



## Participant Information Sheet (PIS)

**Study Title:** Direct REporting of Awareness in MaternitY patients (DREAMY): A prospective evaluation of accidental awareness under general anaesthesia in obstetric surgery patients

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**Chief Investigator:** Dr. Peter Odor, St. George's University Hospitals NHS Foundation Trust, London



We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following carefully (this should take about 10 minutes) and discuss it with others if you wish. Please ask us if there is anything that is not clear. Take time to decide whether you wish to take part.



## Summary of the study:



x2, in hospital



after 30 days  
(and potentially  
up to 12 months)

Only women who have a general anaesthetic for a surgical procedure related to pregnancy may participate in this study. Whilst in hospital you will be asked a short series of questions about what you remember about your general anaesthetic. You will also receive a telephone call at around 30 days after your anaesthetic and asked a further short series of questions. Depending on your responses we may ask to call you again occasionally over the following 12 months to ask further questions about whether you are experiencing any distress related to these memories. Please read on to find out more and help you decide whether to be involved or not.

## What is the purpose of the study?

Some patients who are put to sleep for a surgical procedure later remember something about that procedure. This has been described as awareness under general anaesthesia. It is a rare event but the risk of it happening is higher for pregnant women than other patients. By asking a short series of questions, the purpose of this study is to find out exactly how frequently women can recall events during their anaesthetic, what they can recall, and whether this experience causes any long-term problems.

## Why have I been invited to take part in this study?

You have been invited to participate in this study because you have recently been put to sleep (general anaesthesia) for a surgical procedure related to your pregnancy.



### Do I have to take part?

It is up to you to decide whether or not to take part. This information sheet will describe the research study and help you decide. If you do take part, then you are still free to withdraw at any time and without giving a reason. A decision to not take part in this study or to withdraw at any time will not affect the standard of care you receive.

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

If you agree to participate in this study, the only thing that you need to do is answer a series of short questionnaires. The first three questionnaires contain six questions on memories you may have of your general anaesthetic. Each will take about five minutes to complete. The questionnaire will be provided at the following times: within 24 hours of your anaesthetic, between 24-48 hours following your anaesthetic and 30 days later. A member of our research team will contact you by telephone to ask you the same questions from the questionnaire at 30 days. Your anaesthetist will also submit details of the anaesthetic that you received to our research team.

If you find that you can recall events from during your anaesthetic, your medical team will contact you to provide further support and care if you feel that you would like it. The DREAMY research team will invite you to complete a more detailed questionnaire – either in written format, by telephone or face-to-face interview. This will allow you to discuss in more detail the events you remember and your experience during the awareness event. The DREAMY research team will also contact you by telephone every three months for a period of one year to determine whether you have experienced any long-term effects because of your awareness experience, including common problems that people sometimes have in response to a stressful experience. To help us understand your answers more clearly we may also ask some basic detail about your health and your baby's health, where relevant. Please also note that if you are part of the first group of women to enrol for the study then you may also be asked the above questions about problems in response to stressful experiences, even if you do not remember any events during your general anaesthetic.

### What are the possible disadvantages and risks of taking part?

Participating in this study will not expose you to any risks to your health or wellbeing. You will, however, need to spend some time answering the questionnaires, including at 30 days after the anaesthetic, when you may be at home with your baby. As part of the study we do need to share your contact details with members of the research team, but they will not be shared further or used for any purpose other than this research.

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

If you recall events from your anaesthetic/surgery, you will be offered further medical support, if you feel that you need it. The DREAMY research team will remain in touch with you every three months for a period of one year. If you develop any longer-term effects of your experience during this period of monitoring, you will be offered further appropriate support. Participating in this study will allow us to develop a clearer understanding about anaesthetic





awareness and design better pathways of care to reduce harm for patients who experience awareness whilst under general anaesthesia in the future.

### What if there is a problem?

If you wish to complain, or have any concerns about any aspect of the way you have been treated during this study, then you can speak with the researchers who will do their best to answer your questions or concerns. The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Research Office at St George's University of London on 020 8725 4986.

### Will my taking part in the study be kept confidential?

If you participate in this research your medical team will share some limited information with our research team. This data will be kept confidential and stored on a secure computer database (using REDCap software) hosted by St. George's University of London. Any data used to identify you will only be stored for up to 12 months and after your follow up is complete this data will be erased. All remaining data will be anonymised. Information uploaded to this server will include your name and contact details (which will both be deleted after your follow up is complete), your responses to the research questionnaires and detail about the general anaesthetic you received. This information is shared so that our DREAMY Research Team, who are separate from your local hospital or midwifery team, can contact you for a follow up telephone call 30 days after your anaesthetic and to offer you future interviews, if appropriate. The research team will only have access via password-protected encrypted communications with a server housed in a locked, secure location on the St. George's University of London site. We will share information about whether you experienced any form of anaesthetic awareness with your usual hospital medical team, so that they can offer you appropriate support. Only if the researcher has serious concerns about your own or your baby's wellbeing will any information about your health or your baby's health be shared beyond the research team, in which case the researcher may alert appropriate services.

### Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favorable opinion by London – Fulham REC.

### Further information and contact details

If you require specific information about this research project, advice as to whether you should take part or details of who you should approach if you unhappy with the study:

You can visit the study website at: <http://www.uk-plan.net/DREAMY>

Ask your local Principal Investigator: \_\_\_\_\_

**Chief Investigator:** Dr. Peter Odor. Email: [peter.odor@nhs.net](mailto:peter.odor@nhs.net) Tel: \_\_\_\_\_

If you agree to participate in this study, you will be asked to complete a short consent form and you will be given a copy of this information sheet and your consent form to keep for your records.

