**Title of project: A pilot trial of a novel medical device to alleviate pain during venepuncture**

**Participant Information Sheet**

*What is the research about?*

In this study, we are trying to find out if a new medical device might reduce pain associated with blood test.

We believe that, by utilising the Gate-control theory of pain, this device will effectively reduce, or even eliminate, the pain sensation when the needle enter the skin for the purpose of blood testing.

*What would it involve for me?*

We first need to confirm that the study is suitable for you. For this study, we need female participants who are undergoing blood tests for the purpose of ‘hormones tracking’ during either Ovulation Induction (OI), Intrauterine Insemination (IUI), or In-Vitro Fertilisation (IVF) cycles. You may be ineligible to participate in the study if you are having blood tests for other purposes than the above-mentioned. We expect to recruit a total of 40 patients in this study.

Should you be eligible and willing to participate, we will next ask you to have a pelvic ultrasound, take a blood test (both of which are part of the usual pre- operative work-up), and complete a standardised questionnaire.

To ensure a fair test of our assumptions, we will assign you to one of two groups of participants on a ‘chance’ basis: like flipping a coin. You will have a one-in-two (i.e. 50%) chance of being allocated to either the no device (“control”) or device (“treatment”) groups. After obtaining your blood sample, we will ask you to complete a standardized questionnaire.

To avoid subconsciously influencing the result, you will not know whether you had the blood test using the device, or not. But don’t worry, should you wish, we will be able to inform you of which group you were allocated to, after filling out the questionnaire.

*Are there any risks from participating in this project?*

The device that we are utilising is non-invasive and does not break the skin, merely touching and applying pressure. To further minimise the risk of infection, the device is sterile and single-use only.

There is a possibility that the device does not make any difference to the level of discomfort that you would normally feel at the time of blood testing, however all preliminary data suggest that it certainly does not increase the pain sensation.

*What will happen to my personal data?*

We will keep all personal information confidential and securely stored. All of the collected data will be coded. No personal information about you, such as your name and address will leave the clinic, and in all study information sent out from the clinic you will be identified with a code number only.

**Participant Consent Form**

* I give my consent to participate in this research, the nature and implications of which have been explained to me.
* I have read the Participant Information Sheet entitled “***A pilot trial of a novel medical device to alleviate pain during venepuncture: information for participants***”.
* I have had the opportunity to ask questions about the research and have had all my questions answered to my satisfaction.
* I give approval for data associated with our fertility treatment to be used for analysis.
* I specifically understand that participation in this research project may carry the following risks:
	+ Risks that the device may not reduce pain during blood test

I certify that I have explained the above research project to the participant named above.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Printed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_