Response to Acute Exercise in Eating Disorders

NCT06213883

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University of Wisconsin-Madison Consent to Participate in Research and Authorization to Use Protected Health Information for Research

Title of the Study: Characterizing Acute Exercise Response in Restrictive Eating Disorders

Principal Investigator: Katherine Schaumberg, Ph.D (608-572-7452)

Where Lead Researcher works: University of Wisconsin-Madison, Department of Psychiatry, 6001 Research Park Blvd, Madison, WI 53719

If you are the parent or legal guardian of a minor who is invited to take part in this study, your child can participate in the study only if you give your permission. We will also ask your child if he/she is willing to take part in the study. In this consent form, "you" means the child who takes part in the study.

Invitation:

You are invited to take part in a research study using a procedure that might one day improve treatments for individuals with eating disorders. Specifically, this study aims to recruit individuals with eating disorders and those without any history of eating disorder symptoms.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and for other research in the future and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Why are researchers doing this study?

We are investigating the effects of aerobic exercise (example: swimming) among females with and without eating disorders and comparing levels of certain biological markers that appear before and after aerobic exercise. We are specifically interested in the biological markers endocannabinoids (eCB) and Brain-derived neurotrophic factor (BDNF), which are chemical signals in the body. We are doing this research because eating disorders represent a population with a higher mortality rate than other psychiatric disorders. Individuals with eating disorder use often use physical activity or driven exercise as a means to control things like fear of weight gain. Evidence has shown that engaging in driven exercise have an increased impairment and negatively impact treatment. Our goal is to better understand driven exercise in those with eating disorder and characterize differences in cognitive, affective, and biological response to exercise among adolescents and young adults with eating disorders. This research will provide more precisely targeted treatment for driven exercise, with considerable potential to improve outcomes associated with eating disorders.

This study is being done at the University of Wisconsin-Madison and University of

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California, San Francisco. A total of about 100 people will participate in this study. About 50 will take part in the study here at the UW-Madison.

Funding for this study is provided by the Virginia Horne Henry Fund (VHH) and the National Institutes of Health (NIH) under the R21MH131787 grant.

What will happen in this study?

If you are eligible and choose to participate, we will ask you to attend four visits at the UW Department of Psychiatry Clinical facilities (WisPIC): an initial assessment visit and two task visits within a week of each other. You will also be asked to complete a collection of take-home measures in between the intake and your first study visit.

Initial Visit

Structured Interview and Questionnaires

A trained interviewer will conduct a structured and confidential interview to find out about current symptoms of eating disorder and any psychological symptoms you are experiencing. We will assess your physical status like body mass index and menstrual status. Information from the initial assessment will be used to understand if certain clinical or cognitive symptoms are related to exercise experiences among individuals with eating disorders.

The interview will take about 2-3 hours.

Accelerometer Procedures Leading up to Task Days (Required)

To objectively track levels of physical activity throughout daily life, following this visit, you will be provided with an accelerometer device to wear for **7 days prior to your first task visit**. You will return the accelerometer upon completing the first task visit.

The accelerometer is watch worn device similar to a matchbox-sized pedometer, and the data that we are collecting from the device is representing, in numbers, the device's acceleration (in units of gravity). We are interested in using these data to look at how an individual's general activity levels associate with response to exercise in the lab sessions. Devices do not have the capability to connect to Wi-Fi or GPS, so we are not collecting location data. The data from the accelerometer will be downloaded on a secure server with only study personnel having access to it. The accelerometer data will remain on the UW Dept. of Psychiatry secure server and may be shared with UCSF but will not be sent out to collaborators at other institutions. The unique study code linked to your accelerometer's data would be kept securely at UW-Madison and UCSF.

Take-home measures

Prior to your first study visit day, you will be asked to complete some self- reported questionnaires asking about your mood, thoughts, behaviors, and motivation. The questionnaires can contain sensitive questions that can evoke negative emotions. You may skip any question on the questionnaires that you do not wish to answer.

Take-home measures should take around 1- 1 hour and 30 minutes to complete.

Task Days

On some study visit days, you will be asked to exercise at a moderate intensity for 30 mins.

On some study visit days, you will be asked to drink a protein shake during the visit.

