Patient Registry Consent Form

Harborview Medical Center Madison Clinic and University of Washington Medical Center Virology Clinic

WHAT IS A CONSENT FORM?

- A document that a person signs if they agree to participate in research
- It gives you information about the study, what you would have to do, the possible risks and benefits, your rights, etc.

SO YOU CAN DECIDE WHETHER TO PARTICIPATE IN A STUDY OR NOT

WHO IS DOING IT?

HARBORVIEW MEDICAL CENTER, CENTER FOR AIDS RESEARCH (CFAR)

They conduct research to understand HIV and improve treatment possibilities

The Registry

WHAT IS IT?

- A confidential list of persons who are interested in participating in research. The study team can check this list to see who might qualify for a study.
- By agreeing to be part of the Registry, you are also allowing researchers to use your electronic health record data (once all identifying information has been removed) to answer research questions.

- The list includes some of the patients' medical record and their contact information
- This information is stored securely to protect your name and privacy
- Only the CFAR team (less than 5 people) has access to this list

HOW DOES THE REGISTRY WORK?

If you are part of the Registry, we will check which studies you might qualify for and contact you to tell you about them

If you qualify for a study, you can choose whether to participate in it or not

All research studies have been approved by an IRB (an ethics committee that ensures that the research will be done in a responsible manner, protecting all people involved)

If you do want to participate, we will give your contact information to the researcher leading the study and they will reach out to you

All studies are different! Some may ask you to complete a survey or interview, some might want a blood draw or other testing

Participating in the Registry and in a research study is voluntary. Saying no won't affect your care in Madison.

We can also remove you from the list if you decide later that you want to stop participating

WHY IS RESEARCH IMPORTANT? WHO DOES IT HELP?

Research helps us understand how diseases work → helps us improve prevention and care for patients!

Participating in research is a way to give back to society

and a way to have a voice in science and history!

part of the reason why we have ART is because patient movements in the 1990s pushed for more HIV research

CFAR

INFECTIOUS DISEASE RESEARCH INSTITUTE
SEATTLE CHILDREN'S
UNIVERSITY OF HAWAI'I AT MĀNOA

UNIVERSITY OF WASHINGTON/FRED HUTCH
CENTER FOR AIDS RESEARCH

UW Center for AIDS Research (CFAR)
206-744-6960

INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Exercise to Treat Depression after TBI: The *InMotion Study*

Why are we asking you to be in this study?

We are asking you to participate in this study because you are enrolled in the Traumatic Brain Injury (TBI) Model System study and you reported some symptoms such as low mood or lack of enjoyment after TBI. Mood changes and even depression are common after TBI. People with low mood or depression may also have poor sleep, low energy, difficulty concentrating, changes in appetite, and feeling bad about oneself. These symptoms can make living with TBI much more difficult than it needs to be.

Doctors will often recommend antidepressant medications or counseling to treat these symptoms. However, these treatments do not always work and not everyone wants to try them. An alterntive approach is to use exercise to treat these symptoms. In people without TBI we know that exercise can improve mood, enjoyment, sleep, energy, thinking ability, how people feel about themselves, and quality of life. So far, no one has determined whether exercise also can improve mood, depression, and these other symptoms in people with TBI. That is exactly what this study is designed to do.

We want to learn whether people like you will feel significantly better if they have access to a telehealth coach who helps them become more physically active. The coach will help participants gradually take part in physical activities that they enjoy and can do in their daily lives such as brisk walking, jogging, swimming, playing sports, or even weight-lifting or dancing! We will determine whether this treatment program, called *InMotion,* improves mood, enjoyment, energy, sleep, pain, anxiety, and quality of life.

What will you be asked to do?

If you decide to join the study, we will assign you either to the *InMotion* intervention group or to the Wait List group. Which group you are assigned to will be random, like the flip of a coin. If you are assigned to the Wait List group, you will be able to participate in the *InMotion* intervention 12 weeks later.

The physical activity coach will work with you using the HIPAA-compliant video platform, Zoom, or by phone. The sessions will be scheduled at times convenient for you. There will be eight Zoom calls spread over 12 weeks. The coach will find out what types of physical activity you want to do more of and work with you to meet your goals. The goal of the treatment is to help you gradually build up to a healthy dose of exercise, which is 150 minutes of moderate to vigorous physical activity each week. You will be asked to wear a Fitbit® fitness tracker on your wrist to help measure your progress. (We will send you the Fitbit® and will include a postage paid envelope for you to

send back to us once you complete the intervention.) The amount of exercise will increase gradually over the weeks at a rate that is doable for you. We will ask you questions about your mood, enjoyment, sleep, energy, pain, anxiety, and quality of life before the treatment begins, after the intervention treatment ends at 12 weeks, and at a post treatment follow-up (at 24 weeks for those in the Intervention group and at 36 weeks for those in the Wait List group). The entire study will take place by Zoom or by phone.

