Version Date: 08-23-2022

CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project: A Randomized Clinical Trial of Comprehensive Cognitive Behavioral Therapy (CBT) via reSET-O for a Hub and Spoke Medication Assisted Treatment (MAT) System of Care.

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Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 782-6844. After hours call (717) 531-8521. Ask for the psychiatry doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?
We are asking you to take part in this voluntary research study because you are a new patient who is 18 years of age or older starting opioid use disorder (OUD) treatment with methadone, suboxone, or subutex.

What is the purpose of this research study?
The purpose of this voluntary research study is to test an app call reSET-O and its ability to help patients with OUD stay in treatment for six months or longer.

How long will the research study last?
The research study lasts approximately 24 weeks (6 months).

What will I need to do?
Participants will be expected to attend five research appointments across the 24 weeks of participation. These research appointments will occur simultaneously through a phone or video conference session during your routine clinical care. During the research appointments you will be asked to complete questionnaires and interviews related to drug use and cravings, coping skills, sexual behaviors and health, and use of the reSET-O app, as well as provide a urine drug screen.

What are the main risks of taking part in the study?

For this study, the main risks to know about are the possibility of loss of confidentiality, risk of random assignment as half of the total number of participants will be randomly assigned to use the app, and psychological discomfort from being asked to answer questions related to substance use and cravings, sexual behavior, and coping skills.

What are the possible benefits to me that may reasonably be expected from being in the research?
There are no benefits to you from taking part in this research. However, some evidence suggests that reSET-O may improve adherence with appointments, medication, and learned skills to avoid drug use and relapse. Results of the study may benefit other people in the future by helping us learn more about the treatment of opioid use disorders.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

Instead of being in this research study, your choices may include participating in another research study if one becomes available; engaging in commercially available treatments without the reSET-O app including medication assisted treatment with methadone, suboxone, subutex, or vivitrol and/or individual or group counseling. You may also choose to not treat your medical condition.

DETAILED INFORMATION
The following is more detailed information about this study in addition to the information listed above.

1. **Why is this research study being done?**

   We are asking you to be in this research study because you are a patient starting outpatient treatment for opiod use disorder (OUD).

   This research is being done to find out whether an app program (reSET-O) improves the adherence to and outcome of medication assisted treatment such as methadone, buprenorphine-naloxone (suboxone) or buprenorphine (subutex), all of which are common medications used to treat OUD. The reSET-O app has been developed by a company called Pear Therapeutics, Inc., and works to provide cognitive behavioral therapy, which is a therapy often used to change patterns of negative thinking in patients to change one's behavior.

   The reSET-O app is used on a cell phone or tablet device and provides learning modules related to drug use and coping skills, and provides a chance to earn monetary rewards in the form of a gift card as a result of completing different learning modules within the app. As a part of this study, the app will also provide a chance to earn monetary rewards in the form of a gift card based on patients providing favorable urine samples, which means substances or other drugs are not present in the urine other than those that have been prescribed to the patient. The app itself will not have access to urine lab results; however, once a patient provides a urine sample, the evaluating research staff may enter the app from their own secure login credentials, and record the urine sample as "positive" (meaning substances other than those prescribed to the patient are present) or "negative" (meaning no substances other than those prescribed to the patient are present). When the sample is "negative" or favorable, the recording activates the app to send a rewards response to the app user.

The reward response is a chance to earn monetary rewards in the form of a gift card. When reward responses are activated, the app user has a chance to spin a wheel, which may or may not provide a monetary gift card reward. This is further discussed under section 9 below.

The FDA has approved reSET-O as an electronic method for therapy to be used as an additional treatment for OUD. Therefore, reSET-O is not a treatment that is used by itself to treat OUD.

Approximately 200 people from Pennsylvania Psychiatric Institute (PPI) will take part in this research study. Half of the participants (100 people) will be randomly assigned to use the reSET-O app plus their usual treatment. The other half of the participants (100 people) will be randomly assigned to their usual treatment only.

