Division of Neurology
Department of Medicine

Multiple Sclerosis Centre
7th Flr., Clinical Sciences Building, University of Alberta T6G 2G3 **Fax: 780.407.1365**

UNIVERSITY OF CALGARY

PARTICIPANT CONSENT FORM

Title of Study: My MS and My Menstrual Cycle

Measuring MS symptoms in relation to menstrual cycles: exploring how MS symptoms may be affected at different times during a menstrual cycle in females living with Multiple Sclerosis

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Why am I being asked to take part in this research study?
You are being asked to participate in this study because you are living with MS and have a menstrual cycle. This project is an observational study to observe MS symptoms throughout the menstrual cycle. Symptoms will be tracked using a smartphone app.

Your consent to participate in this study will be completed through this app after reviewing this information sheet.

What is the reason for doing the study?
MS most commonly occurs in young adults and persists lifelong. It is associated with a number of physical symptoms such as numbness, weakness, troubles with balance and walking, and vision. However, invisible symptoms of MS are often more debilitating, such as fatigue and cognition (brain fog).

The course of MS appears to be associated with a number of female-specific features, such as onset in women more after menarche, less inflammatory activity of MS during pregnancy, and increase in the first 3 to 6 months postpartum. Researchers have wondered about the effects of female hormones on the course of MS. More studies are needed to examine the possible relationship between menstruation and MS symptoms.

Despite the knowledge that MS inflammatory activity is related to different hormonal periods throughout women's lives, there is still much that is unknown about the interactions and relationship of female hormones and different female hormonal states upon MS.

We will recruit up to 300 participants total from the University of Alberta and the University of Calgary.

What will happen in the study?
This study will observe MS symptoms as related to the menstrual cycle using smartphone app over a 6-month period. This app is called My Normative, and is a platform that is used to track menstrual cycles in relation to various symptoms for women. My Normative App is a Calgary based company and the app is available to the public. Before reviewing the information here you downloaded the app, read the user agreement, and set up your account. The information collected prior about your date of birth, height and weight, ancestry, sex and gender, life stage (as related to menstruation) and menstrual cycle information will be used with the information that will be collected during the study.

Using the My Normative app on your smart device, you will be sent surveys at intervals related to what point you are at in your menstrual cycle. The surveys will be automatically sent to you, and you will complete them on the app. The surveys will ask questions related to fatigue, anxiety and depression, cognition, coping, sleep quality, MS symptoms. In addition, you will be asked demographic questions (age, race ethnicity, marital status etc) questions about your MS symptoms, medications. There will be questions about your menstrual cycle and the type of contraception you use. When you signed up with My Normative you were asked about allowing notifications, these notifications will be used to send reminders when questionnaires are due.

You can end your enrollment at any time during the study, and participation is completely optional.

What are the risks and discomforts?
There are minimal known risks to participating in the study. Sometimes the questionnaires may be time consuming, but you do not need to complete them all in one sitting, you can come back to them as your energy and focus allows.

What are the benefits to me?
You may not directly benefit from the study. But you may also learn more about your menstrual cycle and how it relates to your MS diagnosis, energy levels, and cycle specific symptoms. The information learned from this study may help us understand more about menstrual cycles and MS and may benefit other people with menstrual cycles in the future.

What will I need to do while I am in the study?
Before you had the opportunity to view this information sheet, you already registered to use the My Normative App. You will be sent reminders to complete surveys electronically through the My Normative app, these will be timed in relation to your menstrual cycle. You will receive reminders to complete them, if you missed the first alert. It is preferred if you can keep the notifications for the app turned "on" to receive these alerts.

If you become pregnant during the study, you will no longer be eligible as there will no longer be cycles to track, you can simply stop responding to the survey prompts, or by notifying the study team.

Do I have to take part in the study?

Being in this study is your choice. If you decide to be in the study, you can change your mind and stop being in the study at any time, this will in no way affect the care or treatment you are entitled to. You can simply stop completing the surveys, or you can notify the study team by phone or email. If you wish to have your data removed from the study, please contact the research team. Data can be withdrawn at any time during the study's data collection phase

What will it cost me to participate?
There are no costs to participate in the study. The My Normative Application is free to download.

Will I be paid to be in the research?
You will not be paid to be a part of this research study.

Will my information be kept private?
The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy.

All identifiable information about you will be replaced with a code. A master list linking the code and your identifiable information will be kept separate from the research data. This list will be stored at the University of Alberta.

All the data will be de-identified (name, date of birth etc.), and stored in Canada and is encrypted throughout the data storage process. "De-identified" means that any information that could potentially identify you, such as your name, date of birth, and personal health number, will be removed before your data is shared. The only people who have access to this information are part of the study team.

Your de-identified data may be used for other MS research projects, provided the project has been approved by the University of Alberta Health Research Ethics Board.

During research studies it is important that the data we get is accurate. For this reason, your data may be looked at by people from the University of Alberta or the University of Calgary auditors, and the Research Ethics Board. By agreeing to participate in the study, you are giving permission for the study team to collect, use and disclose information about you as listed above.

What if I have questions?
If you have questions about the study, you can reach the study team at msstudy@ualberta.ca. If necessary, you can contact the study team to unenroll you in the study.

If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

Use of data for future research
At the end of this form you will be asked if your research can be kept for use in future to learn about, prevent or treat other health-related problems. If this happens, you will be asked to consent again to having your data used in additional studies. This is completely optional, you can participate in the MS and My Menstrual cycle study, and say no to future studies.

Who can I contact before I sign consent?
If you have questions or concerns you would like to talk about before you sign the consent form you can email msstudy@ualberta.ca or call the study team at 780-248-5629 or 780-914-8598.

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Consent to contact for future research?
University of Alberta researchers may contact me in the future to ask me to take part in other research studies.

☐ Yes

☐ No

How do I indicate my agreement to participate?
Your electronic signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to take part in the study. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

By checking the box below, you are indicating that you

- understand you have been asked to be in a research study
- understand you will be shared a copy of your signed consent form
- understand the risks and benefits of taking part in this research study
- understand that you can leave the study at any time without having to give a reason and without affecting your future medical care
- understand only the research team has access to study information
- allow the use of your de-identified data for other MS research projects

I agree to participate in the study:

Participant Name: _____
Participant Signature: _____
Date: _____
Email address: _____