

## Healthcare Professionals - Participant Information Sheet The NeoBath Study: Bathing babies in Neonatal Care

IRAS ID: 329394

### Invitation paragraph

University College London are inviting you to take part in a study called the NeoBath study: developing a study to find out how often we should bath babies in neonatal care to prevent infection. Before you decide we would like you to understand why the study is being done and what it will involve for you. One of our team will go through the following information with you and answer any questions you may have. Talk to friends and relatives if you wish to.

### Part 1 - What is involved in the research study?

Tells you the purpose of this study and what will happen to you if you take part.

### Part 2 – Supporting information

Gives you more detailed information about the conduct of the study.

Ask if there is anything that is not clear or if you would like more information. Please do not hesitate to contact a member of the study team on the telephone numbers given at the end of this Information Sheet if you would like to discuss any aspect of the study further.

### Important things you need to know

- Preterm or unwell babies on neonatal units are at higher risk of infection, as they may have thin skin or procedures that unfortunately damage their skin as part of their care
- Bathing babies could help prevent infection by removing harmful skin bacteria, however we do not know how often to bath babies for this to make a difference
- We are inviting babies who were born at UCLH at 30 weeks of gestation or above, who weigh more than 1kg, and who have healthy skin
- Feasibility studies test a study on a small scale (one neonatal unit), to determine the best way to carry the study out in a larger trial (several neonatal units)
- The study will take part on the neonatal unit, and you may provide care for a baby who takes part
- Babies will be allocated to receive a swaddled bath every 4 or every 7 days
- We will take skin swabs using a cotton-wool-bud type swab from the underarm and groin, before and after each bath
- We will compare the skin bacteria on the swabs before and after the bath, to see what affect the bath has
- We will ask your feedback about the study, in a short interview to learn about what went well, or what could be better
- Results will be used to create a larger study to explore whether bathing babies more frequently can reduce their risk of infection

### How to contact us

If you have any questions about this study, please talk to the study team: Dr Katie Gallagher  
([katie.gallagher13@nhs.uk](mailto:katie.gallagher13@nhs.uk))

### Part 1 – What is involved in this feasibility research study?

NeoBath study: IRAS: 329394, HCP PIS v1.3 05/12/2025

## 1. Why are we doing this study?

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Neonatal sepsis is one of the most commonly treated conditions in neonatal care, estimated to affect 49/1000 neonatal admissions in the UK. Healthy skin colonisation can also be disrupted during a neonatal admission, potentially increasing the risk of sepsis. One potential prevention is infant bathing which in many neonatal units globally is a routine procedure. Few studies have explored optimal bathing frequency and whether this could support a reduction in pathogenic skin colonisation and potentially reduce the risks of neonatal sepsis.

When babies should start being bathed, and how often they should be bathed, however, is unclear and neonatal units across the country are providing different care for babies. This means we do not know how frequently babies should be bathed to prevent harmful skin colonisation. Regularly bathing babies may also improve parent preparedness for discharge. In this feasibility study, babies are being randomised to one of two groups; bathing every 4 days or every 7 days for 28 days. We would like to know if the methodology of this study is appropriate for a larger study with several neonatal units to learn what is the optimal frequency for bathing babies, and whether this will reduce infection rates.

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## 2. Why have I been invited?

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We are asking you to consider taking part as a healthcare professional who has been working with babies and their families, who have taken part in this study. We would like to learn from your experiences of the study will help us decide what the next study will look like.

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## 3. Do you have to take part?

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It is up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw at any time and without giving a reason. You may decline to answer any question you do not want to answer, or not answer an interview question by saying “pass”. To take part, we ask you to consent to recording the interview and so it is worth considering whether you feel comfortable with this aspect of the study.

If you decide to take part, there will be a ‘cooling off’ period of 2 weeks following the interview, should you decide within this time that you no longer want to participate. In this time period, you will still be able to withdraw your data without having to give a reason. The recording will be pseudonymised for these 2 weeks and will then be deleted. Following this, we will be unable to remove your data and it will be included in the analysis.

You will not receive any direct benefit from being in this study, however information learned from this study will help us to improve the study for the next stage to see whether frequent bathing can reduce skin colonisation and sepsis. There are no medical risks if you take part in this study.

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## 4. What do I have to do?

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If you are interested in taking part in the interview, we will ask you to contact one of our researchers; Dr Kathy Chant ([k.chant@ucl.ac.uk](mailto:k.chant@ucl.ac.uk)) to discuss further and find out whether you are eligible. If you would still like to take part, we will arrange a time for the interview which is convenient for you. You can decide whether you would like to do the interview on the telephone or over video chat. We will send you a link to an online consent form for you to complete before the interview. We will ask you if

you are interested in being contacted about the next phase of the research; you can say no and still participate in the interview.

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### **5. What will I have to do?**

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This part of the study is observational. That means that no interventions or treatments will take place. We would like to do a single 30-60 minute interview to explore your thoughts on the study and how it could be improved. The interview will be conducted either over the phone or through video conferencing software (MSTeams). A researcher with previous experience of interviewing neonatal healthcare professionals will conduct the interviews. To ensure that we capture what you would like to tell us correctly, we will record the interview, with your consent. The physical recording will be deleted once we have downloaded the written transcript of the conversation. During the interview we will ask you about your experience of working with families who have taken part in this trial.