2. What will happen in this research study?

- You will be asked to participate in 5 visits (baseline visit and follow up visits at Week 4(+/- 2 weeks), 8(+/- 2 weeks), 12(+/- 2 weeks), & 24(+2/- 4 weeks)), which will occur at the same time as your routine clinical visit or in addition to your routine clinical visits. These sessions will be completed over the phone or in-person with a research staff member.
- You will be randomly assigned to one of two groups. One group will be engaging with the reSET-O app while also engaging in their usual treatment (also known as treatment as usual or TAU). A second group will not be engaging with the reSET-O app and will only engage in their TAU. All research subjects' random assignment is generated by a computer. This is similar to flipping a coin to determine how a participant will be assigned. There is a 50% chance that you will be assigned to the reSET-O + TAU group and a 50% chance you will be assigned to TAU alone group.
- Urine samples collected at your clinical appointment will also be used for the research appointments. Results of these urine drug screens will be recorded in the reSET-O app, and therefore, accessible by Pear Therapeutics.
- If you are assigned to use reSET-O, you will be taught how to download and use the free reSET-O app on your own smartphone or tablet. If you do not have smartphone or tablet, one will be given to you to be used for the duration of the study.
- If you are assigned to use reSET-O, you will use the reSET-O app therapy program regularly over a 24 week(+2/-4 weeks) period.
- All participants will complete several questionnaires at each research visit with a research team member over the phone or through a video conference. There are no plans to record the phone or video conference session. The questionnaires will ask you about your personal drug use, coping skills, sexual behavior, mental health, and your overall experience from using reSET-O. You are free to skip any questions that you would prefer not to answer. All participants are expected to complete the following surveys:
    1. Eligibility Checklist (baseline visit only)
    2. Demographics (baseline visit only)
    3. Locator form (baseline visit only)
    4. Timeline Follow-Back (TLFB)
    5. Coping Strategies Scale (CSS)
    6. PROMIS
    7. Social Connectedness Scale (SCS)
    8. Patient Health Questionnaire (PHQ)
    9. Kessler 10 (K10)
    10. HIV Risk from the Sexual Experiences and Risk Behavior Assessment Schedule (SERBAS)
    11. Columbia Suicide Severity Rating Scale (C-SSRS)

12. Qualitative Interview for reSET-O App Usage (if assigned to reSET-O)
13. Intervention Acceptability/Feedback Form (IAFF; if assigned to reSET-O group)
14. TAU Tracking Form (TTF) – completed by research staff and verified with you, the participant.
15. reSET-O Implementation and Adherence
16. Hurt-Insult-Threaten-Scream screening tool (HITS, baseline and endpoint visits only)
17. Brief Assessment of Recovery Capital (BARC-10)
18. PTSD Checklist- Civilian Version (PCL-C)
19. Overdose History form (baseline visit only)
20. Weiner Intervention Appropriateness, Acceptability and Feasibility Survey
21. First Response Opioid Survey Tool (FROST)

Since we are collaborating with Columbia University, the completion of the TLFB will be done with a Columbia Research team member. You will be instructed to call the Columbia Research Team member upon completion of all other research appointment tasks. There are no plans to record the call.

If you have been assigned to use reSET-O, you will also be asked to complete the following surveys via phone or video conference at each research appointment. There are no plans to record the phone/video conference session, however, the interview at week 8 or 12 will be audio recorded:

1. reSET-O Patient Services Center enrollment form (baseline visit and week 12 visit)
2. Intervention Acceptability/Feedback Form (IAFF; week 4, 8, 12, and 24 visit))
3. At the Week 4 visit, you will participate in a qualitative interview with research staff to assess your initial thoughts on the app and identify barriers to spending time engaging with the app.
4. At either the Week 8 or 12 Visit, you will also participate in an interview to give personal accounts of your experience using the application and make suggestions for improvement. The interview will be audio recorded and stored in a role-based security file on the Penn State Health server. The purpose for the audio recording is ensure that all information from the interview is captured.

- If you have been assigned to use reSET-O, research staff will collect data from the reSET-O data system and dashboard to understand your usage of the reSET-O features, lessons completed, and rewards earned.

