

6 WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

7 WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information:

- at hra.nhs.uk/information-about-patients
- our leaflet available from hra.nhs.uk/patientdataandresearch
- from babysleepresearch.co.uk/bsp-data-privacy-notice
- by asking one of the research team
- by sending an email to babysleep@bristol.co.uk, or
- by ringing us on **07811 038 635**.

8 WHERE CAN YOU GET MORE INFORMATION AND CONTACT THE STUDY TEAM?

The study is being run by researchers at the University of Bristol, funded by the National Institute for Health Research.

If there is anything you do not understand or if you would like more information, please email: either **Anna** or **Becky** (researchers) at: babysleep@bristol.ac.uk or phone them on: **07811 038635**

If you have any concerns or complaints about the study you can contact the University of Bristol's Research Governance Team: research-governance@bristol.ac.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS) by phoning **01173 421050**.

This study and the research team are under the supervision of Professor Peter Blair, Professor Jenny Ingram, Professor Peter Fleming, and Dr Michelle Farr, University of Bristol. The study has been given approval by the South West - Frenchay Research Ethics Committee Ref: 23/SW/0119.

More information about the study is available here: babysleepresearch.co.uk

Thank you very much for taking the time to read this information leaflet.



Baby SLEEP PROJECT

FAMILY MEMBERS

INFORMATION BOOKLET

Supporting families with safer sleep for babies

You can watch a short introduction to the study here: (draft: youtube.com/watch?v=j1A-oh_l2gY)

We would like to invite you to join our study, but we want to be sure you know what is involved. Please read this leaflet carefully, take your time to decide and talk to others if you wish. You can also ask your health professional or a family member to read this with you.

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1 WHAT IS THE STUDY ABOUT?

This study is to assess some new resources to help families with their baby's sleep. As part of this project, we have worked closely with families to develop a number of resources to support families with their baby's sleep, and we would like to find out if these resources are useful. These resources will be provided to you by your health care professional, who will decide which resources are suitable for your family. You can see and use the resources without taking part in the study.

2 WHY HAVE YOU BEEN INVITED?

- You have been invited because you are a parent or carer of a new baby who has been identified as being eligible for extra support with sleep by your midwife, neonatal nurse, health visitor or family nurse, in one of our study locations.
- It is up to you to decide whether or not to take part in this study. Your treatment and your baby's care will not be affected now or in the future if you decide not to take part and you are free to leave the study at any time.

3 WHAT WILL HAPPEN IF YOU TAKE PART?

- If you agree to take part you will be asked to complete two questionnaires, these questionnaires will ask you about how you feel about being a parent and where and how your baby is sleeping (a sleep diary).
- You can decide if you'd like the questionnaires emailed to you to fill out yourself or completed over the phone with a researcher.

- After you have completed questionnaire 2 you will receive a £10 voucher to say thank you for your time.
- We may also ask if you would like to take part in a short interview (approx. 30 mins) with a researcher either over the phone or in person. In this interview we would like to talk about what you thought of the resources. You do not have to take part in this interview. If you agree, the interview will be audio recorded, with your consent.

4 WHAT ARE THE POSSIBLE BENEFITS AND DISADVANTAGES OF TAKING PART?

- The only disadvantage is likely to be the time it takes to complete the questionnaires and take part in the interview.
- If you agree to take part in the interview, you will be asked questions about yourself and your baby. All of these questions are optional and if we ask you anything that you don't want to answer, you will be able to pause or stop the interview without having to give a reason.

- There should be no other risks or problems and taking part in this study will not affect, in any way, your family's medical care now or in the future.
- By taking part you will help us to support families to keep their babies safe during sleep.
- If during the course of the study, we become concerned about you or your child's safety we will seek support for you and your family from the appropriate services. This may involve writing down safety concerns that we have, and if necessary, sharing them with the safeguarding lead in our team, your health visitor, midwife and/or the appropriate services. We would talk to you about this and explain what we are doing and why, if this were to happen.
- To say 'Thank You' for taking part, you will receive a £10 Love2Shop Voucher for completing both questionnaires, and a further £20 voucher if you decide to take part in an interview.

5 HOW WILL WE USE INFORMATION ABOUT YOU?

- We will use information from you in this research project. This information will include your contact details (for sending the questionnaires), your answers to the questionnaires, and the information you share if you take part in an interview.
- People will use this information to do the research or to check your records to make sure that the research is being done properly.

- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- We will keep all information about you safe and secure.
- Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.
- The handling, processing, storage, and destruction of these data will be compliant with the Data Protection Act 2018 and General Data Protection Regulations.
- We can also send you the results from the study if you would like to see them, the researcher will need an email address to do this, but this will be kept separately to any of the other data we collect, and deleted after we've sent you the results.
- Data which have had all personal details removed will be kept safe and secure and be stored on password-protected computers for a minimum of 10 years, in accordance with University of Bristol guidelines.
- The results of this study will be shared with other health staff and parents by reports in medical and health journals, newsletters, and talking about the results at conferences.
- After the study finishes, we may make anonymised transcripts available for future research via the University of Bristol Research Data Repository (data.bris.ac.uk/data). Access will only be granted to researchers with appropriate ethical approval.

