CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY
University of Pittsburgh, UPMC Western Psychiatric Institute & Clinic
Parent Consent & Child Assent
Phase II
Version 0.07

Study Title: Designing a Mobile Intervention for Dysregulated Eating and Weight Gain Prevention in Adolescents

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Study Key Information:
You and your teen are being asked to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether participating in this study is the best decision for your teen. Taking part in this study is completely voluntary. Even if you decide to participate and allow your teen to be in the study, you and your teen are free to leave at any time if you change your minds. The researcher will explain the study to you and your teen and answer any questions you may have. We encourage you to discuss this study with others (your family, friends, or other doctors) before you agree to participate in the research.

You and your teen have been asked to review this consent form in your home on a research website called "REDCap". If you decide to participate and allow your teen to be in the study, you will be asked to sign this consent which states that the study has been explained, that you and your teen's questions have been answered, and that you agree to participate and to have your teen participate. If your child is 8 years old or older, your child's "assent" (agreement) will be obtained by the researcher before you may participate in this study. The assent agreement is located at the end of this form. Your teen must sign the assent agreement. You can print and save a copy of this consent form for your records.

Before we begin, I would like to remind you to find a private, quiet space for today's call, and not to do today's session while driving. If we are using Zoom for today's call, you should know

that Zoom is an app that Northwestern University and the University of Pittsburgh use, and it is HIPAA compliant. There is a small chance your information would not be kept private. Before we go on, let me know if you have any questions about this.

A. What is the purpose of the research?

We are interested in testing a mobile app designed to help teenagers regulate their eating behaviors. This will help us create tools to benefit teenagers who struggle with overeating and/or out-of-control eating.

B. What is experimental/new in this study?

This study is Phase II of a multi-phase project to create and test a mobile app intervention aimed at helping teenagers regulate their eating behaviors. Existing interventions for adolescent eating do not address many of the factors that might affect behavior change. Existing interventions are also costly. A mobile app was developed in Phase I of this study with the help of teens who have eating concerns. We would now like to test the mobile app to see if it is an easy and effective way to help teens with their eating behaviors.

C. What do I have to do in this research study?

You and your teen will be asked to complete an initial virtual visit to determine eligibility and provide baseline information. At this first visit, (~1.5 hours), you and your teen will be asked to sign this consent form and complete questionnaires. Your teen will also be asked to provide height/weight measurements, complete an interview on their eating and thoughts around shape/weight, and complete cognitive games on a computer.

If your teen is still eligible at the end of this visit, your teen will be asked to complete a 16-week test of the VIBE app. Your teen also will get support from a coach during this 16-week period. Support from the coach will be mainly through text messages, plus occasional phone calls (ranging between 10 to 30 minutes).

You and your teen may be asked to complete follow-up virtual visits throughout the study, similar to the one you are completing today. These visits could occur halfway through the 16-week app-testing period, at the end of the 16-week period, and 1-3 months after the 16-week period. All participants will be asked to complete the post-testing visit, but not all participants will be asked to complete the midpoint visit and/or the follow up visit 1-3 months after the test. These follow up visits will include interviews, phone calls, and online surveys. We expect each visit will take about 90 to 120 minutes, and each survey may take 15-30 minutes.

D. What could go wrong?

Risks are considered very minimal in this study. Some of the questions we ask, or parts of the intervention could make your teen feel uncomfortable, sad, or upset. The Fitbit your teen will be asked to wear could irritate their skin or cause a rash. A possible problem for any research study is that confidentiality could be broken – this means that people outside the study might get hold of private study information. We will do everything we can to keep this from happening. Since you are attending virtually, we suggest your teen does

the session in a private space (so other people do not hear them if they do not want them to) to lower the chance of any problems.

E. What are the benefits?
We cannot promise any benefits to you, your teen, or others from being in this research.

F. Other things I should know about this research?
This is not a treatment study for weight control or weight loss.

G. If I don't want to take part in this research, what are my other choices?
Being in this study is voluntary, meaning it is up to you and your teen. You and your teen can choose to join or not join. If you and your teen do not want to be in this study or ask to stop being in the study at any point, your choice will not affect your relationship with the University of Pittsburgh or Northwestern University.

You and your teen can leave the research at any time and it will not be held against you. If you and your teen choose not to join, contact the study leader and you will no longer hear from the study team. If you and your teen choose to start and then leave the study, information already collected from you can still be used.

• Please carefully read this form, additional detail about each item just described is found below
• Please listen to the study team explain the study and this form to you
• Please ask questions about anything that is not clear

1. Nature and Purpose of the Study:

You and your teen are being asked to take part in this research project because we are interested in testing a mobile app that can help teenagers regulate their eating behaviors. We expect to enroll ~70 adolescents and their parents into this study. The study is sponsored by the National Institutes of Health.

