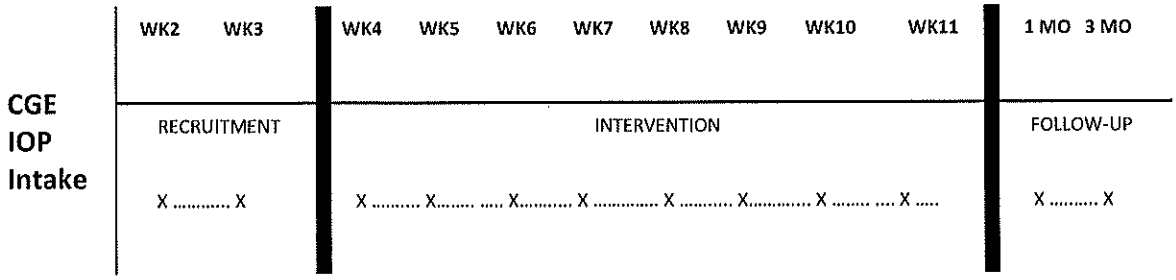
Attachment 1
Informed Consent to Participate in a Research Study

We are conducting a study of new ways to protect people from using alcohol and drugs during and after treatment. As a patient at the Center for Great Expectations (CGE), we are inviting you to participate. The study is conducted by Dr. Marsha Bates and Dr. Jennifer Buckman who are professors at the Center of Alcohol Studies, Rutgers University. Other individuals working as co-investigators or study staff may assist or act for them. The purpose of this study is to understand whether an iPhone "app" that helps control your breathing can be used to help people deal with stress and anxiety, and reduce craving and urges to use alcohol or other drugs during and after treatment. Approximately 170 women age 18 years and older will take part in this study.

You will be assigned randomly to one of two groups; each group will learn to use an iPhone app to breath at a certain rate. Your participation in this study will include 3 stages (recruitment & training, intervention, and follow-up) and 2 laboratory sessions. Below are details to help you understand each part of the study. Please stop to ask questions at any time about anything that is not clear or that you do not understand.

THE STUDY

This study has 3 time stages (recruitment, intervention, follow-up) and 2 laboratory sessions (pre- and post-intervention) as shown and explained below. Some participants (described below) will also be asked to participate in a 2-session (pre- and post-intervention) neuroimaging component.



1. **The recruitment stage** will occur between your 2nd and 4th weeks of treatment at CGE. During

these 2 weeks, we will meet with you at CGE for approximately 30-60 minutes. At our first meeting, you will be administered a clinical interview to confirm the diagnoses (like depression or alcohol use disorder) you may have been given previously at CGE or elsewhere. At our second meeting, you will be asked to complete surveys that ask about your experience with anxiety, depression, personal substance use triggers, alcohol/drug craving and use, as well as information about important people in your life. We will also help you to identify when you are experiencing emotional stress or other "triggers" for which the paced breathing may be helpful.

2. **The intervention stage** will occur during weeks 4 to 12 of your treatment at CGE. You will be given an iPhone pre-loaded with a breathing app (without a phone or data contract), and trained to use the iPhone (if you do not know how) and the app. You will be asked to use the iPhone app for at least 5 minutes when you feel you may drink or use drugs, or when you experience any trigger that may cause you to feel stress. On any day that you do not feel stress, anxiety, depression or urges to use, we ask that you simply use the app for 5 minutes before going to bed at night. Once a week, one of our research staff members will collect information from you about (1) your experiences using the app (2) types of triggers you have been experiencing, and (3) any alcohol or drugs you may have used. During these weekly visits, our research staff will also help make sure that you are using the app correctly. To do this, we will sit you in front of a computer screen and attach sensors to your upper arms. Then, together, we will observe your heart rate and respiration using biofeedback technology called Thought Technology. During the fourth week of the study, this information will be recorded. There are no known risks associated with the use of Thought Technology. New sterile sensors are used for each participant. Throughout the intervention stage, you can earn money towards a gift card for using the app, as described below.
3. **The follow-up stage** will occur one month and three months after you complete your second lab visit. We will ask about your anxiety, depression, craving, alcohol/drug use, and your quality of

life. We will also ask about whether you have continued to use the iPhone app we gave to you.