- If you have been assigned to use reSET-O, the total time it may take to complete the baseline visit, which includes reviewing this consent form, completing study questionnaires, and getting set-up with the app, may be 1 to 1.5 hours.

- If you have been assigned to participate in your treatment as usual only (no reSET-O use), the total time it may take to complete the baseline visit, which includes reviewing this consent form and completing study questionnaires, may be 45 minutes to 1 hour.

- If you have been assigned to use reSET-O, it may take approximately 30-45 minutes to complete questionnaires during visits 2-5. The third visit (week 8 visit) may take 50-65 minutes as a result of a follow-up interview that will be conducted in addition to the listed questionnaires above. If the interview is not completed at the third visit (week 8 visit), then it will be completed at the fourth visit (week 12 visit).

- If you have been assigned to participate in your treatment as usual alone (no reSET-O use), it may take approximately 20-30 minutes to complete questionnaires during visits 2-5.

- For all participants, we will conduct two phone check-ins between the last two visits (week 12 and week 24 visits). No data is collected from these phone check-ins, other than documenting them as complete. The purpose of these phone check-ins is to ensure that your contact information has not changed, and to remind you of the next research appointment.

3. What are the risks and possible discomforts from being in this research study?

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

If you choose to participate in this study, you will be asked to electronically sign to indicate your consent to participate. A copy of this consent form, along with the electronic signatures of yourself, the individual obtaining consent, and witness, will be emailed or mailed to you. We may also email the signed consent form to your PPI OTP clinical provider, who is also part of the study team, to then print and physically hand to you. It is up to you how you would like to receive the signed consent form copy. There is a risk of loss of confidentiality as people may know you have agreed to participate in this research study should your email be breached or mail is stolen or lost and opened by unauthorized individuals.
You will be assigned to a study group by chance. Participants who are not assigned to the reSET-O app intervention will not engage with the app and its content including education about skills avoiding drug use, and will not receive monetary rewards as provided by the app.

The questionnaires or surveys completed at each research visit may lead to some psychological discomfort as you discuss sensitive information related to drug use and/or sexual behaviors. You may feel distressed or uncomfortable answering such questions; however, you are not required to answer any question that makes you feel uncomfortable.

Some of the questionnaires and interview questions will be about your feelings, such as depression, sadness, and anxiety. If your responses indicate that you are having suicidal thoughts or may be at risk of hurting yourself or others, we will need to respond to that. The response may involve breaking confidentiality and contacting a licensed mental health professional or a law enforcement officer. All patients who express any suicidal thoughts will be referred for follow-up mental health counseling.

For participants who have been assigned to engage with the reSET-O app, you may interact with all the functionalities of reSET-O with or without a wireless signal or WiFi. If the device you are using with the application loses an internet connection, the app program will update whenever it reconnects with a WiFi signal. Although information and answers within reSET-O cannot be accessed, the reSET-O website may become known. Someone could look up the general website of the developer and see that reSET-O (in general) and Pear Therapeutics (the company that developed the reSET-O app) are generally linked to substance abuse prevention and treatment.

The interventions (reSET-O) may be ineffective, and your opioid use or associated problems may get worse.

The reSET-O app should not induce any more discomfort than other treatments offered as part of outpatient substance abuse treatment. If you become overly distressed, you should inform the clinical staff working at your treatment program.

If you are pregnant or become pregnant, you may choose to continue in the study. There is no risk to you as the pregnant individual or to the fetus.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. However, some evidence suggests that reSET-O may improve adherence with appointments, medication, and learned skills to avoid drug use and relapse.

4b. What are the possible benefits to others?

The results of this research may help guide the treatment of other patients with opioid use disorder in the future.

5. What other options are available instead of being in this research study?

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive commercially available treatments without the reSET-O app, including: medication assisted treatment with methadone, dispensed and prescribed buprenorphine-naloxone (suboxone) or buprenorphine (subutex), and extended release naltrexone. Counseling with individual and group settings is also available.
- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition.

