Participant Information Leaflet (Non-COVID)

Implementing LEANBH Ambulatory Integrated Blood Pressure Monitoring in Maternity Services (LEANBH IRELAND)

INTRODUCTION

You are being invited to take part in a research study. Before you decide whether to take part it is important for you to understand why we are doing this research and what is involved. Please take time to read this leaflet, and if you want to, discuss it with your doctor, midwives, family or friends. Please feel free to ask us if anything is not clear, or if you would like more information. Thank you for taking the time to read this.

ABOUT THE STUDY

The COVID-19 pandemic has caused us to look for alternative means to safely monitor women in pregnancy and reduce the need to have to come to hospital for blood pressure assessment. Whilst many women enjoy a healthy pregnancy, about 6% to 8% of these pregnancies have a diagnosis of high blood pressure (BP). The current model of antenatal care worldwide is to measure BP at healthcare clinic visits periodically to diagnose high blood pressure prior to the onset of associated complications to the woman and her baby. Although diagnosis of high BP in pregnancy is important, mislabelling of a normal pregnancy as one complicated by high BP could cause unnecessary anxiety, interventions and costs.
The purpose of this LEANBH IRELAND study is to recruit women who need closer BP monitoring. When recruited, women will be provided with their own blood pressure machine and access to a smart phone app called LEANBH. This computer platform will collect BP readings throughout your pregnancy (via telemonitoring for home readings) and allow monitoring of your blood pressure. All your BP readings and information on the app can be viewed by your clinical team who will monitor your BP and contact you with advice.

WHY HAVE I BEEN CHOSEN?

You have been chosen because you are expecting a baby and have been identified as someone who needs additional blood pressure monitoring. Because of COVID-19 we want to limit your visits to hospital while providing you with safe care.

DO I HAVE TO TAKE PART?

It is entirely your choice. If you agree to join the study, you will be asked to sign a consent form and will be given a copy to keep. You are free to change your mind and withdraw yourself and/or your information from the study at any time without giving a reason. The care you receive, now or in the future, will not be affected in anyway by your decision whether to take part in this study.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

As you have been identified with suspected/ confirmed high blood pressure, you will be equipped with a Microlife Home Blood Pressure Monitor and a mobile application (which will be connected to the monitor and device via Bluetooth). You will be shown how and when to use the device and mobile application correctly when you agree to join the study. Prior to enrolment you will also be informed of the importance of understanding the parameter being measured (Your BP), the technology being employed, and the significance of abnormal readings. You will be asked to take your BP three times daily which will be automatically uploaded via the LEANBH mobile application. The duration of your time in the study will vary depending on what stage in your pregnancy you were recruited to the study but potentially it could be from week 12 of your pregnancy up to 6 weeks after the birth of your baby.
Once you are finished in the study you will be asked to return the device to the study team in CUMH at your earliest convenience. The research team will liaise with you throughout your participation in this study and you are free to drop out at any time and you will then resume your normal clinical care as directed by your named consultant.
Once you have completed the study you will also be asked to complete an online satisfaction questionnaire.
All information will be stored on an external host server (not HSE linked) but readings from the app will be put into your electronic health record by the clinical team who are overseeing this study. Once your pregnancy is completed, your data will be **anonymised** prior to analysis by the research team. After your baby is born, information regarding the delivery and birth outcome will be obtained from your medical notes. The device will be returned to the research team at the end of your pregnancy or if you decide to withdraw from the study.

BENEFITS, RISKS and SAFETY

This study may benefit you by reducing the need to attend hospital or your general practitioner while safely monitoring your blood pressure. The testing of the LEANBH solution is intended to enable us to improve the care given to pregnant women in the future as well as enabling them to take control of their pregnancy. The study may therefore benefit future generations of pregnant women around the world.
This platform only tests and monitors blood pressure therefore if you have any other concerns regarding your pregnancy you should contact your medical team as normal.
We do not anticipate any risks associated with this study, however in the unlikely event that the LEANBH system fails to work the following steps will be taken by the research team to deal with any unforeseen problems.

1. **Should your BP readings not be visible;** The LEANBH App is a communication device which will aid communication between patients and their clinician. Once enrolled in the study, you will be contacted regularly (every 1-3 days) to review symptoms and BP readings. In the unlikely event of the LEANBH app not functioning or the clinical team not been able to see BP and symptom recordings you will be contacted by the research team by telephone and asked to attend the day assessment unit.