4. This study also includes **2 laboratory sessions** so that we can see whether using the app speeds up recovery during treatment. The laboratory sessions will occur at the beginning (4th week) and end (12th week) of the intervention phase. Each session will last approximately 2-3 hours and take place in our lab in Piscataway at Rutgers University. We will provide transportation both ways, and the travel time is about 10 minutes from CGE. We will also provide lunch.

During these sessions:

a. We will perform a few simple measurements of things like blood pressure, weight, height, and the length of your arm. You will be seated in a comfortable chair in our laboratory and sensors will be attached to your arms and legs to allow us to measure your heart rate, respiration, skin conductance, skin temperature, and blood pressure. There are no known risks associated with this assessment; we are only recording your physiological response. New sterile sensors will be used for each participant.

b. You will complete a few questionnaires about your history of alcohol and drug use, and physical and mental health, and about your family history.

c. You will complete four tasks; each will take 5 minutes. During the first task, you will be asked to watch colored blocks on a television screen and count the number of blue blocks. During the second and third tasks, you will be asked to breathe at two different speeds along with a pacer shown on the television screen. We will show you how to breathe correctly, but not too deeply. If you breathe too deeply you might feel a bit dizzy or lightheaded. If you experience these feelings, do not be worried; they will go away immediately after you stop the deep breathing. During the fourth task, you will perform a visual processing task.

d. During one of the two lab sessions, you will be asked whether you would be willing to provide a genetic sample. Genetic collection is a simple, painless procedure that takes less

than 1 minute. The sample is collected from the inside of your cheek using two soft swabs that look like long Q-tips. You do not have to agree to the genetic sample to be a part of this study.

5. You may also be asked to take part in **an optional part of the study that involves a brain scan** using an MRI. If you are invited to participate in this part of the study, we will discuss the details of the brain scan study separately. You do not have to agree to the brain scan to be a part of this study.
6. We are asking for your permission for **CGE to provide us with information** about your urine drug screens and your attendance at treatment. We need this information to better determine how the app is helpful to you while in treatment and after you leave. The clinical researcher who will be interacting with you will not be given the results of your urine drug screens.

COMPENSATION

If you choose to participate in the study, you will be able to earn a free iPhone with a paced breathing app already installed. As shown below, you will also be able to earn a total of $390 in the form of meals and gift cards to Walmart and Dunkin' Donuts. also for participating in follow-up interviews and visits to the brain imaging center.

All transportation to the lab and brain imaging center will be provided; lunch will also be provided.

If you decide to withdraw from the study at any time, you still will be given all gift cards that you have earned up to that point. If you complete the second laboratory session, you will be given the iPhone you had been using in the study to keep for your own use and a $50 Walmart gift card. Before that time, all iPhones will be deactivated and unusable if lost or stolen.

COMPENSATION	RATE	#	TOTAL
Total possible weekly	$10/week	8 weeks	$80
Total possible monthly bonuses	$10/month	2 months	$20
One-month follow-up interview	$25		$25
Three-month follow-up interview	$25		$25
MRI visits	$50/each	2 visits	$100
Meals (4)	$10 value/each	4 visits	$40
Second Lab Visit	$50		$50
TOTAL POSSIBLE EARNINGS			**$340**

Note: If you currently own an iPhone 5s or newer, you will have the option of having the breathing app downloaded on your personal phone for use in this study. If you choose this option, and if you complete the second laboratory session, in exchange for us providing a free iPhone for you to keep, we will provide you with equal compensation in Walmart gift cards (~$$150).