2. Explanation of Procedures:

1. If you agree to participate and to have your teen take part in this study, you and your teen will be asked to complete a **virtual assessment visit** via HIPAA-compliant Zoom. At this visit, you and your teen will both show proof of identification (e.g. driver's license, Social Security card, school ID, birth certificate, library card) to confirm U.S. residence and eligibility. Your teen will then remain on the call and complete an interview about their eating behaviors and computer tasks to assess how they think and solve problems. After your teen completes the interview, they will then complete surveys that ask about their personal and contact information, eating-related thoughts and behaviors, food security, mood, and experiences with technology. The surveys will also ask your teen to tell us their height and weight and to send us a picture of their weight while standing on a scale. Your teen will be e-mailed a link to fill out the surveys on their own. You will also complete surveys about your food security and eating behaviors, and your teen's health history. You and your teen can

choose not to answer any questions as a part of the interview or surveys. You and your teen can stop the assessment at any time.

2. If your and your teen's responses show your teen is eligible for the study, your teen will be invited to enroll in the trial. Prior to starting the trial, your teen may be asked to complete a **test-run week** to make sure this study is a good fit for them and their schedule. They will be mailed an electronic scale and Fitbit to use during the study. Your teen will be asked to take a picture of the scale while standing on it at various time points. With the help of the research team, your teen will create a new Google account to connect to the Fitbit app, which must be downloaded on your teen's smartphone to use the device. The research team will know the username and password to this account and may use it to view the Fitbit use data. Your teen cannot change the password to this account. Your teen's name and birthdate may be used when creating the account. The account may also be used to integrate the intervention with the Google suite, so your teen may be able to view their progress in the intervention more easily. The account should not be used for anything unrelated to the study. After the study, your teen may connect the Fitbit device to another Google account and continue to use it. If your teen receives an electronic scale and continues using the scale after the 16-week intervention period has ended, we can continue to collect their weight measurements for up to four months, and we will stop after that. The Fitbit is a research tool only and is not part of the intervention itself.

   If participating in the test-run week, your teen may be asked to wear the Fitbit continuously. They may also complete up to 3 dietary recall calls with a member of the research team (~15-minute phone call). Depending on how engaged your teen is during this test-run week, they may or may not be invited to participate in the 16-week trial. Participants that are not invited to participate in the 16-week trial or participants that decide not to continue to the 16-week trial will be asked to return the Fitbit and electronic scale using a prepaid shipping label provided by the research team.

3. If your teen is still eligible for the intervention after the test-run week, your teen will schedule a **call with their VIBE coach** to get started with the trial. The call will be by telephone or using an internet-based phone service such as Zoom or TextLine. During the call, your teen's coach will help them log in and get started with using the app.

4. Your teen will be asked to **use the VIBE app with coaching for 4 months** (16 weeks). They can talk with their coach through texting and occasional phone calls. Your teen will have their own account credentials to log in to VIBE using a web browser on their smartphone or computer. Your teen can use or not use the app and still be in the study. After the 16-week intervention period, they may continue using the app without coaching. If your teen chooses to continue using the app after the intervention period has ended, we can continue to examine their use of the app for the time that they are using it.

Your teen will also be asked to download an app that will help them with skill building and problem solving through short tasks/games, to be used while they are participating in the 16-week intervention. Your teen will be given a research account where they can access these tasks. Your teen will have their own account credentials, however the app will have access to the data your teen provides.

5. Throughout the study, your teen may be invited to complete up to **3 additional study visits**. Virtual visits could happen:
   - Half-way through the intervention ("mid-intervention"; about 8 weeks after starting the intervention)
   - After the intervention ("post-intervention"; 16 weeks after starting the intervention)
   - 1-3-months after the intervention ("follow-up"; 1-3 months after the 16-week intervention period).

   All participants will be asked to complete the post-intervention visit, but not all participants will be asked to complete the midpoint visit and/or the follow up visit 1-3 months after the intervention. These study assessments may include an interview, a weight measurement using the electronic scale, Fitbit usage for one week, up to 3 dietary recall phone calls, computerized tasks to assess how they think and solve problems, and online surveys. Like today's session, the interview and computerized tasks will be done using Zoom video calls, or by telephone or an internet-based phone service. The interviews will be video- and/or audio-recorded. The topics that we talk about at each of these later sessions will be similar to the topics we talk about today. Each assessment will take about 90 – 120 minutes to complete.

3. Study Risks

There is a low chance that being in this study could harm your teen. They may feel bored or upset when talking about eating and weight-related topics. Your teen may experience no change or worsening in their eating behavior . Your teen may experience discomfort related to wearing the Fitbit. It is uncommon but sometimes the band can irritate people's skin. Please inform the study staff if rash/irritation occurs.

A possible problem for any research is that confidentiality could be broken – meaning that people outside the study might get hold of private study information. This is also possible when using third-party smartphone apps, such as the Fitbit app. We will do everything we can to keep this from happening. For example, we will remind you and your teen to do all the study assessments in a private, quiet place so other people do not hear you if you do not want them to. The VIBE app is hosted on a secure encrypted server, and your teen will have their own password, known only to them and the research team, to use the program.

We will not ask if your teen has any thoughts of suicide. However, if at any point during today's interview, your teen discloses thoughts of wanting to hurt themselves, we will pause the interview and ask some questions to assess how they are doing and provide appropriate intervention or referrals as needed to ensure they are safe. If your teen is eligible and enrolls in the study and they disclose thoughts of suicidality at any point during the study, one of our

trained assessors will call to assess how they are doing and provide appropriate intervention or referrals as needed to ensure your teen is safe.

4. Study Benefits

We cannot promise any benefits to you, your teen, or others from being in this research. Your teen may see improvements in their overeating/out of control eating. Your teen also may benefit from knowing that their feedback may lead to ways to help others work on these topics.

5. Confidentiality

Any information about you or your teen obtained from this research will be kept as confidential (private) as possible. The information that we get from you and your teen will be known by only a unique study number. All information will be kept on a computer with a password that can only be opened by the research team. All audio and/or video files will be transcribed using Zoom or by an approved person on the research team. Once the assessments have been transcribed, the audio and/or video file and transcript will be saved on secure files that only approved members of the research team can access and removed from where they were recorded. Transcripts will be de-identified, which means the information will not include things that could let others know who it was from. The Zoom meetings will all be hosted on HIPAA-compliant accounts.

The VIBE app is hosted on a secure encrypted server. Your teen will receive account credentials for the program. Research staff will use secure logins to view the information your teen enters into VIBE and to view the data from the electronic scale and Fitbit. The information that your teen enters into the app will not include anything that can make them known to other people. It also will not include the information you and your teen give in study assessments. Each month, and at the end of the study, we will copy the information from VIBE into a file that is saved with a password that only people on the research team can open. Your teen's information will be encrypted during the transmission of data from the VIBE web interface to the secure server database using TLS (HTTPS). The Google account will have a random username and password, and the username and password will be kept in a secure server database only accessed by the research team. Information on your teen's use of VIBE will be kept separate from the information that can identify your teen. Only approved people on the research team will be able to combine these pieces of information to make it known again who is in the study.

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to you and your teen's participation in this research study:

- Authorized representatives of the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections may review you and your teen's identifiable research information for purposes of monitoring the conduct of this research study.
- If investigators learn that you, your teen, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by state law.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that

collected for research purposed may be captured and used by others not associated with this study.

At some point, you and your teen's information may be de-identified and used by other researchers for future research studies. If this happens, we will not contact you for additional consent. In addition, per University of Pittsburgh data retention policy, research records will be maintained for at least 7 years following final reporting or publication of a project. Research records for teens will be maintained until the teen reaches the age of 25, or at least 7 years following the final reporting or publication of a project, whichever is longest. If your teen participates in any other studies with Dr. Goldschmidt or Dr. Graham, we will retain your data with identifiers from this study for use with their other studies.

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you and your teen. The researchers may not disclose information that may identify you or your teen, even under a court order or subpoena, unless you give your permission to release this information. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you or your teen if required by law (such as to report teen abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your teen's medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in you or your teen's medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented your teen to in this informed consent document. The Certificate does not stop you or your teen from voluntarily releasing information about themselves or your teen's involvement in this research. If others obtain your written consent to receive research information about your teen, then the researchers may not use the Certificate to withhold that information.

A description of this clinical trial will be available on *http://www.clinicaltrials.gov/*, as required by U.S. law. This Website will not include information that can identify you or your teen. At most, the Website will include a summary of the results. You can search this Website at any time.

6. Access to Study Results

You and your teen will not receive any study results, as the testing is being done purely for research purposes.

7. Costs for Participating in this Study:

There will be no costs to you or your insurance company resulting from your participation in this research study.

8. Payments:

Your teen will get $50 for completing today's interview and surveys. Your teen will receive this money as a reloadable debit card. This card will be mailed to your teen approximately 1 week

after they complete all visit activities. The research team will coordinate with you via email or phone call to activate the card once it is received.