2. **Elevated BP readings;** All results will be reviewed by the research team on a daily basis and appropriate action taken if required. This will be documented in your electronic medical records.
3. **Participants who wish to withdraw:** If you wish to withdraw from the study your managing clinician will be informed and the you will be asked to attend for a clinic appointment the following day.
4. **Suspicion of an incorrect blood pressure reading**; All blood pressure cuffs are CE marked Microlife devices that are tested prior to dispensing to patients to ensure they are working to manufacturers specifications. All BP recordings will be reviewed by the research team a daily and you will be contacted by the research team by telephone and asked to attend the day assessment unit if they suspect the system is not functioning properly. However, if you suspect your blood pressure machine is not recording your blood pressure readings properly please contact the study team immediately.
5. **Should you have symptoms:** You will be educated when recruited to this study on symptoms to be aware of that would cause concern to your clinical team. If you become symptomatic and experience any "red flag" symptoms you should contact the CUMH emergency room immediately and notify the research team as soon as possible.
   "Red Flag" symptoms are as follows:
   - Severe headache that won't go away even with medication
   - Swelling of the face and hands
   - Weight gain of more than five pounds in one week
   - Difficulty breathing, gasping, or panting
   - Nausea after mid-pregnancy
   - Changes in vision (spots, light flashes, or vision loss)
   - Upper right belly pain often mistaken for indigestion or the flu
   - Reduced baby movement
6. **Development of pre-eclampsia** or growth restriction (small baby); If you develop pre-eclampsia (persistently high blood pressure and protein in the urine) or if there are concerns that your baby is small, you will be admitted under the care of your named consultant as per routine hospital policy and your participation in the study will end.

You will be provided with a contact number for queries/concerns and the Emergency Room at CUMH is open 24 hours to assist you.

Emergency Room Tel: +353 (0)21 4920545

WHAT HAPPENS TO THE INFORMATION AND RECORDINGS COLLECTED?

By participating in this study, information from you (also called "personal data") will be collected for the purposes mentioned above in this Participant Information Leaflet. This personal data includes, for example:

- Information that directly identifies you (such as your name, and your year of birth)
- Information on your health and medical condition including your medical history
- Information contained in the results after analysis.

To ensure confidentiality, the data generated during the study is **coded** with a unique Study ID Number that you will be allocated once recruited to the study. Any information that leaves

the clinical site will be labelled with your ID Number. Every person that has access to your uncoded data (that is kept at Cork University Maternity Hospital) is subject to professional secrecy and confidentiality.

Data that directly identifies you (uncoded data) is stored in a locked filing cabinet separate to study documentation. Only study personnel can match your name to the unique Study ID Number. This data will be accessible solely to the study research team, the study Sponsor and their representatives to check if the study is conducted properly and that your rights are being respected. If this occurs all personal information made available for inspection will be handled in the strictest confidence and in accordance with legal data protection requirements. All information collected about you will be kept private and confidential and will be stored in a secure web based database. The information will be pseudo-anonymised and any information that could identify you **will not be stored** on the database. Only anonymized data will be shared with the study collaborators for analysis and possible publications.

WHAT HAPPENS TO THE INFORMATION FROM THE STUDY?

University College Cork (UCC) is the study's Sponsor and will act as the data controller for this study. Any personal data which you provide to the University will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation.

Any personal data you provide to us during the study will be processed fairly and lawfully. Signing the Informed Consent Form means that your personal data will be used for the purposes outlined in this Participant Information Leaflet (PIL).

The clinical site, the study investigators and the members of the study team will use your personal data within the scope defined here. The General Data Protection Regulation allows us to process your data because you have provided your consent. You have a right to request access to this information and to have a copy of it. You have the right to have any incorrect or inaccurate data deleted, unless this request makes it impossible or very hard to conduct the study.

You are entitled to withdraw your consent at any time. If you do withdraw your consent, we will keep your coded personal data collected prior to withdrawal, for processing along with other data collected as part of the study to preserve the integrity of the study.
Your personal information will be stored securely at the INFANT Centre. An anonymised database (where participants are assigned unique numbers and there is no identifiable information) will also be stored on researcher's encrypted, password protected computers at UCC. All information management will adhere to the Data Protection Act and GDPR.

