



Our ref: <BABY Study ID>

<Participant Name>
<Address 1>
<Address 2>
<Address 3>
<Address 4>
<Postcode>

Dear <Participant Name>,

**Identifying Depression in Pregnancy & Early Motherhood:
BABY PaNDA Study**

Thank you for taking part in the BABY study. We are now writing to invite you to take part in BABY PaNDA, a special aspect of the BABY study.

The BABY PaNDA Study is being carried out by researchers in the Department of Health Sciences at the University of York in partnership with doctors, midwives and health visitors involved in the care of women during pregnancy and early motherhood in local NHS Trusts. The study has been funded by the government through the Health Services & Delivery Research Programme. The study has been reviewed and approved by the North East Northern and Yorkshire Research Ethics Committee.

The BABY PaNDA Study involves investigating screening for depression in pregnancy and early motherhood. We want to know whether a brief screening questionnaire is a good way of identifying women with depression during pregnancy and after birth. We hope to involve 350-400 women in the study. The enclosed information sheet describes the study in more detail. Please take time to read it carefully and discuss it with others if you wish. If you would like more information about the study, our contact details are at the top of this letter.

If you would like to take part in the study, please fill in the enclosed consent form and send it to the research team in the enclosed pre-paid stamped addressed envelope. You will also need to keep this letter and the information sheet. You will have the chance to ask more questions about the study when the researcher makes contact with you.

You are under no obligation to take part if you do not feel that the study is right for you. If you decide you are not interested, your normal care will continue.

Yours sincerely,

Simon Gilbody
Professor of Psychological Research & Health Services Research

Identifying Depression in Pregnancy & Early Motherhood: BABY PaNDA Study

Participant Information Sheet

Thank you for taking part in the BABY study. You are now being invited to take part in BABY PaNDA, a special aspect of BABY investigating screening for depression in pregnancy and early motherhood. Before you decide, please take time to read the following information carefully and discuss it with family, friends or your GP if you wish. Our contact details are on the back page if you would like any more information.

You can continue to take part in other aspects of the BABY study even if you decide to take part in BABY PaNDA.

What is the purpose of BABY PaNDA?

We would like to find out more about depression during pregnancy and early motherhood, and the best ways of identifying it. Approximately 1 in every 10 women is thought to experience depression during this time. Unfortunately, it is often not identified with around half the women affected not getting the help and support they need.

The National Institute for Health and Clinical Excellence (NICE) have recommended that a brief two-question screening questionnaire should be used to identify women with depression during pregnancy and after birth. However, it is not yet known how well this brief questionnaire works compared to other longer screening questionnaires. BABY PaNDA aims to find out.

Why have I been invited?

We are inviting women who have joined the BABY study early in their pregnancy to also take part in BABY PaNDA. We hope approximately 350-400 women will agree to take part in BABY PaNDA.

What does BABY PaNDA involve?

The study involves taking part in three questionnaire sessions with a specially trained researcher to find out how you feel at three time points during your pregnancy and

after your baby is born. Each session will last around 30 to 40 minutes and take place at approximately:-

1. 20 weeks of pregnancy
2. 3-4 months after the birth of your baby
3. 1 year after the birth of your baby

You will be asked some brief questions and you will also be asked to fill in some short questionnaires (we can help you with these if necessary).

A researcher will telephone you before each session to arrange them at a time and place of your choice. Your first two sessions will take place face-to-face. The final session, at around the time of your baby's first birthday, will take place by telephone; if you prefer, you can complete the questionnaires online through a secure website, or we can send some of the questionnaires to you by post for you to complete and return to us.

Additional Interviews

Approximately 25-30 women taking part in BABY PaNDA will be asked to take part in up to three additional face-to-face interviews. These are to help us collect more information, including women's views on the depression screening questionnaires and how they feel about them. This information is very important as we need to find out if women are happy with the questions used to identify depression during pregnancy and early motherhood. If you have given us consent to look at your medical records as part of the BABY study, we may also collect information from your medical records about the NHS services you have used whilst taking part in BABY PaNDA.

