**INFORMED CONSENT FORM**

**Participant number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant date of birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- |
| **Study Title:** | OpTIMUM |
| **Protocol number** | Version X.X, XX.XX.XX |
| **Study Sponsor:** | St George’s, University of London |
| **REC reference** | XXX |
| **IRAS number** | 249236 |

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| --- | --- |
|  | Please initial |
| I have read and considered the Participant Information Sheet (version X.X, XX.XX.XX) about the OpTIMUM study. This leaflet provides enough information so that I understand what is involved and any questions I had about the study have been answered to my satisfaction. |  |
| I consent to my GP being informed about my participation in this study. I agree that if the study team is unable to contact me during this study they may ask my GP for my contact details and if I change my GP they may use my NHS number to find details of my new GP. |  |
| I understand that relevant sections of medical notes and data collected during the study may be looked at by the researchers, the Sponsor, my hospital and regulatory authorities.  I give permission for these individuals to have access to these notes where it is relevant to my  participation in this research. |  |
| I agree to the processing of my personal data as explained in the section on "How will my personal data be handled?" of the Participant Information Sheet (version X.X, XX.XX.XX) which I have read and understood. |  |
| I understand that I will be randomised (allocated by chance) to one of the three timing groups and I will receive my whooping cough vaccine according to this |  |
| I consent to being given the whooping cough vaccine by a member of the study team and having three blood samples taken |  |
| I consent to a cord blood sample being taken and I understand that if this is not obtained a member of the study team will ask for my permission to take an additional blood sample from my baby |  |
| I consent to my baby having a blood sample taken by a member of the study team after they have completed their first set of vaccinations |  |
| I understand that participation is voluntary and that I may withdraw from the study at any time without having to give a reason and that this will not affect my routine care |  |
| I understand that if I withdraw from the study any data or samples which have already been collected can continue to be used |  |
| I agree to take part in the study |  |
| *OPTIONAL: I agree that any remaining blood may be used for further ethically approved research to help improve the understanding of vaccinations in pregnancy* |  |
| Signed:  Date:  Name (block capitals): | |
| I have explained and discussed the study with the above participant. I have answered all her questions regarding the study and I am satisfied that the above signature denotes her informed consent to take part in the trial.  Signature of study staff: Date:    Name (block capitals): | |