We will ask to audio record the sessions to make sure the physical activity coach is following study procedures. If you don't want us to record the audio, you can still participate in the study. You can ask us to delete any or all portions of the recordings by contacting us.

PROCEDURES	***InMotion*** **Intervention Group**	**Wait List Group**
Contacts - We will get names and contact information for people who can help us find you if we are unable to reach you during the study	X	X
TBIMS Data Collection – We will get your information from the National Data Statistical Center Traumatic Brain Injury Model Systems database. This data includes age, sex, ethnicity/race, education level, employment status, marital status, details about your TBI	X	X
Baseline Phone Assessment – You will have a 45 minute phone or video call with study staff. They will ask you questions about your mood and whether it affects your activities, any pain your are having, medications you are taking, your satisfaction with life, and whether you have feelings of hurting yourself.	X	X
Group Assignment – You will be assigned to either the intervention or wait list group	X	X
InMotion **Intervention Sessions –** Week 1, 2, 3, 4, 6, 8, 10, 12	X	
Week 12 Phone Assessment – Procedures are the same as at baseline	X	X
Week 12 – Wait list group begin intervention		X
InMotion **Intervention –** Week 13, 14, 15, 16, 18, 20, 22, 24		X
Week 24 Phone Assessment – Procedures are the same as at baseline	X	
Week 36 Phone Assessment – Procedures are the same as at baseline		X

Why might you want, or not want, to participate?

You may want to take part in the study because the intervention may improve your mood, enjoyment, energy, sleep, pain, and other symptoms as well as quality of life. Even if you don't benefit directly, your participation will us help us learn more about future treatments for low mood and depression in people with TBI.

While taking part in this study, we encourage you to continue any medications or therapies that you are already using. You can continue to get treatment for low mood or depression as you normally would.

You may not want to take part in the study if you will be uncomfortable discussing depression and your mood with us. You may find some of the questions personal or sensitive. We will ask you questions like, "How satisfied are you with the level of motivation to do things?" "In the last two weeks, how often have you been bothered by thoughts you would be better off dead, or of hurting yourself?" "What medications are you currently taking?" You can choose not to answer any questions you don't want to answer and can stop any study procedures at any time.

Some people get an itchy rash from the band of the Fitbit®. It can be treated with lotion. If the Fitbit® isn't positioned right, it can cause bruising, irritation or rubbing which may require you to reposition the device. If you have a history of skin irritation from plastic wristband or if you have problems during the study, please tell us.

We do not expect you to experience negative side effects from the assessments or exercise sessions, but if you do, you can talk to [PI name] who is the Principal Investigator and a licensed clinical psychologist. He can give you referral information or other help, if needed. His phone number is: **206.XXX.XXXX**.

There are other ways to treat low mood or depression. These other ways include medications and counseling. You can speak with your doctor about the different options that are available to you outside this study.

How will we protect the information you provide?

We will protect your confidentiality. We will store your name and other identifiable information separate from the study data. Access to your identifying information will be limited to certain members of the study team and any individuals from the UW or other agencies that may need to audit study records. When we publish the results of this study, we will not use your name. If we learn you intend to harm yourself or others, we must report that to the appropriate authorities. Using a FitBit® may involve additional confidentiality risks because FitBit® stores the data collected from the device. We advise you to read the FitBit® user agreements and let us know if you have any questions or concerns about it.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and then use it for future research studies or give it to other investigators without getting additional permission from you. If we want to use or share study information/specimens that might identify you, a review board will decide whether or not we need to get additional permission from you. We will share your study data with the TBI National Data and Statistical Center.

We have a Certificate of Confidentiality from the U.S. Federal National Institutes of Health which allows us to keep your identifiable research information confidential from legal proceedings or in response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including mandatory reporting, institutional monitoring and others as listed elsewhere in this consent form.

The Certificate expires when the NIH funding for this study ends. Currently this is 12/31/23 (we will apply for an extension and once this is approved, this date will be extended). Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

Other information about this study.

Participation is voluntary. This means that you can refuse to participate. It also means that if you do enroll, you can decide to stop participating at any time without penalty.

We are receiving financial support from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR).

