**[NAME OF STUDY]**

MATERNAL BIOSPECIMEN COLLECTIONS

INFORMED CONSENT TEMPLATE

**Section 1- Participation in the study**

1. I confirm that I have read and understood the information sheet dated (provide date and version number of study information form) for the above study. I have had the opportunity to consider the information, ask questions and have received satisfactory answers.
2. I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I understand that relevant sections of my and my baby’s medical notes and data collected during the study may be looked at now and in the future.
4. I understand the purpose of the study and how my baby and I will be involved.
5. I understand and accept that if my baby and I take part in the study I will not gain any direct personal benefit from it.
6. I understand that all information collected in the study will be held in confidence and that, if it is presented or published, all my and my baby’s personal details will be removed.
7. I confirm that I will be taking part in this study of my own free will and I understand that I may withdraw from it at any time and for any reason, without my medical care or legal rights being affected.
8. I confirm that I am consenting for my baby to take part in the above study and I understand that I may withdraw his/her participation at any time and for any reason, without his/her medical care or legal rights being affected.
9. I confirm that I have been given a chance to ask questions and feel that all of my questions have been answered.
10. I confirm that I know that I can withdraw my consent at any time in the future.
11. I confirm that I have been given a copy of the consent form to keep.

**Section 2 – Storage and use of biological samples**

1. I understand that the researchers are asking for biological samples and agree to give the biological samples (LIST ALL BIOLOGICAL SAMPLES THAT WILL BE COLLECTED) described in the information sheet dated (provide date/version) to be used for research into problems in pregnancy such as preterm birth.
2. I agree to the use of the biological samples (LIST ALL BIOLOGICAL SAMPLES THAT WILL BE COLLECTED) as normal control samples, if appropriate.
3. I agree to the use of the biological samples (LIST ALL BIOLOGICAL SAMPLES THAT WILL BE COLLECTED) in approved research carried out in [INSERT NAME OF LOCAL RESEARCH CENTER].
4. I agree to the use of my samples (LIST ALL BIOLOGICAL SAMPLES THAT WILL BE COLLECTED) in approved research carried out in the [INSERT LOCATION OF PARTNERING RESEARCH INSTITUTE, IF APPLICABLE].
5. I agree to the use of the biological samples (LIST ALL BIOLOGICAL SAMPLES THAT WILL BE COLLECTED] in future approved studies.

**SECTION 3 – Disposal of biological samples**

Retained biological samples can be preserved for many years. However, it may eventually become necessary to dispose of them. This will be done in accordance with the law and governmental guidance in effect at that date.

1. I agree to the samples being disposed of when they can be of no further use.

**AGREEMENT TO PARTICIPATE**

A member of the research team in my country has explained the [INSERT NAME OF STUDY] research study to my satisfaction. I agree to participate and will receive a copy of this consent form after I sign it.

**Participant Information**

Name of participant Signature Date

**Principal Investigator or his/her authorized representative confirmation**

I described the [INSERT NAME OF STUDY] research study, including conditions of participation, to the participant. Any questions were answered. I explained that participation was entirely voluntary.

Investigator/Designee Name Signature Date

**Translator Information** *(if applicable)*

I was present during the meeting between the research team member and the participant. I translated, for the participant, the consent form and all information presented regarding the research study.

Translator Name Signature Date

When completed: 1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes.