Consent Form (includes HIPAA Authorization)

Title of Research Study: Targeting transdiagnostic self-regulatory factors and eating disorder pathology among adults with BInge-spectrum eating disOrders: A mHEALTH interoceptive exposure intervention (the Bio-HEALTH Study)

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Carol Peterson, PhD Investigator Departmental Affiliation: Department of Psychiatry and Behavioral Sciences Phone Number: 612-273-9811 Email Address: peter161@umn.edu	Co-Investigator Name: Kelly Romano, PhD Investigator Departmental Affiliation: Department of Psychiatry and Behavioral Sciences Phone Number: 860-707-2044 Email Address: kromano@umn.edu

Supported By: This research is supported by the National Institutes of Health.

Key Information You Should Know Before Agreeing to Participate

The information below will help you learn about this research study and decide if you want to join. Make sure to read the whole consent form or have someone read it with you. If you have any questions or don't understand something, ask the researcher or study team before you sign the consent form.

What is this study about?

We are studying two treatments that are designed to help people who are struggling with their eating behaviors. Each day of this 6-week study, you will be asked to wear a chest-worn Holter monitor and answer brief surveys on your smartphone. You will also be asked to complete brief app-guided mind-body interventions on your smartphone for 4 of the 6 weeks. This is a remote (completely virtual) study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are an adult who experiences disordered eating behaviors.

What are the risks I should know about?

- There is a risk of distress while completing the surveys. You may feel uncomfortable answering some questions. You do not have to answer any questions that you do not feel comfortable answering.
- There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.
- There is a risk of minor, momentary emotional distress from completing the app-guided mind-body interventions.

Will this study benefit me or others?

- Participating in this study may give you insight into your own personal experiences and eating behaviors.
- You may experience a reduction in the severity of your eating disorder symptoms.
- You may experience an improvement in your overall emotional/mental health as well as your overall physical long-term health.

How is research different from clinical care?

- The goal of research is to learn new things to help people in the future.
- Researchers follow the same plan with many participants and usually don't change that plan for one research participant.
- By volunteering for a research study, you might or might not be helped personally.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Voluntary Participation and Right to Stop at Any Time

- You get to decide whether you participate or not.
- You can decide not to participate.
- You can say yes at first and then change your mind at any time.
- If you decide not to participate or to leave the study, it won't change your relationship with your doctors or the medical care you receive.

How long will the research last?

We expect that you will be in this research study for about 6 weeks.

What will I need to do to participate?

The study will be fully remote (virtual). During this study, you will complete study tasks and short surveys on your smartphone every day for 6 weeks. You will also wear a heartrate monitor around your chest during your waking hours each day of this study.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study. You do not have to participate in this research. Participation is voluntary and you can leave the research at any time, and it will not be held against you.

Will it cost me anything to participate in this study?

It will not cost you any money to participate in this study.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

More Information About This Research Study

The following is more detailed information about this study in addition to the information listed

How many people will be studied?

We expect about 80 people here will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you agree to participate in the study, we will ask you to complete the following study activities:

You will receive an email from study staff that contains a link to complete an online survey that will ask about your health behaviors. Study staff will mail you a heartrate (Holter) monitor, which will be worn around your chest during your waking hours each day of this 6-week study, except when you are showering or swimming. Study staff will send emails or have zoom calls with you (based on your preferred method of contact) to make sure you received the heartrate monitor, and see if you have any questions prior to proceeding with the study.

Next, for 7-days, you will receive prompts from an app on your smartphone to complete six

short (3-5-minutes) surveys. You will be given detailed instructions for how to complete the surveys on your smartphone. During this timeframe, you will also be asked to wear the heartrate monitor daily during your waking hours.

Next, for 4-weeks, you will complete daily mind-body interventions. The interventions consist of brief (5-10 minutes) tasks, such as guided deep breathing exercises and body scans, that you will receive through apps on your smartphone. During these 4-weeks, you will continue to complete the six brief surveys on your smartphone each day.

Finally, for 7-days, you will complete one 30 minute survey. You will also continue to complete the six semi-randomly prompted surveys on your smartphone each day and wear the chest-worn Holter monitor. After this timeframe, you will be asked to mail the monitor back to study staff via a pre-paid and pre-addressed envelope.

You will be contacted by study staff by email, phone or zoom depending you your preference throughout the study to troubleshoot any issues you may have with the study procedures or have any questions.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed. If you stop being in the research, the researchers may use all data collected from you prior to your withdrawal.

Can I be removed from the research?

It is possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed. Possible reasons for removal include:

- If you are unable to follow study instructions
- If you want to pursue eating disorder treatment that is not part of this study
- The researchers feel it is not in your best interest to continue in the study.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this

information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission to be collected and used by study teams as part of the research study you are participating in.

If this research study requires any of the sensitive information below, **the applicable boxes will be checked by the study team**.

Below, you will be asked if you agree to the collection and/or use of this information by the research team, as described in this Consent Form, by providing your initials under #1 at the end of this section.

If you change your mind, you are able to cancel your consent at any time; however, you may no longer be able to participate in the study if the information is required by the study team.

If the research study you are participating in will **not** be collecting the sensitive information below, **the N/A box will be marked by the study team**, and you will be asked to provide your initials under #2 at the end of this section.

Sensitive Information Collected and/or Used

The following will be collected or used as part of this study:

☐ My drug and alcohol abuse, diagnoses, and treatment records

☐ My HIV/AIDS testing records

☒ My mental health diagnosis and/or treatment records

☐ My genetic testing records

☐ My sickle cell anemia records

☐ **Not Applicable**. The sensitive information listed above is not collected or used as part of this study.

Research Participant Initials

- If the study team requires my sensitive health information to participate, I understand what sensitive information they will collect and/or use based on the boxes checked by the team.
- If the study team selected "N/A," I understand that my sensitive health information will not be collected and/or used as part of this study.
- By providing my initials below, I confirm that I have had the opportunity to ask questions and receive explanations if I request them.

Research participant, please initial one of these two options:

1. **Yes, I allow the collection and/or use of the selected "sensitive health information" items as part of this study:**

   Participant's Initials: _____

2. **It has been explained to me that there will be no collection and/or use of my "sensitive health information" as part of this study:**

   Participant's Initials: _____

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

How will my information be used in publications and presentations?

Data sharing with other researchers or members of the public will only be done upon request. If this occurs, only de-identified data will be shared.

What will be done with my data when this study is over?

We will use and store data for future research within the University of Minnesota. They will not be shared with researchers/institutions outside of University of Minnesota. We will remove identifiers from your data, which means that nobody who works for UMN in future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Participant Initials Required:
Please indicate whether you will allow the identifiable data to be used for future research by putting your initials next to one of the following choices:

_____ (initials) NO, my identifiable data may not be used for future research. They may be used for this study only.

_____ (initials) YES, my identifiable data may be used for other future research studies

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

If you consent to participate in this study by signing the bottom of this Consent Form, you are providing two forms of consent. The first is consent to participate in the research activities as described in this document. The second is consent to share your personal medical information, either taken from your medical records or collected as part of this research (or both), as described above. This second form of consent, sometimes referred to as "HIPAA authorization," is what is meant by "providing permission for making your health information available for use and sharing."

You may cancel your permission for either form of consent at any time, for any reason, and without penalty. You may revoke your consent to participate in research (sometimes referred to as "withdrawing from the study") simply by telling the researcher listed on the first page of this Consent Form that you no longer wish to participate. Verbal communication is sufficient to withdraw this first form of consent. However, canceling your permission to share your medical information, the second form of consent, must be done in writing to the researcher listed at the address on the first page of this Consent Form.

If you cancel either form of permission, you will no longer be in the research study. If you cancel permission to share your medical information, you may want to ask someone on the research team if doing so will affect any research-related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue

to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information gives results that do have meaning for your health, the investigators will contact you to let you know what they have found.

You will be given the option to choose if you would like to be contacted with information about the overall study results once all data are collected and analyzed. If you choose this option, we will send you a copy following publication. Your contact information will be separated from your study data.

Whom do I contact if I have questions, concerns or feedback about my experience?

If you have questions later regarding the study or your participation, you are encouraged to contact the research team. Please see the "Investigator Contact Information" section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB which is part of the Human Research Protections Program (HRPP). If there is an issue you would like to discuss with someone who is *not* on the research team you are encouraged to call the HRPP Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. For example:

- Your questions, concerns, or complaints are not being answered by the research team.
- You are having difficulty reaching the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

- You want to provide feedback about this research to someone who is not on the study team.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you as follows:

- $16 for completing the two cross-sectional surveys
- $42 for the surveys that you will complete on your smartphone each day of the 6-week study. If you complete at least 85% of these surveys you will be entered into a raffle with a chance to win a $20 bonus
- $50 for the 4 week intervention period

You will receive payment in the form of an Amazon gift card.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Signature Block for Witness:

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____