

## PARTICIPANT INFORMATION SHEET

# ***6-month Cyclic Progesterone/Spironolactone Pilot Therapy Trial in Polycystic Ovary Syndrome—pre-post single-arm feasibility study***



### **BACKGROUND AND STUDY AIMS**

Dr. Jerilynn Prior and the UBC Centre of Menstrual Cycle and Ovulation (CeMCOR, [www.cemcor.ubc.ca](http://www.cemcor.ubc.ca)) are inviting women/non-binary persons between the ages of 19-35 years who have been diagnosed with having Polycystic Ovary Syndrome (PCOS) including unwanted facial hair/acne/head hair loss to join a unique new therapy study.

Currently, there is only one main treatment for PCOS and it has many limitations. For the last 40 years the main treatment for PCOS was The Pill (combined hormonal contraceptives) unless a woman was wanting to become pregnant. But, not all women feel well on or can take The Pill. Women living with PCOS feel dismissed and undervalued with no therapy choices besides The Pill.

During Dr. Prior's twenty plus year clinical practice in endocrinology with a special interest in women's health and hormones, taught her that women with PCOS felt better on progesterone treatment taken for two weeks every month. They got regular periods, had less bloating, breast tenderness, nighttime peeing and started feeling healthy. She also learned, however, that women with a lot of facial hair were not helped fast enough by progesterone alone; therefore, she added spironolactone.

The combination of progesterone, given for the last 14 days of a month or menstrual cycle (called "Cyclic Progesterone") and spironolactone may become an important new therapy for women struggling with PCOS and its unwanted experiences.

Both progesterone (a pill of the same hormone as our ovaries make after releasing an egg—progesterone is estrogen's natural partner hormone) and spironolactone (that blocks the actions of testosterone and other male-type hormones) are Health Canada approved medicines. They've just never before been used for PCOS or together.

### **For the very first time ever, we will test Cyclic Progesterone and Spironolactone as a new treatment for PCOS**

The two medicines worked very well together, but that clinical experience is not enough. We need a careful, planned study. This research study is the first to do that.

## PURPOSE OF THE STUDY

The main goal of the study is to learn the changes women living with PCOS experience in their quality of life, menstrual cycles, and in luteinizing hormone and testosterone levels as they take Cyclic Progesterone and Spironolactone for 6-months.

### WHO CAN BE PART OF THIS STUDY?

Women or non-binary persons, between the ages of 19-35, whose physician has diagnosed you with androgenic PCOS.

You must not be at risk for diabetes, must be willing to stop The Pill or metformin for a month if you were taking either or both, and willing to prevent pregnancy using the non-hormonal contraceptives the study will provide.

### WHAT DOES THE STUDY INVOLVE?

This study asks women/non-binary folks to come in person to the CeMCOR office (a building on Laurel Street across from the Vancouver General Hospital tower) four times over about 6 months. We will be using a combination of questionnaires, body measurements, quick registering temperature collection, two quick blood tests, three times of collecting saliva and daily recording (electronically fillable PDFs you do at home at night, takes about 2-3minutes) of the Menstrual Cycle Diary to learn about this new PCOS therapy.

Participants will be thanked for their time and conscientious efforts by being given a \$50 VISA giftcard card. If you wish, we will also give you an appropriately sized menstrual cup (donated by DivaCup, value \$40-50.00) so you can conveniently manage menstruation while decreasing the environmental risks and the costs of pads and tampons.

If you need contraception, we will provide you with condoms and with a tube of spermicidal jelly that, (consistently used together with each intercourse), make an effective non-hormonal contraceptive. Finally, at the end of the study we will give you a novel about perimenopause that Dr. Prior wrote and CeMCOR published (value ~\$23.00) to help women prepare and to understand their experiences.

### INVESTIGATORS AND COLLABORATORS

<b>Jerilynn C. Prior</b>	BA, MD, FRCPC
<b>Kaitlin Nelson</b>	BSc
<b>Sonia Shirin</b>	MBBS, MPH, MPhil
<b>Dharani Kalidasan</b>	MSc
<b>Joel Singer</b>	PhD
<b>Marshall Dahl</b>	MD, PhD, FRCPC
<b>Johnny Yip</b>	BSc, Pharm, RPh
<b>Azita Goshtasebi</b>	MD, MPH, PhD
<b>Faye Murray</b>	BA, MA, MBA
<b>Niyoosha Yoosefi</b>	BSc

### STUDY IS FUNDED BY

This PCOS treatment trial is funded by the BC Women's Health Research Institute (WHRI) and supported locally by Pure Integrative Pharmacy who will dispense the medications that the study will provide. Besins Healthcare International, headquartered in Ireland, that make oral micronized progesterone capsules, are donating these for our study.

### **When is the study starting and how long is it expected to run for?**

We will begin recruitment for the study during September 2021 and expect to keep enrolling women until February 2022. We are hoping to have learned the main study results by the end of October 2022.

### **BENEFITS OF PARTICIPATING IN THIS STUDY**

By keeping the Menstrual Cycle Diary, you will learn more about yourself and how things change while taking these medicines. You will also have a chance to ask experts personal questions about your own menstrual cycles and experiences with PCOS. Together all of you who join this study contribute toward developing a new, and potentially important alternative PCOS treatment.

### **POTENTIAL HARMS AND DISCOMFORTS**

Both therapies we are giving you have been approved by Health Canada and used for many years thus we have good information about their safety and effects. However, given that women/people differ, it is possible you could experience something unwanted.

There are minor study risks from having your blood drawn, such as discomfort, bruising, minor infection, or bleeding. If this happens, we will ensure you are quickly and easily treated.

### **ABOUT DR. JERILYNN PRIOR**



Jerilynn C. Prior BA, MD, FRCPC is a Professor of Endocrinology and Metabolism at the University of British Columbia in Vancouver, BC. She has spent her career studying menstrual cycles and the effects of the cycle's changing estrogen and progesterone hormone levels on women's health. She is the founder (2002) and Scientific Director of the Centre for Menstrual Cycle and Ovulation Research (CeMCOR).

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