Task Day A

On this day you will complete two "tasks." For the first task you will be asked to refrain from eating or drinking anything besides water after 1pm. We will provide you with a nutritional supplement as a snack at the beginning of your visit. If you are on prescription acute sedatives / pain killers (e.g., benzodiazepines, opioids) or prescription stimulants (e.g., methylphenidate, amphetamines) to treat ADHD or other psychiatric conditions, you will also be asked to refrain from using these for 24 hours prior to the lab sessions and 2 hours after the session. You will also be asked to refrain from exercising on study visit days.

A staff member will collect a sample of your blood for analysis to look at, which will amount to around 2 teaspoons of blood. You will be asked to answer some self-report question about your thoughts and feelings in the present moment. You will be asked complete two computer tasks during the visit.

Task Day B

On this day, you will be asked to refrain from eating or drinking anything besides water after 1pm. We will provide you with a nutritional supplement as a snack at the beginning of your visit. If you are on prescription acute sedatives / pain killers (e.g., benzodiazepines, opioids) or prescription stimulants (e.g., methylphenidate, amphetamines) to treat ADHD or other psychiatric conditions, you also be asked to refrain from using these for 24 hours prior to the lab sessions and 2 hours after the session. You will also be asked to refrain from exercising on study visit days.

A staff member will collect a sample of your blood for analysis to look at, which will amount to around 2 teaspoons of blood. You will then be asked complete two computer tasks during the visit.

Task Day C

On this day, you will be asked to refrain from eating or drinking anything besides water after 1pm. We will provide you with a nutritional supplement as a snack at the beginning of your visit. If you are on prescription acute sedatives / pain killers (e.g., benzodiazepines, opioids) or prescription stimulants (e.g., methylphenidate, amphetamines) to treat ADHD or other psychiatric conditions, you also be asked to refrain from using these for 24 hours prior to the lab sessions and 2 hours after the session. You will also be asked to refrain from exercising on study visit days.

During this visit, you will be asked to complete some self- reported questionnaires asking about your mood, thoughts, behaviors, and motivation. The questionnaires can contain sensitive questions that can evoke negative emotions. You may skip any question on the questionnaires that you do not wish to answer. After questionnaires you will again be asked to answer some self-report question about your thoughts and feelings in the present moment. You will also be asked to complete a task to measure response to a reward.

Reward Task.

In this task, each round, you will be given a probability of earning money for completing a task, and then asked to choose between two different task difficulty levels resulting in differing monetary rewards. Both tasks require pressing the computer space bar for a varying amount of times, but you will use your index finger of your dominant hand to press the space bar for the easy task and your pinky finger of your non-dominant hand for the hard task. This task will last

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~25 minutes.

The order of task day (A, B, and C) will be randomly chosen, like flipping a coin. Random means that study staff will have no control over which task day you will do first, second, and last. The decision of which order you will complete the task days will be made by a computer-generated program.

Each task day should take 2 hours to complete.

Blood Sample

A staff member will collect a sample of your blood (about 2 teaspoons) at two different timepoints. Your samples will be stored frozen in a locked room in WisPIC at the Health Emotions Research Institute. The samples will be used to measure levels of certain chemicals (BDNF, leptin, serotonin, and endocannabinoids) in your bloodstream. We will also perform genetic testing, which is done on your DNA. DNA, or deoxyribonucleic acid, carries the genetic instructions for the cells that make up your body. Genes tell your body how to do things like form your spine, or what color your eyes should be. Any remaining blood samples may be combined with samples from other larger future studies to look at the relationship between various biomarkers and behavior. In order to protect your privacy, the labels on these samples will not have any information that directly identifies you, but they will be labeled with a number that can be linked to you. The information that links you to the sample will be kept in the locked and secured office of the PI or designated research staff.

You may request that your sample be destroyed at any time, by calling the EMBARK Lab at (608) 572-7452. However, even if the sample is destroyed, any information from tests that were done before this time can be used.

Aerobic Exercise

Depending on the day, participants will be asked to ride on a stationary bike for 30 minutes at their own intensity or rest for 30 minutes. You will be given a heart rate monitor so study staff can assess your heart rate while you exercise. Once your heart rate reaches a certain percentage of your maximum heart rate (~70-75% maximum heart rate), you will be asked to continue at that level of effort.

At various times throughout exercising, research staff will measure your heart rate and ask you to rate how intense your physical activity feels. A staff member will be monitoring you to make sure that you are physically safe and comfortable.

Cognitive tasks

After exercising at each visit, you will complete a cognitive task. You will be provided instructions for the task before the task begins. Basically, your job during the task is to win as many fake coins as possible by using left and right arrow keys to choose one of two ‘magic carpets’ to navigate to one of two mountains displayed on the screen. Upon arriving at the mountain, you will have to choose between a left or right lamp, one of which results in receiving a coin.

In addition to this first task, you will also be asked to complete two other tasks where basically your job during the first task is to win as many real coins (these coins will translate into real money) as possible by using the space bar. You will be provided instructions for the task before the task begins. The second task you will be winning exercise time by using the space bar. Again, more instructions for the task will be provided before you begin the task.

Audio Recording

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As part of the study, we will collect an audio recording during your intake. The audio recording is being collected for reliability checks only (to make sure the study team is being consistent between each participant). Recordings will be kept till the end of the study and destroyed following completion of the study. Recordings will not be used for purposes outside of the study or in any papers or publications.

How we will use your protected health information (PHI)

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth. To do this study, we will use the following kinds of PHI:

Results of tests or procedures done as part of the study

Things you tell the researchers about your health

How long will I be in this study?

You will be part of the study for about one month, which will consist of one intake and three visits. How long you are in the study depends only on when we are able to schedule your task visits. We hope to schedule the task visits within one month of the initial visit, but based on your schedule and availability, this might be up to 90 days later.
The researchers may take you out of the study, even if you want to continue, if you do not follow the study rules or no longer meet the requirements to be in the study.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.
Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. Authorizing the research team to use your PHI means that we can release it to the people or groups listed in this form for the purposes described in this form. Once data has been anonymized and uploaded/shared with other researchers, we cannot retroactively go back and remove your data from the larger dataset. However:

You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.

If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.

If you take back your authorization, you will not be able to take part in the research study.

To take back your authorization, you will need to tell the researchers by writing to the Lead

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Researcher:
Dr. Katherine Schaumberg Department of
Psychiatry University of Wisconsin 6001
Research Park Blvd Madison, WI 53719

Will I receive the results of research tests?

All of the tests that are part of this study are for research purposes only. Because of this, we will not tell you or your doctors the results of these research tests. We may have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

What are the risks?

Interview and Questionnaires: The risk of completing psychological interviews and written tests may include fatigue and the feeling of unpleasant emotions. You can refuse to answer any of the questions you do not want to answer. You can take breaks if you want to. The interviewer will check with you at the end of the testing to see if you are anxious or distressed. If you are feeling especially uneasy about the questions, Dr. Schaumberg will be available to speak with you if you would like.

Confidentiality: This study involves asking questions about mental health symptoms. There is a chance that someone outside of the study could find out about the answers to your questions during our interview. If that happens, this could expose you to legal risks or damage your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job. We will try to keep others from getting this information by keeping your name and identifying information separate from your answers and data, keeping all records and study materials under lock, and allowing only limited access to the information within our study team. The study is protected by a Certificate of Confidentiality from the National Institutes of Health (NIH). This means that even if the police or courts ask to look at the data we have collected, we will not share any information that would identify you as a participant in the study.

Furthermore, any data made publicly available (or shared with other researchers by request/application) will be deidentified-which means that it will be made so that it cannot be linked to you in anyway as much as possible. It is impossible to guarantee that your data will never be linked back to you, but through extensive deidentification making your data available to the public will involve only the minimal amount of harm or risk that is possible to you. Due to the nature of open data sharing, it is impossible to guarantee that data will not be reidentified or linked back to you personally or to estimate the likelihood that this will happen. Rather, we will take all steps in our power to minimize this risk to you as a participant. These steps will include removing identifiers such as names and birthdates, compiling data into groups not defined by participants, etc. If any of your demographic or other information puts you at risk for being identified based off where your live or the population you are a part of, additional steps will be taken to ensure this information is not enough to tie the data back to you. If you would like to participate in the study but are concerned about the public nature of the data, you can opt out of having your data made publicly available while still participating in the study. In this instance, your data will be viewed only by the researchers, and will not be included in the dataset that will be made available to the public.

Organizations like the National Institutes of Health (NIH) have created large databases that collect data from research studies. We will put data from this study in a federal database information broadly

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available. We cannot predict how this information will be used in the future. Because it can be used for many kinds of research, your information may be used for research that you disagree with or would not choose to be involved in. This study will also be sharing data with the National Data Archive (NDA). The NDA is a controlled access database, meaning the NDA will provide basic descriptive and aggregate summary information for general public use. Access to subject level datasets submitted and stored in the NDA will only be provided for researchers who are sponsored by an institution registered in the NIH's eRA Commons with an active Federal-wide Assurance issued through the Office for Human Research Protections (OHRP).