You will not have to pay anything directly to be in the study. But you will need to have a working phone and internet connection for the exercise sessions and assessments. You will also need a device like a computer or smart phone to communicate with the Fitbit®.

We will pay you $30 to complete each of the three assessments for a total of $90. We can give you a check or pay you using the electronic payment system called, Zelle. We will send the $30 payment within one week of completing each assessment.

A description of this clinical trial will be available on https://clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What can you do if you want more information?

Talk to the study team. We are here to help you understand the study. Feel free to ask us any questions you may have, even about things that are not in this document. It is our responsibility to give you the information you need to make a decision and to give you time to think about whether or not you want to sign up. If you feel you have been harmed by participating, you can contact us about that too.

Talk to someone else. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division at: hsdinfo@uw.edu or 206.543.0098.

Study Team	206.XXX.XXXX	[Name], PhD, Principal Investigator
	206.XXX.XXXX	[Name], Research Coordinator
	206. XXX.XXXX	[Name], MSW, Interventionist
	206. XXX.XXXX	[Name], MPA, Research Asssistant

INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

The regulatory role of natural progesterone on barrier immunity

What is this study about and what will you be asked to do?

We are asking you to be in a **research study** because we want to learn more about the interaction between the menstrual cycle and the immune system.

If you decide to be in this study, you will provide samples during a screening visit and then 2 more visits over the span of **1-2 months**.

Some of the study procedures include:

Procedure	Description of procedure
Vaginal biopsies & cervical swabs	We will use a device called a speculum to examine your vagina. This is the same procedure used during a Pap smear. We will take 2 swabs using a small brush. We also will collect 3 tissue samples the size of a grain of rice.
Rectal biopsies & fluid collection	We will use an anoscope, similar to a speculum, to examine your rectum. We will collect rectal fluids and 3 tissue samples the size of a grain of rice
Skin samples	We will numb your skin and then collect 2 small skin samples from healthy skin, such as from your upper arm or torso.
At-home procedures	You will be taught how to perform and record urine ovulation tests for daily, at-home use.
Other procedures	Throat and nose swabs, blood draws, STI testing, and questionnaires.

For more details about study visits, review **More Information About Research Procedures** on page 2.

Possible risks of participation.

- Biopsies can be uncomfortable or cause bleeding and pain. In rare cases there can be infection or scarring. We will numb biopsy sites, as needed, to reduce any pain you might feel. You may still feel a tugging sensation or pressure.
- The medications used in this study including lidocaine used to numb biopsy pain can cause allergic reactions. Lidocaine may sting when injected.
- You may feel anxiety and discomfort while the speculum or anoscope are inserted and while swabs are being taken.

- If you test positive for an STI, we have to report that to the Department of Public Health. They may notify your sexual partners if you have a reportable STI but keep your identity confidential.

Reasons you might say "yes" to being in the study.

What we hope to learn from this study may help in the design of future treatments for, and prevention of, sexually transmitted infections like chlamydia or HIV. **You will not directly benefit from taking part in this study.**

What can you do if you want more information?

Read more about this study. The next pages of this form give you more information about the study including a table that outlines which procedures will happen at which study visit.

Talk to the study team. We are here to help you understand the study. It is our job to give you the information you need to make a decision and to give you time to think about whether or not you want to sign up.

PI Name	206.XXX.XXXX (8:00am-5:00pm)
24-Hour Emergency Number	206.XXX.XXXX (page the Virology Research Clinic clinician)

Talk with someone about your rights as a subject. The UW Human Subjects Division reviews studies like this to make sure they are safe and ethical. You can contact them at hsdinfo@uw.edu or 206.543.0098.

More information about why we want to do this study.

Progesterone is an important sex hormone that controls the menstrual cycle. Progesterone is produced by the ovary after ovulation. It also affects the immune system but we don't know very much about how it does that. We hope to learn about how the immune system changes during the menstrual cycle. Some questions we want to answer are: Is it better to to get a vaccine during one part of the cycle? Do auto-immune diseases get worse during one part of the cycle? Does risk of getting a sexually transmitted infection change during the cycle?

More information about research procedures.

Screening Visit *(approx. 1.5 hours)*

At the first visit we will make sure you are eligible to be in the study. If you agree to take part in the screening visit, we will conduct the procedures listed in the "Table of Study Procedures", below. A positive pregnancy test or a positive test for sexually transmitted infection or other vaginal infection will exclude you from participating in the rest of the study. You can re-screen after STI treatment.

You will be taught how to perform and record ovulation tests for at-home use and record the results in a diary. You will be asked to bring the diary to both of the remaining clinic visits.