Before you decide if you want to be in this research or if you decide to stop participating in the research after initially consenting to participate, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

reSET-O is FDA approved and commercially available, which means that you could receive this app without participating in this study if your prescribing doctor is willing and able to prescribe the app. Receiving the app this way would involve billing your primary health insurance.

6. How long will I take part in this research study?

If you agree to take part, it will take you about 24 weeks to complete this research study, including two phone check-ins at weeks 16 and 20. You will be asked to complete research tasks with a research team member via phone or video conference for a total of five times. These tasks will be completed during your routine clinical care appointments.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

In our research files at Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: names and/or initials, address, date of birth, telephone numbers, email address, medical record number, voice recording, study ID code number, and a username associated with the reSET-O app if you have been assigned to use the reSET-O app.

- A list that matches your name with your study ID code number will be kept On the Penn State Health Network server, only accessible by research staff.
- Your research records will be entered into an electronic database, as protected by Penn State's IT team.
- A copy of this consent form along with your electronic signature indicating your consent to participate in the research study will be included in your Opioid Treatment Program medical record. This means that other healthcare providers within the Opioid Treatment Program may know that you are in this study.
- Audio-recorded interviews provide in-depth open-ended answers about the likes, dislikes, and suggestions for improvement on the app. These interviews will not contain PHI and will be stored on the Penn State Health Network server, only accessible by research staff.
    - The audio-recording device is an external flash-drive that connects into a computer or laptop and allows the recorded file to be uploaded to the server. The audio-recorded file will be labeled with your subject ID only and the research visit number in which the interview occurred. For example: "Qualitative Interview-0001-week 8".
    - Once the file is uploaded to the server, the file will be deleted from the flash-drive device.
    - Once all audio-recorded files have been transcribed (the audio-recording is written or typed out in a way that provides a readable file), the audio-recording will be destroyed.

For participants assigned to use reSET-O, completed enrollment forms will be sent to the patient services center. These forms will ask for identifying information such as your name, a phone number, and an email address. A date of birth is also required but we will provide a fake or a dummy date of birth for you that is not connected to your actual date of birth (i.e.: 01-001-0001; dd-mmm-yyyy). This information has to be collected and sent to Pear Therapeutics, Inc.'s (owners of reSET-O) patient services center, because this is how they will identify who you are if you were to call them for technical support or to discuss experiences with the app. The phone number may be a phone number that you use regularly, or a phone number at PPI, or a phone number that is connected to a study device (if applicable). The patient services center will call you on a weekly basis to ensure that you are not having trouble using the app. You are allowed to opt out of these calls. Pear Therapeutics does not sell phone numbers or use them to conduct sales calls. The email may be an email that you use regularly or study staff can help you set up a free email account that is only used for the purposes of this study. An email has to be collected in order for you to reset your login credentials such as your password, if needed. Pear Therapeutics does not sell email addresses or use email addresses for marketing or advertisements.

For research records sent to collaborating researchers at Columbia University, as well as the Research Foundation of Mental Health (RFMH) as associated with Columbia University, you will be

identified by only a code number. Penn State research staff will securely receive reSET-O phone app data from Pear Therapeutics Inc. for participants who have been assigned to use reSET-O, as well as your survey data (surveys listed in section 2). This data will in turn be provided to researchers at Columbia University or RFMH for data analysis.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research.

For additional information ask the principal investigator or a member of the study team or contact the Human Subjects Protection Office at (717) 531-5687.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. What will happen to my research information and/or samples after the study is completed?
We may use your research information, such as your responses to the study questionnaires, and your biological samples, such as results of urine drug screens, in future studies or may share your information or urine drug screen results with other investigators for future research without your additional informed consent. Before we use or share your information or samples we will remove any information that shows your identity.

Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies. They share this information with each other by putting it into scientific databases. Your coded research information may be put in one or more databases and used for future research. Your information stored in these databases will not include any identifying information such as your name, address, telephone number, or social security number. Your research data will only be available to researchers who have received approval from data access committees and/or Institutional Review Boards. Some of these databases are maintained by PSH/PSU, some are maintained by the federal government, and some are maintained by private companies and other institutions.