If your teen is eligible for and chooses to join this study, your teen will also receive compensation for completing other research activities:

- $5 for completing each dietary recall call (up to $60)
- $20 for wearing the watch for at least 10 hours on 5/7 days each week we ask (up to $80)
- $50 for completing the cognitive task and surveys at the 8-week "midpoint" assessment, if asked to
- $70 for completing an interview and surveys at the 16-week "post-intervention" assessment
- $90 for completing an interview and surveys at the 1-3-month "follow-up" assessment, if asked to

This means that your teen can earn up to $400 total if they do all the study assessments over the course of the 8-month trial; however, not all participants will be asked to complete all assessments. Your teen can also keep the scale and Fitbit that we will send to use during the 16-week intervention, regardless of if they complete the study or subsequent virtual visits; however, they must start the 16-week intervention in order to keep them. Your teen will not get paid for using the VIBE app or for talking or messaging with their coach.

If your teen is eligible for and chooses to join the study, you, the parent, will get a $15 debit card for completing surveys at every time point (now, midpoint, post-intervention, and follow-up). This means you can earn up to $60 total if you are asked to do all of the study assessments and complete them.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 - Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding'; thus, you would only receive 76% of the expected payment.

If your teen stops being in the study at any time, they will be paid for only the activities they already did. If at any point during the study, the research team no longer finds your teen eligible, your teen will be paid for only the activities they already did, and they will be withdrawn from the study.

9. Refusal/Withdrawal:

It is up to you whether you want to participate and want your teen to be in the study. You are not required to enroll your teen or have them participate. If you decide you do not want you and your teen to participate, you can always change your mind and leave the study at any time. If you decide not to have your teen be in the study, or if you remove them later, your teen will still be able to get the health care services they would normally get. If you enroll your teen but later the researcher or your teen's doctor feels being in the study is no longer good for your teen, they

may choose to take your teen out of the study before it is over. Participants may be withdrawn for any other reason that could impact data integrity, prevent them from completing the study, or present a clearly not beneficial risk/benefit ratio for the participant. If new information becomes available that might change your mind about whether you and your teen want to stay in the study, the researcher will share this information with you as soon as possible.

If you and your teen decide to quit the study after signing this form, no new information will be collected about you and your teen. However, the researchers may continue to use information that was collected before you and your teen quit the study to complete analysis and reports of this research.

10. Rights and Complaints:

Signing this form does not take away any of your lawful rights. If you or your teen have any further questions about this research study, you or your teen may contact the investigators listed at the beginning of this consent form. If you or your teen have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh, at 1-866-212-2668. By signing this consent, I give the researchers my permission to video- and audio-record the virtual visits. Video and audio recordings will be kept for at least seven years after the conclusion of the study. The research team will have access to the video and audio recordings to ensure consistent interview processes.

Contact for Future Studies: Your teen's participation in **any research** is completely voluntary and you/ your teen should feel no pressure to have them participate in another research study.

Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ Yes, I may be contacted about my teen participating in other research projects studying eating behaviors and/or treatment. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator.

_____ No, I do not want to be contacted about my teen participating in other research projects. **Do not** give my contact information to the staff of any other research studies.

Return of Study Materials: Please initial the statement below.

_____ I understand that I may be asked to return study materials (e.g., Fitbit, Smartscale) if I do not enroll in the 16-week intervention. By initialing here, I indicate my willingness to return study materials, should I decide not to participate in the 16-week intervention or if research staff determine I am not eligible for the 16-week intervention.

11. Signatures:

PARENTAL PERMISSION
The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any part of this research study at any time. Any future questions will be answered by a qualified person or by an investigator listed on the first page of this consent document at the telephone number(s) given.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

Printed Name of Teen-Subject_____

I understand that, as a minor (age less than 18 years), the above-named teen is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for my teen's participation in this research study. A copy of this consent form will be given to me/my teen.

Parent's or Guardian's Name (Print)_____

Relationship to Participant (Teen)_____

Parent or Guardian Signature_____ Date_____

By signing this form, I give my consent for my participation in this research study.

Parent or Guardian Signature_____ Date_____

CERTIFICATION of INFORMED CONSENT
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Name of Person Obtaining Consent (Print)_____

Role in Research Study_____

Signature of Person Obtaining Consent_____

Date_____

TEEN ASSENT
This research has been explained to me, and I agree to participate.

Signature of Teen-Subject_____ Date_____

VERIFICATION OF EXPLANATION

I certify that I have carefully explained the purpose and nature of this research to (name of teen) in age-appropriate language. They have had the opportunity to discuss it with me in detail. I have answered all their questions, and they provided affirmative agreement (i.e., assent) to participate in this research.

Signature of Person Obtaining Assent_____ Date_____