1. **RISKS, PROCEDURES THAT WE USE TO PROTECT YOU, & BENEFITS**You will be assigned an ID number, and this number, not your name, will be used on all information and data that you provide to us. Any articles that are published from this study, or presentations at scientific conferences, will use data from groups, not from individuals. If any individual data are presented (for example, a heart rate record), it will not be possible to determine your identity. This research is strictly confidential. This means that we will keep a list that links your identity to your ID number and the information you provide to us, but we will limit access to this list to only key research personnel and we will keep the list in a locked cabinet in a secure office at Rutgers University.
2. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose

information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if you threaten to harm yourself or another person or report any incidents of child or elder abuse (or if it is strongly suspected). In these cases the investigator is required to notify the appropriate authorities of the suspected abuse, but not your participation in the study.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project (National Institute of Alcohol Abuse and Alcoholism) and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

3. The research team and the Institutional Review Board (a committee that reviews research studies in order to protect research participants) at Rutgers University are the only parties that will be allowed to see the data.
4. No information about alcohol, drug use, or anything else that you tell us, will be shared with the CGE clinical staff. In addition, if we detect a possibly abnormal ECG during our laboratory sessions, we will inform you and, if you wish, your clinician at CGE in the event that you might want to follow up with a physician. We will not provide the actual ECG or other physiological records because our procedures are not designed for clinical diagnosis.
5. Your participation is entirely voluntary and you may withdraw from the study at any time without

penalty. **Your choice to participate or not participate will not affect any services that you are eligible for now or in the future from the CGE.**

6. You may refuse to answer any individual question you are asked if you choose.
7. You may refuse to provide a genetic sample and still be eligible for this study.
8. A free text messaging app (Skype, Microsoft Corporation, Redmond, WA) will be downloaded onto your iPhone and you can text our research staff with any questions you have. We will also provide a laboratory telephone number to call if you cannot text.
9. We have the right to withdraw you from the study at any time in such cases as:
    - If we determine that you gave us incorrect data that fall under exclusion criteria.
    - You are not able to fill out required questionnaires or obey study requirements (e.g., sit still in a chair for about 5 min).
    - You become pregnant.
10. There are some minor risks associated with this study.
    a. Slow breathing may make you feel a bit dizzy or lightheaded if you breathe too deeply. This will go away immediately after you stop the breathing exercise.
    b. Some questions we ask deal with challenging issues, including how you feel emotionally and your alcohol and drug use. Although unlikely, if answering these questions upsets you, please let us know. We will arrange a session with your CGE clinician, or you may speak to a research clinician not on CGE staff, depending on your wishes.
    c. You may find the iPhone or the iPhone app you are assigned frustrating to learn, but we will train you to use these items and help you at any time when you experience a problem with them. You can also text or call us anytime, as stated above.
    d. If you choose to provide a genetic sample, the risks and potential side effects are no more than that experienced with brushing your teeth. The swab does have a stiff core, so the use

of excessive force during collection could produce scratches inside the cheek. When applied correctly, however, only a slight tickling sensation should be felt.

11. You may receive some benefits from participating in this study. For example, the app you use may help when you feel stressed or anxious. In addition, an indirect benefit from your participation is in contributing to knowledge about how to help people who have difficulties with alcohol or drugs. This knowledge may have implications for the design of substance use prevention and interventions.
12. Research results will be available upon completion of the study if you are interested.
13. Five years after the conclusion of the study, the list linking your data to your personal identity will be destroyed and only anonymous data will be kept.
14. Any questions about this study should be addressed to one of the following investigators:

Dr. Marsha Bates
Distinguished Research Professor
848-445-3559
mebates@rci.rutgers.edu

Dr. Jennifer Buckman
Associate Research Professor
848-445-0793
jbuckman@rutgers.edu

Address: Center of Alcohol Studies, 607 Allison Rd, Rutgers University, Piscataway, NJ 08854.

15. Any questions or concerns about your rights as a research participant should be addressed to the Rutgers Office of Research and Sponsored Programs at 732-235-9806.

    Address: Rutgers University Institutional Review Board for the Protection of Human Subjects, Office of Research Regulatory Affairs, Rutgers University, 335 George Street, Liberty Plaza, 3rd floor, Suite 3200, New Brunswick, NJ 08901 /Email: human-subjects@ored.rutgers.edu

PROJECT IMPACT 9

CONSENT TO PARTICIPATE IN THIS INTERVENTION STUDY

I have carefully read and fully understand the above, and affirm that the information I have provided about my age, background, substance use and alcohol use is accurate and truthful. I have received a copy of this consent form.