The additional interviews will take place one to two weeks after each BABY PaNDA questionnaire session has been carried out, and take up to one hour to complete. You will be interviewed by an experienced female researcher from the study team at a time and place of your choice. If you agree, the interviews will be recorded and any information that could identify you will be removed when the interview is written up afterwards.

If you decide not to take part in the additional interviews, you can still take part in BABY PaNDA by completing the questionnaire sessions at 20 weeks of pregnancy, and 3-4 months and 1 year following the birth of your baby.

Do I have to take part in BABY PaNDA?

It is up to you to decide whether to not to take part. If you do decide to take part, you are free to withdraw from the study at any time without giving a reason. You can remain in the BABY study even if you decide to withdraw from BABY PaNDA. Whatever your decision, it will not affect the standard of care you receive or your relationship with your doctor, midwife or health visitor.

If you take part, you may find that during your maternity care your midwife and/or health visitor may ask you to complete some of the same screening questions to identify depression that we are using in BABY PaNDA. Please do not worry if this happens. The questionnaires that you complete as part of BABY PaNDA will only be used for research purposes.

Why should I help?

Your contribution to BABY PaNDA will be very valuable in helping us understand whether the brief screening questionnaire is effective at identifying depression during pregnancy and early motherhood. There will be no benefits to your usual maternity care or the care you receive from your health visitor. Taking part in this study will involve some of your time to complete the questionnaires. We do not anticipate any other disadvantages to you taking part in the study.

Will my information be kept confidential?

Yes. All information collected about you during the study will be treated confidentially and in accordance with the Data Protection Act. Any personal information which could identify you will be kept separately from your study information and will only be accessed by members of the research team.

We will destroy all personal information immediately after the end of the study. We will store your study information securely for 20 years and then destroy it.

If you decide to withdraw from the study, your personal information will be securely destroyed. We would still, however, like to use other information collected from you for the BABY PaNDA study. Please let us know if you do not want us to keep this information if you withdraw from BABY PaNDA.

Will my GP be involved?

All GP practices in the study area have received information about BABY and BABY PaNDA. We will let your GP know if you decide to take part in BABY PaNDA. We will also tell your GP if you later decide to withdraw from the study.

If we are worried about your welfare or safety, or the welfare or safety of your baby or other people, the researcher may need to contact your GP so it is important your GP is aware that you are taking part in BABY PaNDA. Please ask the researcher if you have any concerns or questions about this.

You will continue to receive your usual care from your GP, midwife and health visitor throughout the duration of the study.

What will happen to the results at the end of the study?

The study findings will be published in a research report and in articles for health professionals. We will also send you a summary of the study findings at the end of BABY PaNDA. You will not be personally identified in any publications from this study.

Who has reviewed the research?

The research has been reviewed and approved by the North East - York Research Ethics Committee.

Who is organising and funding the research?

This research is being done by researchers in the Department of Health Sciences at the University of York and doctors, midwives and health visitors involved in the care of women during pregnancy and after birth in the local NHS Trust. The research is being funded by the National Institute for Health Research Health Services and Delivery Research (NIHR HS&DR) Programme.

What should I do now?

If you would like to take part, please read and sign the consent form and send it back to us in the pre-paid envelope enclosed. A researcher will then contact you to arrange your first questionnaire session. If you would like more information before deciding, please contact us – our contact details are on the back page.

If you decide that you do not wish to take part, no further action is required.

What do I do if I want to withdraw or complain?

Every care will be taken during this study. If you wish to withdraw from BABY PaNDA or have a concern about any aspect of this study, please contact the study coordinator using the details below. If you do not want to contact the study coordinator you can contact the Chief Investigator, Professor Simon Gilbody (telephone number: *[insert contact number]* / email: *[insert email address]*).

Standard NHS indemnity arrangements apply to this research. While we anticipate no harm or distress to anyone as a result of this study, if you are harmed during this study due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. If you wish to complain formally, the normal NHS complaint mechanisms are available to you.

