers, presentations and workshops. However, the quotes will be **anonymous** and your name will never be included in any paper or presentation.

We would like, with your permission, to offer the anonymous typed up (text) version of your interview to the UK Data Archive. This is so that other researchers can also use the data in the future for different projects, which will mean that the maximum benefit is gained from this study. The UK Data Archive is carefully managed. Researchers have to register with the archive, and they have to sign agreements which strictly regulate the ways in which they can use data held in the archive. You can still take part in the study even if you do not want us to put your data in the archive. You will have a choice about this on the consent form.

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 (*two hospitals named*), five researchers from the University of York and a lay representative.

Who should I contact with questions?

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- Access to the recordings will be restricted to the research team. In addition, the recordings will be sent to a professional transcribing team. All members of the research and transcribing teams have a duty to protect your anonymity and confidentiality. Nothing that could reveal your identity will be disclosed beyond these teams.
- The original recordings will be kept until the data analysis process is complete, including possible use in follow-up studies (subject to your consent). After this, the original recordings will be destroyed securely (although the anonymised versions of the data will be retained).

Will you transfer my data internationally?

Possibly. The University's cloud storage solution is provided by Google which means that data can be located at any of Google's globally spread data centres. The University has data protection compliant arrangements

in place with this provider. For further information see, <https://www.york.ac.uk/it-services/google/policy/privacy/>.

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