A Global Unique Identifier (GUID), an alphanumeric code, will be created by the NDA to be used as an identifier for participants. The GUID will link research participants to their data, however the GUID is fully de-identified and the ID itself will not have and personally identifiable information or PHI. However, there is a chance of loss of confidentiality as the GUID created can be linked to other studies that have submitted their data to the NDA in which you have participated in. This is because more information and combination of information can increase identifiability. There are two questionnaires that ask for date of assessment, which is considered an indirect identifier and may increase the chance for loss of confidentiality.

Blood sample and analysis: Possible risks associated with the blood sample include discomfort, bleeding, and in rare cases, dizziness/fainting, and/or infection. To safeguard the privacy of your blood sample, all samples are de-identified (labeled with a random code and not your name) with only the study team having access to the code. There may be other risks related to genetic testing that we don't know about right now. This is because the field of genetics is moving forward very quickly.

The Genetic Information Nondiscrimination Act of 2008 is a Federal law that is supposed to prevent health insurance companies and employers from discriminating against people based on genetic information. There are some limits to this law:

- It does not apply to businesses that employ fewer than 15 people. So, if you work somewhere with fewer than 15 employees, your employer could fire you or make other decisions about employment using genetic information.
- Regardless of where you work, it does not apply to life insurance, disability insurance, or long-term care insurance.
- This means that if you had an abnormal genetic test result, and that result became known, then you could be denied or pay higher rates for life insurance, disability insurance, or long-term care insurance.

Cardiac event related to exercise: Physical activity can suddenly and briefly increase the risk of sudden cardiac death and acute myocardial infarction (heart attack) in prone persons. Individuals at increased risk for cardiovascular events (e.g., prior experiences with chest pain during exercise, history of heart disease, untreated high blood pressure) are not eligible to participate in the study. Throughout the exercise intervention, research personnel will monitor heart rate through a heart rate monitor strapped to the chest while observing your behavior and exertion. You are encouraged to communicate discomfort/pain, and you can terminate the task at any time without penalty. If alarming signs appear (e. chest pain, radiating pains, exhaustion) you may be asked to stop. If unexpected, non-emergency physiological problems appear, research personnel will call an on-call study physician. If necessary, research personnel will call 911 to transport you to a local hospital.

Other risks related to exercise: Participation in any physical activity or exercise can involve risk. These risks might include fatigue, dizziness, nausea, shortness of breath, low blood sugar, chest

pain, exhaustion, or muscle soreness. Sometimes, exercise can involve more severe physical problems, such as bone fracture, joint damage, hospitalization, or even death. Generally, more severe risks of participating in exercise are related to the presence of known or unknown cardiovascular, pulmonary, or metabolic diseases. The risk of cardiac events is higher in older adults than young adults (18-24 years). We have certain procedures in place to identify the presence, signs, symptoms, and/or risk factors of such diseases in subjects, and we hope that you feel comfortable communicating any discomfort and pain related to these procedures.

Withholding Benzodiazepines and/or prescription stimulants. Possible withdrawal symptoms include increased anxiety, insomnia, fatigue, body aches, and a general feeling of unhappiness. Participants are advised to talk with their healthcare provider and determine if withholding medication is acceptable and safe before entering the study. Participants will be told of the possible withdrawal symptoms above and advised to contact their physician or 911 in the event of an emergency if any symptoms appear.

Will being in this study help me in any way?

Taking part in this research is not expected to benefit you personally. However, we may learn things that will result in understanding how to improve treatments for Eating Disorder.

Will I be paid or receive anything for being in this study?

You will receive $30 for the assessment visit and you will receive $40 for the task visits. Additionally, you will be eligible for a perform based bonus of $30 if you finish all procedures on Task Days A, B, and C. UW is not responsible for lost electronic gift cards or checks.

Will being in this study cost me anything?