Follicular and Luteal Visits *(approx. 3 hours)*

If you are eligible for the study and decide you want to participate, you will have two more study visits, one during each phase of your menstrual cycle. The *follicular phase* is before you ovulate. The *luteal phase* is after you ovulate. About half the participants will have their first visit during the follicular phase and the other half during the luteal phase. Assignments will be made by a process similar to flipping a coin. If you have your first visit in the follicular phase, you will call the clinic when your menstruation starts. If you have your first visit in the luteal phase, we will ask you to take ovulation tests daily and call the clinic when the test becomes positive.

Timing of collection. You have the option for the samples collected during the follicular and luteal visits to occur over a 2-3 day period rather than all on the same day.

About the study procedures. In addition to the information about procedures provided at the beginning of this form, you should know:

- **Biopsies.** For five days before, you cannot take medicines that thin your blood or prevent blood clots. These include aspirin, ibuprofen (brand name Advil), and naproxen (brand name Aleve). We may use medicines to help stop any bleeding such as silver nitrate or Monsel's solution. After the procedure you can take pain relievers such as Tylenol or ibuprofen. We will ask you not to have sex or put anything in your vagina or anus (including tampons) until the biopsy sites are healed. This is at least 48 hours. We will call you 1-3 days after the biopsies to make sure you're healing well.
- **Rectal fluid collection.** We will insert and gently inflate a small balloon that touches the surface of the rectum for several seconds to collect local fluids.
- **Vaginal and cervical wash.** We will use salty water (saline) to rinse your vagina and cervix and collect the fluid.
- **STI testing.** This includes gonorrhea, trichomonas, and chlamydia as well as genital infections such as bacterial vaginosis and yeast infections. If you are diagnosed with a sexually transmitted infection or other vaginal infection, we will either provide prescriptions for treatment or refer you to a health care provider for treatment.
- **Nose and throat swabs.** You will spray salty water into your own nose. Then we will insert two foam swabs into your nose to collect samples. We will numb the back of your throat. Then we will rub one bristly swab and one cotton swab in the back of your throat to collect samples.

- **Blood draw.** We will take about 2 tablespoons and use it to test hormone levels.
- **Lidocaine** (used for numbing) is given as an injection using a needle.
- **Questionnaire.** We will ask you about recent vaginal sexual intercourse and vaginal symptoms you are experiencing.
- **At-home daily ovulation testing and diary.** We will ask you to test daily and contact the clinic when you receive a positive ovulation result. Bring the diary to both clinic visits.

Study Visits & Procedures				
Procedures	**Screening visit**	**Daily At-Home**	**Follicular visit**	**Luteal visit**
Consent & Eligibility Review	X		X[1]	
Medical and Interim History	X		X	X
Urine Pregnancy Test	X		X	X
Vaginal Exam Using a Speculum	X		X	X
Rectal Exam Using an Anoscope			X	X
Vaginal Cotton Swab	X		X	X
STI Testing	X[2]		X[2]	X[2]
Blood Draw			X	X
Cervicovaginal Wash (x1)			X	X
Urinary Ovulation Test Recorded in Diary		X[3]		
Cervical Swab (x2)			X	X
Vaginal Biopsy (x3)			X	X
Rectal Fluid Collection (x1)			X	X
Rectal Biopsies (x3)			X	X
Nasal Swabs (x2)			X	X
Throat Cotton Swab (x1)			X	X
Throat Bristly Swab (x1)			X	X
Skin Samples (Biopsies) (x2)			X	X
Questionnaire	X		X	X

[1] Eligibility review only
[2] If a STI is diagnosed, you will be treated per most recent CDC STI guidelines either by prescription or referral.
[3] Once a positive test is recorded, call the clinic to schedule your next visit.

More potential risks of participation.

In addition to the risks described at the beginning of the consent form, you should know that:

- **The speculum and anoscope** procedures may cause anxiety or discomfort while the instruments are inserted. You may feel the urge to have a bowel movement during the rectal exam and during the rectal fluid collection.
- **During rectal fluid collection,** you may feel mild discomfort and feelings of pressure while the balloon is inflated.
- **The nose and throat swabs** may cause dryness, pain or bleeding and discomfort similar to a sore throat.
- **Having blood drawn** may cause some pain. A bruise may form where the needle enters the vein. You may feel light-headed or experience dizziness.
- **If any of the sexual, health, and medication history questions** are embarrassing or uncomfortable to answer, you may refuse to answer them.

How will we protect the information you provide?