7c. How will my identifiable health information be used?
In general, under federal law (including the Health Insurance Portability and Accountability Act – HIPAA or privacy laws) your health information is private. By signing this form, you are authorizing us to collect, use, and disclose your identifiable health information, sometimes referred to as "Protected Health Information" or "PHI" under HIPAA, for the purposes of this research study. We will use and disclose your information only as described in this form, in the PSH Privacy Notice, and as may be required or allowed under the applicable privacy laws.

As with information contained in research records generally, we will use and disclose your identifiable health information when we are required to do so by law, such as for laws that require us to report child abuse or abuse of elderly or disabled adults.

The research team may use the following health information:

- Past, present, and future medical records, including identifiable information
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- PSH/PSU research staff involved in this study
- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Subjects Protection Office
- The PSH/PSU Research Quality Assurance Office
- Non-research staff within PSH/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- A group that oversees the data (study information) and safety of this research
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original PSH/PSU records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable health information and samples may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.

- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The reSET-O app will be provided by Pear Therapeutics, Inc. at no cost to you while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
    - Urine drug screens provided for your routine clinical appointments may be charged to your insurance.
- The research-related tests and procedures that will be provided at no cost to you include the questionnaires and interview listed above under section 2.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will

arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

PSH/PSU compensation for injury

- There are no plans for PSH/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you electronically sign to indicate your participation in this research study you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will receive a $40 gift card for the baseline intake appointment and then a $25 gift card per research appointment after that for your participation in this research study, for a total of $140. For participants who have been assigned to engage with the reSET-O app, an additional $25 gift card will be given at either the week 8 or week 12 visit when the interview is completed, resulting in a total of $165. If you do not complete the study for any reason, you will be paid for the visits you have completed. Gift cards will be sent to your email address on file. The study is not responsible for lost or deleted gift cards and there are no plans to replace these gift cards.

In addition to the gift cards described above, you also have a chance at receiving additional gift cards (Amazon or Starbucks) provided by the reSET-O app, if you have been assigned to participate in this app. The rewards are provided by the reSET-O app in the form of a lottery. You will be eligible to "spin a wheel" directly in the app program every time you complete a learning module within the app and provide a favorable urine sample during the research visits. The rewards you may receive include positive and encouraging messages, $5 e-gift card, $20 e-gift card, or a $100 e-gift card. The rewards are provided at random and are managed by the reSET-O app and its owners, Pear Therapeutics, Inc. Penn State Health/ Penn State College of Medicine have no involvement in the randomization of rewards provided by the reSET-O app. It is your responsibility to report gifts and monetary stipends as income received to the government when filing taxes.

It is possible that your research information and/or specimens (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Institutes of Health (NIH) to support this research. From the funding provided by NIH, Penn State College of Medicine will be purchasing tablet devices, managed by research staff, which will only be provided to study participants who do not have their own tablet or smartphone to run the reSET-O app. Participants will receive one tablet only and will be allowed only one replacement tablet should anything happen to the first tablet provided. Should anything happen to the second tablet, there are no additional plans to replace the device or provide reimbursement for the device. Once the study is over, all tablets used by participants will be returned to the study team.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you decide to leave the research, you will no longer have access to the reSET-O app, unless you decide to receive services from another provider who is able to prescribe the app commercially. You will be paid for all completed research visits. All rewards earned through the reSET-O app will be yours, even if you decide to leave the research; however, if you decide to leave the research, you will not be able to earn further rewards through the app, starting from the date of discontinuation.

The research doctor may take you out of the research study without your permission.

- Some possible reasons for this are: your condition has become worse, you did not follow the instructions of the study doctor.
- Also, the sponsor of the research may end the research study early.
- If your participation ends early, you may be asked to visit the research doctor for a final visit.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Kawasaki at 717-782-6844 or the psychiatry doctor on 24-hour call at 717-531-8521 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

A description of this clinical trial will be available on http://www.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.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name