_____ _____

Date **Name and Signature of Participant**

RESEARCH STAFF:

I have explained the objectives of the study listed above and indicated any known risks to the above participant. I have assured the participant that I will answer any inquiries concerning the procedures involved. The participant has also been informed that he/she is free to withdraw from this study at any htime without penalty.

_____ _____

Date **Name and Signature of Investigator**

PROJECT IMPACT 10

CONSENT TO PROVIDE A GENETIC SAMPLE

Procedure: **Participation includes donating a DNA sample and takes approximately 1 minute.** The collection procedure will consist of swirling a soft swab against the inside of one cheek for 30 seconds, followed by swirling a second swab against the inside of the other cheek for 30 seconds. The entire procedure is painless and causes no cuts, scratches, or bruises inside the mouth.

Confidentiality: As with the other data associated with this study, your name will not be used in association with your DNA samples. Only primary research staff will have access to your identity. After the DNA is isolated from your cells, the collection swabs will be discarded. The DNA will be stored at the Rutgers University Bionomics Research and Technology Center (BRTC) for 5 years following completion of the study, at which point any remaining DNA samples will be de-identified.

Linking Data Across Studies: Note that you are participating in one of several studies that collects genetic data in addition to physiological and psychological data. Data from all studies (past and present) performed in this laboratory may be linked. Linking of data across these studies does not lessen the confidentiality of your data. The protection of confidentiality applies to all data used by all investigators participating in these projects.

Participation is Voluntary: You do not have to provide a genetic sample to participate in the intervention study. Whether you decide to give a genetic sample or not, it will not change your involvement in the main intervention study or the treatment you receive from CGE in any way now or in the future.

Withdrawal from the Research Project: You have the right to leave the study at any time without giving a reason, and without penalty. Contact Dr. Buckman to remove your test DNA from use in the study.

Dr. Jennifer Buckman
Associate Research Professor
848-445-0793
Address: Center of Alcohol Studies, 607 Allison Rd, Rutgers University, Piscataway, NJ 08854.

I have carefully read and fully understand the above, and affirm that the information I have provided about my age, background, substance use and alcohol use is accurate and truthful. I have received a copy of this consent form.

I choose to provide a genetic sample

_____ _____

Date **Name and Signature of Participant**

I DO NOT choose to provide a genetic sample

_____ _____

Date **Name and Signature of Participant**

RESEARCH STAFF:

I have explained the objectives of the study listed above and indicated any known risks to the above participant. I have assured the participant that I will answer any inquiries concerning the procedures involved. The participant has also been informed that he/she is free to withdraw from this study at any time without penalty.

_____ _____

Date **Name and Signature of Investigator**

PROJECT IMPACT 12

CONSENT FOR CONTACT IN THE FUTURE

We will be conducting additional studies in the future. Your signature below indicates that we have permission to contact you in the future to ask if you are interested in participating in another study. Please list all contact information we may use:

Telephone: _____

E-mail: _____

_____ _____

Date **Signature of Participant**

Attachment 4 (MRI)

Informed Consent to Participate in a Brain Imaging Research Study

We are conducting a study of new ways to protect people from using alcohol and drugs during and after treatment. As a patient at the Center for Great Expectations (CGE), we are inviting you to participate. The study is part of the larger study that you are currently participating in that uses iPhone apps. This study is also being conducted by Dr. Marsha Bates and Dr. Jennifer Buckman who are professors at the Center of Alcohol Studies, Rutgers University. Other individuals working as co-investigators or study staff may assist or act for her. The purpose of this study is to understand how the brain works together with our body to deal with stress, anxiety, and craving, and whether iPhone app interventions change this. Approximately 56 people will take part in this study.

THE STUDY

1. There are 2 sessions; one will occur during week 4 and one during week 12 of your treatment at CGE.
2. Each session will last approximately 2hours.
3. Both sessions will take place at the Rutgers University Brain Imaging Center (RUBIC) in Newark, NJ.
4. You will be driven to and from the RUBIC by a research staff member.
5. During the first session, you will answer a series of screening questions to ensure that it is safe for you to be imaged.
6. You will also be required to take a pregnancy test before each session because pregnant women cannot participate in this study.
7. You will be given a light lunch.