There will be no costs to you as a result of participating in this study.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

If it is an emergency, call 911 right away or go to the emergency room.
For non-emergency medical problems, contact your regular health care provider.
Call the Lead Researcher, Dr. Schaumberg, at 608-572-7452 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
Your health insurance company may or may not pay for this care.
No other compensation (such as lost wages or damages) is usually available.
UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

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HOW WILL MY CONFIDENTIALITY BE PROTECTED?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.
The NDA uses GUIDS in order to ensure that the data submitted to the archive is de-identified. Data sent to the NDA is stored in the secure database maintained by NDA's security team in the Amazon cloud.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

Any information that can link you to this study will be removed prior to any data being made publicly available or shared with other researchers who request the data.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

This study will also be registered as a clinical trial. A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

Who at UW-Madison can use my information?

Researchers in the University of Wisconsin Department of Psychiatry
UW-Madison regulatory and research oversight boards and offices
Accounting and billing personnel at the UW-Madison, University of Wisconsin
Medical Foundation, and University of Wisconsin Hospital and Clinics
Research support services staff at the UW-Madison and its affiliates

Who outside the UW-Madison may receive my information?

U.S. Office for Human Research Protections
The study sponsor, VHH
National Institute of Mental Health (NIMH) Data Archive
Collaborating researchers outside UW-Madison, including researchers at UCSF (University of California, San Francisco)

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your

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medical record.

Future studies

We would like to keep your contact information so that we can reach you to be in future possible studies to better understand eating disorders. Your contact information will be kept in a secure location separate from your study ID. This is completely voluntary. You can choose to have the study team destroy your contact information after this study is completed, and you will not be contacted for any follow-up studies. Please state your preference by signing your initials on the appropriate line:

_____Yes, the research team may keep my contact information, for possible follow-up studies.
_____No, I do not want the research team to keep my contact information after this study is completed, and I do not want to be part of any follow-up studies.

What will happen to my data and biospecimens after my participation ends?

We will keep your data and biospecimens for an indefinite period of time, meaning we have no plans of ever destroying your data and biospecimens. Keeping data or biospecimens for future research is called "banking." The banked data and biospecimens will be kept in a secure location for use by researchers.

This is what will happen with your banked data and biospecimens:

- We will use the data and biospecimens in future research projects about eating disorders.
- Because data from this research study can be useful for many different kinds of research, if you choose to enroll in the #2023-0719 POWERED study also conducted within the EMBARK Lab, your screening assessment data will be shared with this study. This will ensure participants only complete one intake assessment between the two studies if enrollment is within a 3 month period.
- Data will be added to the National Institute of Mental Health Data Archive.
- We may also use them for other types of research.
- The data and biospecimens may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data and biospecimens will be labeled with a unique study code instead of your name.
- When we give your data and biospecimens to other investigators for research projects, they will not be able to use the code to figure out which data and biospecimens are yours.
- The research team will maintain a link between your data and biospecimens and your identifiable information kept by the study team.
- You can request to have your data and biospecimens removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data and biospecimens:

- Banked data and biospecimens will not be shared with your health care providers or used in your treatment outside this study.

Because data from this research study can be useful for many different kinds of research, if you choose to enroll in the #2023-0719 POWERED study also conducted within the EMBARK Lab, your screening assessment data will be shared with this study and vice versa. This will ensure participants only complete one intake assessment between the two studies if enrollment is within a 3 month period.

You may request that your remaining samples be destroyed at any time, by calling the EMBARK Lab at 608-572-7452. Alternatively, you may request your sample to be fully de-identified, so that there is no link between coded samples and other data collected. However, even if the sample is destroyed, any information from tests that were done before this time can be used.

Use of email and phone calls to communicate

We are requesting your email address and phone number so we can schedule and confirm research appointments for this study. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Lauren Pictor at 812-243-8544. You must provide at least one form of contact information (email or phone number) to participate in this study.

What if I have questions?

You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the Principal Investigator Dr. Katherine Schaumberg at 608-572-7452.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact the confidential research compliance line at 1-833-652-2506. UW Staff not part of the study team will work with you to address concerns about research participation and assist in resolving problems.

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Agreement to Participate in this Study and Permission to Use and/or Disclose My Health Information

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study or what to have your child in this study.
- You give authorization for your/child protected health information to be used and shared as described in this form.

Printed Name of Research Participant

_____

My Signature **Date**

_____

Parent/Legal Guardian Name (Please Print)

_____

Parent/Legal Guardian Signature
(if participant is under 18) **Date**

_____

Printed Name of Person Obtaining Informed Consent and Authorization

_____

Signature of Person Obtaining Informed
Consent and Authorization **Date**

_____

YOU SHOULD RECEIVE A COPY OF THIS FORM AFTER SIGNING IT**

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