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SW17 0QT

Version 0.3

15 October 2023

Name of Chief Investigator: Dr Amarnath Bhide

REC: 23/LO/0744

IRAS ID: 330204

CONSENT FORM

Title of project: AMBulatory Fetal ECG Monitoring in low and High-Risk Pregnancies:

Proof of concept study (The AMBER 2 Study)

Name of Chief Investigator: Dr Amarnath Bhide

Please initial the boxes below:

1. I confirm that I have read and understood the information sheet dated October 2023 (Version 0.5) about this study and have had the opportunity to ask questions.
2. I confirm that I have had enough time to consider whether or not I want to take part in the study and all my questions have been answered.
3. 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.
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from BIORITHM, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records.
5. I understand that the data from monitoring of my baby will not be analysed until a later date, perhaps until after my baby is born.
6. I agree for my GP to be informed about my participation in the above study.
7. I agree to take part in this study.

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8. I would like my contact information to be stored in order to receive the optional summary of results at the end of the study.

yes

☐

no

☐

Name of Patient

Date

Signature

Name and designation of Person taking consent

Date

Signature

Name of Interpreter

Date

Signature

Researcher to be contacted if there are any queries: Dr Claire Pegorie on claire.pegorie00@stgeorges.nhs.uk.

If you have any comments or concerns, please discuss them with the investigator. If you wish to complain further about any aspect of the way you have been approached or treated during the course of the study, you should contact Vila Nair, Biorhythm on 02080898285 (E-mail: vilanair@bio-rhythm.com).