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### **6. What are the disadvantages and risks of taking part?**

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There are minimal risks in taking part in this study. We would like to ask you about your experiences of caring for babies on the neonatal unit, who have taken part in this study. You may be concerned about having an interview, but we will ensure this is confidential and that you won't be identifiable in any results we present.

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### **7. What are the possible benefits of taking part?**

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Your participation will support the development of a larger study to determine whether regularly bathing babies in neonatal care can reduce their risk of infection. Your potential feedback can also help us to ensure that the larger study is acceptable to the healthcare professionals that will be looking after the babies taking part in the study.

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### **8. What if there is a problem?**

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Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information concerning this is given in Part 2 of this information sheet – Supporting information. If you have any concerns or complaints you should contact the study team in the first instance.

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

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Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2 – Supporting Information.

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### **10. Contact details**

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Study lead investigator

Name: Dr Katie Gallagher

Tel. Number: 020 3108 2301

Research Nurse  
Name: Dr Kathy Chant

Tel. Number: 0207 679 6031

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## Part 2 – Supporting information

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

You can stop being part of the study at any time, without giving a reason. If you withdraw from the study following the 2 week cooling off period, we will be unable to extract your data from the analysis and so this will be used in the study.

### 2. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this via the hospital's Patient Advisory Liaison Service (PALS). Details can be obtained from [uclh.pals@nhs.net](mailto:uclh.pals@nhs.net). When contacting them, please quote the study number at the footer of this information sheet.

However, if you remain unhappy or have a complaint about any aspect of this study and wish to speak to someone independent of the research team/hospital, please email the UCL OR UCLH Joint Research Office on: [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk)

### 3. How will we use information about you?

We will collect the following information from you including:

- Name, contact details, gender, ethnicity, job title, age, length of time in current area of care

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 study code number instead. In rare cases, researchers may need to break confidentiality if they discover something that suggests someone is at serious risk of harm, including the person taking part in the study or someone else. If this happens, the researcher will tell you what action is being taken, unless doing so would put someone at greater risk.

University College London is the sponsor of this research. University College London is responsible for looking after your information. We will not share your information related to this research project with any other organisation. We will keep all information about you safe and secure. Consent forms will be archived with restricted access. Online data will be stored in a secure, password-protected system, and we will follow all privacy and data protection rules.

### 4. International transfers

Your data will not be shared outside the UK.

### 5. How will we use information about you after the study ends?

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. We will keep your

study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

#### 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. You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

You can withdraw from the study within the first two weeks after taking part in the study. If you withdraw from the study following the 2 week cooling off period, we will be unable to extract your data from the analysis and so this will be used in the 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 [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/) the [UCL website](http://www.ucl.ac.uk) or <https://www.ucl.ac.uk/legal-services/privacy>, by asking one of the research team, or by sending an email to [katie.gallagher@ucl.ac.uk](mailto:katie.gallagher@ucl.ac.uk) or Sponsor Data Protection Officer [data-protection@ucl.ac.uk](mailto:data-protection@ucl.ac.uk).

Further information can also be found at; <http://www.hra.nhs.uk/patientdataandresearch> (if you are unable to access the internet and/or would prefer a paper copy, please ask us).

#### 8. What will happen to the results of the research study?

The results will contribute to the development of a larger study exploring frequency of bathing in neonatal care. Fully anonymised results will contribute towards publication in academic journals and conference presentations and will be shared on relevant social media pages (e.g University College London). We will ask you during consent if you would like to receive a copy of the results. If you would, we will contact you at the end of the study and share our findings.

#### 9. Who is organising and funding the research?

The research is sponsored by University College London and is funded by the National Institute for Health Research (NIHR). The specialist neonatal healthcare professionals (nurses, doctors, allied healthcare professionals) in the team paid by the NIHR to conduct the study do not have any conflicts of interest.

#### 10. How have patients and the public been involved in this study?

Parents and neonatal nurses on our neonatal unit identified the need for this study. Many parents had not bathed their baby but said they would love to do so, and that it would increase confidence in their parenting skills. Neonatal nurses identified a need to have better evidence to understand how often babies should be bathed to reduce the risk of potential infection, and to standardise care across different neonatal units. A parent advisory group has been created for this study of parents whose baby was admitted for neonatal care. This group will provide input into all aspects of the study to ensure that it remains family-focused.

## 11. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Nottingham Research Ethics Committee.

## 12. Further information and contact details

You are encouraged to ask any questions you wish, before, during or after the study. If you have any questions, please speak to your study nurse or doctor, who will be able to provide you with up-to-date information. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

- Study lead investigator: Dr Katie Gallagher ([katie.gallagher@ucl.ac.uk](mailto:katie.gallagher@ucl.ac.uk))

Research Nurse

Name: Dr Kathy Chant

Tel. Number: 0207 679 6031

## Thank you

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep. A copy of the signed consent form will be filed with the study records and one may be sent to the Research Sponsor. You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.