WHAT WILL HAPPEN TO THE RESULTS OF THIS RESEARCH?

Results of this research study may be published in medical journals and presented at scientific meetings. However, you will never be identified individually during these presentations and

will not be revealed in any reports or publications. Your name or anything else identifiable to you will not be released or published. A copy of the signed informed consent form will be scanned and included in your electronic medical notes.

FOR HOW LONG WILL THIS DATA BE KEPT?

We will keep identifiable information about you from this study for a minimum of 10 years after the study has concluded, as per UCC Code of Research Conduct document. We would like your permission to allow us to store your de-identified data and the recordings for future related research for a period of 25 years. Further research analyses may be performed but this will be subject to further ethics approval if applicable.

If you have any complaints in connection with our processing of your personal data, you can contact UCC's Data Protection Officer:

Office of Corporate & Legal Affairs,
University College Cork,
Western Road, Cork
E: foi@ucc.ie Tel: +353 21 4903949

You also have the right to lodge a complaint with the Data Protection Commission if you are unhappy with our processing of your personal data. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.

WHO HAS REVIEWED THIS STUDY?

All research in Ireland is carefully reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been approved by the Cork Research Ethics Committee (CREC).

WHAT WILL HAPPEN IF I DO NOT WISH TO CARRY ON IN THIS STUDY?

You are free to withdraw at any time, for any reason without giving that reason. Your withdrawal will not affect the high level of care you will expect for yourself. We would however like your permission to use the information that has already been collected up to the point of withdrawal.

WHERE CAN I GET MORE INFORMATION?

The study will be fully explained to you and any questions answered before you decide if you want to take part. If you have any further questions regarding this study, please contact the Principal Investigator: Dr Fergus McCarthy; Tel:, 083 0409737 email: Fergus.mccarthy@ucc.ie

Ospideal Maithreachais na h'Ollscoile Corcaigh
Cork University Maternity Hospital

Infant
Irish Centre for Maternal and Child Health Research

Participant Informed Consent Form

Implementing LEANBH Ambulatory Integrated Blood Pressure Monitoring in Maternity Services (LEANBH IRELAND)

Participant Name: _____

Participant DOB: _____

Study Number: _____

Chief Investigator: Dr Fergus McCarthy

Contact details: *Phone: 083 0409737*
Email: fergus.mccarthy@ucc.ie

Please initial each section to show you have read and understood each statement. If you agree to take part, please sign the bottom of the form.

	Please initial
1. I have read the information leaflet about this study and have been given a copy to keep. The information has been fully explained to me and I have been able to ask questions and have them answered satisfactorily. I understand why the research is being done and any risks involved.	
2. I am aware that participation is voluntary, and I may withdraw my consent at any time. If I withdraw from the study, I agree that the coded personal data collected prior to withdrawal may still be processed along with other data collected as part of the study to preserve the integrity of the study. I am aware that my decision not to continue participation at any stage will not restrict my access to health care services normally available to me.	
3. I give permission for my medical records to be reviewed and information to be taken from them to be analysed in confidence by the study team.	
4. I agree to record my BP at least 3 times daily on the device that has been provided to me. I agree to return the device to the Principal Investigator on completion of my role in the study.	
5. I am aware that confidentiality of records concerning my involvement in this study will be maintained according to national and EU Data Protection Laws. When required by law, the records of this study may be reviewed by government agencies, ethics committee and sponsors of the study.	
6. I understand that the sponsors and Investigators have such insurance as is required by law in the event of injury resulting from this research.	
7. I give permission for all anonymised information collected from me to be stored for possible future related research *without my further consent being required* but subject to approval of a Research Ethics Committee.	
8. I give permission to the research team to contact me in the future for follow up information regarding my health or for future related research.	
9. If I have further queries concerning my rights in connection with the research, I can contact the Clinical Research Ethics Committee of the Cork Teaching Hospitals, Lancaster Hall, Little Hanover Street, Cork (Tel 021 4901901).	

Participant Signature:	Date:	Time: Circle AM/PM
Consent obtained by: Researcher's Signature	Date:	Time: Circle AM/PM