To protect the confidentiality of the information you provide, we will store your name and other identifiable information separate from the study data. The information and samples that you give us for this study, including screening information, and the link between your name and your study data will be kept indefinitely. You will not be referred to by your name in any report of the study. Individuals from the UW or other agencies may need look at your records to make sure it is being done safely and legally.

We may use your samples and information for future studies. Information and samples may be given to another investigator at the University of Washington, other institutions, or companies, without getting additional permission from you. We will remove anything that might identify you from the information and samples. If you decide you don't want to be in the study anymore, we will keep your samples for further research unless you ask that they be destroyed. If you decide you don't want to be in the study anymore and would like your samples destroyed, please notify the lead investigator, in writing, at the following address:

PI Name
Harborview Medical Center
325 9th Ave, Box XXXXX
Seattle, WA 98104

We have a Certificate of Confidentiality from the U.S. federal National Institutes of Health which allows us to keep your identifiable research information confidential from legal proceedings or in

response to a legal request unless you give us permission to release it. You or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection, including mandatory reporting, institutional monitoring and others as listed elsewhere in this consent form.

The Certificate expires when the NIH funding for this study ends. Currently this is August 31, 2027. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

How will we test, store, and share your samples?

Commercial profit. The samples we collect as part of this research may be used for commercial profit. There is no plan to share this profit with you.

Genetic testing. For this study, we will use the blood sample you have provided to look at sequences of your genetic material. Studying these sequences will help us understand what genes turn on and off during the menstrual cycle and may explain some of the differences in the way people to respond to diseases. The genetic material you provide currently cannot be used to identify you or close relatives.

Sharing your information. One way researchers learn more is by sharing data and information. The United States National Institutes of Health (NIH) has developed data (information) banks that collect genetic data. The NIH stores this information in these public data banks for other researchers to use in future studies on any topic. This public information will not include your name or other information that could identify you. You will not receive any results from allowing your data to be placed in the NIH data banks. You will not be able to withdraw your information after it has been submitted to the NIH data banks.

We cannot guarantee that you will never be identified if your information is placed in the NIH data banks. The risk of others being able to trace this information back to you or relatives currently is very small but may grow in the future as new technologies are developed. There may be other risks that are not yet known.

Will you get to know your research results?

We will give you the results of your urine pregnancy and sexually transmitted infection (STI) testing conducted at your screening visit as soon as the results are available.

Other information about this study.

Being in this study is **voluntary**. This means that you can **refuse to sign up**. It also means that if you do sign up, you can decide to **stop being in the study at any time without penalty**. If you stop being in this study, it won't affect your participation in other studies at our clinic.

We are receiving financial support from the National Institutes of Health (NIH) to conduct this study.

We will keep your contact information and may contact you in the future to ask if you would like to participate in other studies. Your contact information will be kept confidential and will not be shared.

We may decide to stop your participation at any time without your consent. We may do this if we think it is in your best interest, if you are not able to perform all of the study procedures, or for administrative reasons such as if the study is stopped, or we have reached the required number of subjects.

If you have been injured or otherwise harmed by particpating in this study, contact PI Name (8:00am-5:00pm) or the 24-hour emergency line listed on page 2 of this consent form. You will be treated or referred for treatment.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

You will be paid for taking part in this study as noted in the tables below. If you decide to stop being in the study before finishing all the procedures, you will receive a partial payment based upon the study procedures you completed. It may take up to 4 weeks to receive your payment. Parking validation or bus tickets will be provided for each study visit.

Visit	Visit 1 / Screen	At-Home Collection	Visit 2	Visit 3
Amount	$50	$100	$275 (plus up to $400 for biopsies)	$275 (plus up to $400 for biopsies)

Type of Biopsy at Visits 2 and 3	Vaginal (up to 3)	Rectal (up to 3)	Healthy Skin (up to 2)
Amount	$150	$150	$100

If you earn $600 or more in subject payments from the University of Washington during a calendar year, the UW will report this to the Internal Revenue Service as Miscellaneous Income. This means we will ask you to provide us with your Social Security number.

Consent presenter's statement

By printing my name on this form, I am attesting that I have provided the subject) with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of **study staff** obtaining consent Date

Subject's statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form.

Digital Photographs

☐ I **give permission** for digital photographs of my skin biopsy sites to be taken for study procedures. I understand that these photographs will not be made publicly available and will be accessed only by the study team. _____ (Initials and date)

☐ I **do not** want digital photographs of my skin biopsy sites to be taken for study procedures.

_____ (Initials and date)

Printed name of **subject** Signature of **subject** Date

Copies to: Researcher
Subject