

Why are these activities being done?

Babies who stay in hospital are at risk of having bacteria that respond poorly to antibiotics on their bodies (called colonisation). Babies who are born before their due date and who need to stay in hospital for longer periods of time are at higher risk of acquiring such potentially harmful bacteria on their bodies.

The more babies on the unit that have harmful bacteria on their skin, the higher the risk that other babies will pick up these bacteria.

These activities are looking to count the number of babies that have different types of potentially harmful bacteria on their bodies at different time points. It will also look at how this may change over time.

What will these activities involve for my baby?

On the day of the activity, we will collect information about the medical history of your baby including how they were born, how long they have been in hospital, why they are in hospital, any treatments they have received. Your baby will have a poo sample collected from their nappy/diaper and a swab from various areas of their skin taken to check for any potentially harmful bacteria. These samples will be taken by medically trained staff who will be careful to avoid causing your baby any discomfort.

Your baby will only have these data and samples collected on the day of the activity.

Your baby will be assigned an anonymous identification number for these data and samples so they are kept secure and confidential and will not be able to identify your baby.

These activities will happen on [X, Y, Z] dates

Does my baby have to participate?

It is helpful to have as many babies as possible on the neonatal unit participate in these activities to understand the full picture. If you do not want your baby to take part in these activities, please speak to the study team [XXXXXXX] to have your decision documented. All information will be collected anonymously, so it will not be possible to connect it to your baby. For this reason, it will also not be possible to remove the data from your baby after it has been collected.

These activities will happen several times between X and Y dates. Your baby may be on the neonatal unit for more than one sample day. Even if your baby has participated once, you can choose for your baby to not participate in the future.

Where will my baby's information and samples go?

Your baby's information will be collected anonymously and will not be linked to any information that could identify your baby, such as date of birth. The information will be entered into a database that is hosted at St. George's, University of London in London, United Kingdom. It is stored securely and confidentially and will only be available to specific staff running these activities.

The samples taken from your baby's poo and skin swabs will be frozen and shipped to a laboratory at the University of Antwerp in Belgium to look for potentially harmful bacteria. The method that will be used is to look for bacterial genes. The samples will be stored securely, and it will not be possible to link them to your baby. The samples may contain bits of your baby's DNA, but these will be removed before looking for bacteria.

Specific agreements will be in place to ship these samples from your baby's hospital to the laboratory to ensure confidentiality and security.

The information collected and findings from the samples will only be used to count the types of potentially harmful bacteria in babies from the neonatal unit. This information will help plan future studies to see if cleaning the skin of babies on the neonatal unit helps decrease the amount and types of potentially harmful bacteria. The hospital will be informed

of the types of bacteria that are found in their neonatal unit.

Additional information

These activities are funded by the European Union's Horizon 2020 research and innovation programme under grant agreement No 965328 – NeoIPC Project.

The sponsor of these activities is Fondazione Penta Onlus (Penta) in Padua, Italy. They have a lot of experience working on research involving babies and children.

These activities have been reviewed and approved by the ethics committee at St. George's, University of London (United Kingdom) and the ethics committee at [XXXX hospital]

What do I need to do now?

If you are happy for your baby to participate in these activities, you do not need to do anything.

If you would like more information or have questions, please ask the study team: **Contact information: name/role, email/phone**
You can also speak to the Parent Advice and Liaison Service (PALS) team at [XXXX hospital]:
[Phone/Email]

If you would NOT like your baby to take part in these activities, please contact the study team **[Contact information]** to let them know of your decision. You can choose at any point for your baby not to take part even if they have participated previously. Once the information and samples have been collected, they cannot be removed as they will not be linked to your baby's identifiable information.



[insert hospital logo]

Information about surveillance activity happening on this neonatal unit

Research activity called 'NeoIPC'

[Contact information]