Participant Information Sheet

Project Title: The effect of the vaccine for COVID-19 on menstrual cycle symptoms in healthy women

HREC Number: HREC/79070/Austin-2021

Principal Investigator: Dr Michal Amir

Dear Participant,

We are inviting you to take part in our project. We are doing this project to learn about possible menstrual changes after the COVID vaccine. We aim to recruit 1200 participants for this study.

Recently, there have been reports in the media and on social media about temporary changes in the pattern of menstrual bleeding and menstrual pain after receiving the COVID-19 vaccine. These are not scientific reports and may or may not be true.

Key Information: You are being asked to participate in a voluntary research study. The purpose of this study is to compare women's menstrual patterns in the 3 months prior to the vaccine to 3, 6, 9 and 12 months post COVID vaccination. Participating in this study will involve completing a short secure online survey.

This project is not funded and is an investigator initiative.

Responsible Principal Investigator: **Dr Michal Amir,** The Royal Women's Hospital, VIC **Michal.Amir@thewomens.org.au**

If you meet our inclusion criteria below and agree to participate, you will be asked questions about your menstrual cycle, COVID-19 vaccination(s), reproductive health, stress, anxiety and general health through a secure online survey. Please consult with your GP if you are concerned about your menstrual cycle or anxiety levels.

Inclusion criteria:

- Premenopausal individuals who have had at least one period in the past
- Currently having periods or
- Currently not having periods due to other reasons eg. using hormonal contraceptives, using gender affirming hormones
- Have not yet been vaccinated but are planning on having the COVID-19 vaccine soon/today
- Age 18-45

Exclusion criteria (not eligible for the study):

- Post-menopausal
- Has had a hysterectomy
- Planning to get pregnant in the next 12 months
- Are pregnant
- Are breastfeeding

The survey will take approximately 10-15 minutes. You can skip or choose not to answer a question at any time. Follow up shorter questionnaires will be sent to you via email link 3, 6, 9 and 12 months after your first vaccine.

The online survey will be administered through REDCap which is a highly secure survey management application. Your responses will be saved for the purposes of analysis but will not be shown to anyone outside of the research group. The findings will be used to better understand possible effects of the COVID-19 vaccine on menstrual bleeding and pain. The researchers will not share information that might identify a participant. If you provide consent to this study, de-identifiable information collected may be used for future research.

The information collected as part of this research will be kept for at least 7 years following the last publication of the project.

Discomfort and Risks: The risks to you are minimal. Risks related to this research include the potential to feel uncomfortable answering questions about your body and health. You have the right to refuse to answer any question at any time. You have the right to stop participating at any time while taking the survey and the right to exit the survey at any point while taking it. Your

responses will be saved for the purposes of analysis but will not be shown to anyone outside of the research group.

Benefits: You will not receive any direct benefit from participating in this research. Benefits related to this research include being able to share your experiences and contribute to an often-overlooked area of health research.

Statement of Confidentiality: In general, we will not tell anyone any information about you. When this research is discussed or published, no one will know that you were in the study. However, study information which identifies you and the consent form signed by you may be seen by the following people or groups:

- The Royal Women's Hospital Gynaecology research group.
- The University of Melbourne, Department of Obstetrics & Gynaecology

Compensation: Participants will not be compensated for their participation.

Cost of participating: There are no costs associated with participating in this research.

Whom to contact: If you have any questions regarding your participation, please ask the researcher before signing this form. If you have any questions or concerns during or after your participation, please contact **Dr Michal Amir Michal.Amir@thewomens.org.au**

☐ I consent to the processing of my personal information for the purpose of research as set forth in this online Patient information Sheet. I understand that I may withdraw my consent at any time but doing so will not affect the processing of my personal information before my withdrawal of consent.

Authorisation:

(Please check and tick each item to indicate you understand each statement)

☐ I am 18 – 45 years of age

☐ I have had at least one menstrual period over the course of my life and I am not postmenopausal, pregnant, breast feeding or planning pregnancy soon

☐ I was never vaccinated for COVID-19 or prior to today

☐ I have read and understand the above Patient Information Sheet and voluntarily agree to participate in this study. I know the possible risks and benefits.

☐ I know that being in this study is voluntary. I choose to be in this study. I know that I can withdraw at any time.

☐ I know the results and written excerpts of this study - with my name and other identifying information removed - may be published or presented in academic papers, articles, and conferences

***If you would like to consider participating in another study that includes endometrial lining sampling after COVID vaccine, please contact Dr Michal Amir via email - Michal.Amir@thewomens.org.au**

Yours sincerely,

Dr Michal Amir

Senior visiting medical officer

The Royal Women's Hospital, VIC

If you have any concerns and/or complaints about the project, the way it is being conducted, or your rights as a participant, and would like to speak to someone independent of the project, please contact: the Complaints Contact Person, Austin Health on telephone: (03) 9496 4090

This project has been reviewed by the Austin Health Office for Research and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – including all updates.