Further information and contact details

For further general information about research, please see the INVOLVE website at <http://www.invo.org.uk>

For specific information about BABY PaNDA, please contact:

BaBY PaNDA Coordinator: [*insert name*]

Address: [*insert current address*]

Freephone: [*insert contact number*]

Email: [*insert email address*]

Website: [*insert website address*]

Thank you for reading this information.

The BABY PaNDA Study: Identifying Depression in Pregnancy & Early Motherhood Summary Information Sheet

BABY PaNDA is a special part of the BABY study set up to investigate screening for depression in pregnancy and early motherhood. Women who join the BaBY study early in pregnancy may be invited to take part in BaBY PaNDA too.

What is the purpose of BABY PaNDA?

To find out more about depression during pregnancy and early motherhood and the best ways to identify it. We know that around half the women affected are not getting the help and support they need because their depression is often not identified. BABY PaNDA hopes to find out whether brief screening questionnaires are a good way to identify women with depression during this time.

Who is being invited to take part in BaBY PaNDA?

Women who have recently joined the BaBY study early in their pregnancy. Invitation letters are being sent to eligible women between 15 and 18 weeks of pregnancy. We hope that 350-400 women will agree to take part in BaBY PaNDA too.

What does BABY PaNDA involve?

Three meetings with a specially trained researcher to find out how you feel at three time points; once during pregnancy and twice during your baby's first year. Women will be asked some brief questions and to fill in some short questionnaires. Each session lasts 30 – 40 minutes and takes place at approximately 20 weeks of pregnancy, and 3-4 months and 1 year after your baby is born.

A few women will be asked to take part in up to three additional face-to-face interviews. These are to collect information about women's views on the depression screening questionnaires and how they feel about them. Women may still take part in BABY PaNDA even if they prefer not to take part in the additional interviews.

What should I do if I would like to take part in BaBY PaNDA?

Please read the Participant Information Sheet enclosed with your PaNDA invitation letter. It contains more detailed information about what the study involves. Then read and complete the consent form and post it back to us in the pre-paid envelope

provided. A researcher will contact you before each meeting to arrange them at a time and place of your choice.

If you would like more information about taking part in BaBY PaNDA:

Please contact the study coordinator, [*insert name*]: Freephone: [*insert contact number*] or Email: [*insert email address*]



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If you would like to take part in the BABY PaNDA Study, it would be really helpful if you could complete the information below to allow us to keep our records up-to-date. Please send this form, along with your completed consent form, to the research team in the pre-paid envelope enclosed.

Name:	
Address:	
Postcode:	
Mobile No:	
Landline No:	
Email Address:	
GP Name:	
GP Address:	
Date & location of 20 week scan, if known/booked	



Identifying Depression in Pregnancy & Early Motherhood: BABY PaNDA Study

Consent Form

Thank you for reading the information about this study. If you would like to take part, please read and sign this form. Please put your initials in the boxes of the statements you agree with:

- 1. I have read the patient information sheet and have been given a copy to keep. I have been able to ask questions about the study and I understand why the research is being done.
2. I understand that my participation in this research is entirely voluntary and that I will not receive any payment. I understand that I am free to withdraw my consent at any time without giving a reason and without my medical care being affected.
3. I am willing to complete the BABY PaNDA questionnaires at approximately 20 weeks of pregnancy and at approximately 3-4 months and 1 year after my baby's birth.
4. I am willing to be interviewed by an experienced researcher approximately one week after completing the BABY PaNDA questionnaires if I am approached to do so.
a. I am happy for these interviews to be recorded and kept safe in an anonymised format.
b. I understand that direct quotes from these interviews may be used in the publication of the study results but that these will be anonymised.
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of York, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give my permission for these individuals to have access to my records.
6. I agree to my GP being informed of my participation in this study and updated with information from this study relevant to my medical care.

Name of patient (BLOCK CAPITALS)

Date

Signature

PLEASE RETURN THIS FORM IN THE STAMPED ADDRESSED ENVELOPE PROVIDED / PLEASE RETAIN THIS FORM FOR YOUR RECORDS