**C-Stich2 Consent Form**

***Please initial inside each box***

|  |  |  |
| --- | --- | --- |
| **1** | I confirm that I have read and understood the information sheet, dated DD / MMM / YYYY version number \_\_.\_\_ for C-STICH2 ***(check if the version refers to the main study or the observational study only)*** . I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. |  |
| **2** | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may be used.  |  |
| **3** | I understand that relevant sections of my medical notes and data collected during the study may be looked at by appropriate individuals from the University of Birmingham Clinical Trials Unit research team, representatives of the sponsor, from regulatory authorities, or from the NHS Trust, where this is relevant to my taking part in this research. I give permission for these individuals to have direct access to my medical records. |  |
| **4** | I agree to my GP being informed of my participation in this study.  |  |
| **5** | Data collected that identifies me by name, (consent form), will be transferred from where it is collected, and stored at the University of BirminghamClinical Trials Unit. I agree to the transfer and storage of this data. |  |
| **6** | I understand that relevant sections of my, and my baby’s, medical notes, i.e., those held by my GP, or those held at the hospital where I deliver my baby, including data held by NHS Digital (England and Wales) or ISD Scotland, and other central UK NHS bodies, may be used or looked at to provide information about my and my baby’s health status. I give permission for individuals from the University of Birmingham Clinical Trials Unit, representatives of the sponsor, regulatory authorities or the NHS Trust to have direct access to my records. |  |
| **7** | I agree to take part in the C-STICH2 **randomised** study. ***Please initial inside relevant box*** | Yes NO  |
| **8** | If you have indicated NO to taking part in the randomised study would you agree to take part in the **Observational study *Please initial inside relevant box*** | Yes NO  |
| **9** | I agree to be contacted when my baby is two years old to complete a follow up health questionnaire. |  |
| **10** | I agree to be contacted for further trial follow-up. |  |

 DD / MM / YYYY

*Name of Patient Date Signature*

 DD / MM / YYYY

*Name of Person taking Consent Date Signature*

C-STICH2 Patient Trial Number: (Please complete when patient is enrolled)