

Lactamica 9: Defining upper respiratory colonisation and microbiome evolution in mother-infant pairs following *Neisseria lactamica* inoculation in late pregnancy

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Principal Investigator: Dr AA Theodosiou

Please initial each box if you agree with the statement:

1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions, and have these answered.

2. I understand that my participation is voluntary, and that I am free to withdraw at any time without giving a reason, without any penalty to my own or my baby's medical care or legal rights.

3. I understand that there may be no direct benefit to me or my baby from participating in this study.

4. I agree to having nose, throat and saliva swabs taken, and to nose and saliva swabs being collected from my baby, for storage and use in this study. I understand that these swabs may contain my own and my baby's cells and DNA, but this DNA will not be analysed in this study or in future studies.

5. I agree for samples collected from me and my baby to be stored for use in future infection and immunity studies, subject to appropriate scientific and ethical review.

6. If I withdraw (or if I am withdrawn) from the study, I agree for any information and samples collected prior to my withdrawal to be stored and used anonymously in this study and in future studies. I also agree for the research team to contact me for safety reasons following my withdrawal.

7. I agree for my participation in this study to be documented in my medical notes and in a letter to my GP. I agree to my medical records being accessed by doctors and nurses involved in this study, as well as by monitors auditing the conduct of this study. I agree to be registered on The Over-volunteering Prevention System (www.TOPS.org.uk).

8. I agree to participate in this study.

Items 9 to 14 are optional, and do not affect eligibility to participate in the study.

9. I agree to provide expressed breast milk samples at Visits 3, 4, 5 and 6.	Y L N L
10. I agree for an umbilical cord blood sample to be collected at Visit 3.	$_{\rm Y}$ \square $_{\rm N}$ \square
11. I agree for a blood sample to be collected from my baby at Visits 5 and 6.	Y D N D
12. I agree for a blood sample to be collected from me at Visit 6.	Y N N
13. I agree to saliva and throat swabs from my other children (<5 years) at Visit 6.	Y N N
14. I agree to complete two questionnaires about my experiences in this study.	Y 🗌 N 🗌

Participant name	(print):
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Study doctor name (print):

Participan	t signature:
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Study doctor signature:

Date (dd/mm/yyyy):

Date (dd/mm/yyyy):