

a)



Opptimum

Progesterone prophylaxis
to prevent pre-term labour

Centre Number: [][]

Trial (Screening) Number:
[][][][][][][][]

**Title of study: Does progesterone prophylaxis to prevent preterm labour improve outcome?
CONSENT FORM (FIBRONECTIN TESTING)**

Insert name of local researcher (PI):

TO BE COMPLETED BY THE PARTICIPANT: If you agree to the following statements, please confirm by initialling boxes below:

1. I confirm that I have read and understand the OPPTIMUM Study Patient Information entitled "Participation Information Leaflet (Fibronectin testing)" dated January 2012 (Version 7.0) for the above study. 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, 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 by individuals from the University of Edinburgh, the University of Glasgow, from regulatory authorities or from the NHS Organisation, where it is relevant to my taking part in this research study. I give permission for these individuals to have access to my records.
4. I agree to take part in the above study.
5. I would like my GP to be informed of my participation in the study.

Signature of
Person
taking
Consent:

Date:

PRINT _____
NAME: _____

Participant's
signature:
PRINT
NAME:

Date:



Centre Number: [][]
 Trial (Screening) Number: [][][][][][][]
 Trial Subject (Randomisation) identification:
 [][][][][][][]

b) Title of study: Does progesterone prophylaxis to prevent preterm labour improve outcome?

CONSENT FORM (MAIN)

Insert name of local researcher (PI) _____

TO BE COMPLETED BY THE PARTICIPANT : If you agree to the following statements, please confirm by **initialling boxes below**:

1. I confirm that I have read and understand the OPPTIMUM Study Patient Information entitled "Participation Information Leaflet (Main)" dated January 2012 (Version 7.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I confirm that I agree to sections of placental tissue being examined.
3. I confirm that I agree to placental DNA stored for use in subsequent research.
4. I confirm that I agree to my baby having a neonatal head scan.
5. I understand that my, and my baby's, participation is voluntary, that the study will last until my baby is two years of age; and that I and my baby are free to withdraw at any time without giving any reason, without our medical care or legal rights being affected.
6. I understand that relevant sections of my, and my baby's, medical notes and data collected during the study may be looked at by individuals from the University of Edinburgh, the University of Glasgow, from regulatory authorities or from the NHS Organisation, where it is relevant to my taking part in this research study. I give permission for these individuals to have access to my records
7. I agree to take part in the above study.
8. I would like my GP to be informed of my participation in the study.

Participant's signature: _____

Date: _____

PRINT NAME: _____

Signature of Person taking Consent: _____

Date: _____

PRINT NAME: _____