8. The study will begin by attaching sensors to your arms, finger, legs and abdomen. This part will be similar to your laboratory session on the Rutgers, New Brunswick Campus. New sterile sensors are used for each participant. The sensors are non-invasive and should not cause you any discomfort. There are no known health risks associated with these assessments.
9. You will then be brought into the MRI scanner where we will take pictures of your brain. You will wear earphones or plugs, lie on table, enter a small noisy tube, and remain still for approximately30 minutes.
10. Your brain will be imaged using a Siemens 3T TRIO (head only) magnet while you view visual stimuli projected onto a mirror inside the MRI scanner.
11. The visual stimuli will be used in 4 tasks, just like the ones you performed in the other laboratory session on the Rutgers, New Brunswick Campus: During the first task, you will count colored rectangles. During the second and third, you will breathe at two different rates, following the visual pacer. During the fourth, visual cues will be presented and your response time will be recorded.

<u>You cannot participate in this study if any of the following apply:</u>

- You have any magnetic metal such as iron, nickel or cobalt implanted in or on your body or clothes including metal flakes or filings, surgical pins or plates, electrical devices such as a pace maker, jewelry, or metal ink tattoos.
- You are pregnant.
- You are claustrophobic or anxious in small spaces.

RISKS, PROCEDURES THAT WE USE TO PROTECT YOU, & BENEFITS

1. <u>There are no known health risks</u>associated with this study. However,
    a. You make feel claustrophobic or uncomfortable in the MRI scanner. If you experience these

feelings, please alert the researcher and we will remove you from the scanner immediately.

b. The MRI scanner makes a lot of noise. Do not be alarmed, these banging and clicking sounds are normal. You will be given earplugs to reduce the noise, but if you find the noise uncomfortable, we will remove you from the scanner immediately.

c. Slow breathing may make you feel a bit dizzy or lightheaded if you breathe too deeply. We will show you how to breathe so that this doesn't happen. Any dizziness will go away immediately after you stop the breathing exercise.

2. There are no direct benefits to you for participation in this study. An indirect benefit is in contributing to knowledge about how to help people who have difficulties with alcohol or drugs.
3. You will receive a gift card worth $50.00 to reimburse you for your time at the end of each session. If we determine that you are not eligible to take part in the experiment, or you withdraw from the study prior to its completion, you will receive a gift card worth $25.00.
4. Your participation is entirely voluntary and you may withdraw from the study at any time without penalty. **Your choice to participate or not participate will not affect any services that you are eligible for now or in the future from the CGE.** It will also not affect your participation in the other iPhone study.
5. We have the right to withdraw you from the study at any time in such cases as:
   a. If we determine that you gave us incorrect data that fall under exclusion criteria.
   b. You are not able to obey study requirements (e.g., remain still in scanner for 30 min).
   c. You arrive at these sessions intoxicated or under the influence of drugs.
6. **CONFIDENTIALITY:** This study is compliant with federal regulations. This research is confidential. You give permission for the scientific use of your data. If the data from the study are published, or made part of an archive or database accessible to individuals other than the

investigators and their collaborators your data will never be associated with any identifying characteristics such as your: name, address, or other identifying number, or any combination of data about you which could reasonably lead, directly or indirectly by reference to other information, to your identification. The researcher will associate a unique code with your data files. This code will be secured by the researcher in a different database or physical location, and be available only to those directly associated with the research study. Please note that we will keep this information confidential by limiting access to the research data and keeping it in a secure location. Five years after the conclusion of the study, the list linking your data to your personal identity will be destroyed and only de-identified data will be kept. Research results will be available upon completion of the study if you are interested.

7. Any questions about this study should be addressed to one of the following investigators:

Dr. Marsha Bates	Dr. Jennifer Buckman
Research Professor	Associate Research Professor
848-445-3559	848-445-0793
mebates@rutgers.edu	jbuckman@rutgers.edu

Address: Center of Alcohol Studies, 607 Allison Rd, Rutgers University, Piscataway, NJ 08854.

8. Any questions or concerns about your rights as a research participant should be addressed to the Rutgers Office of Research Regulatory Affairs, Rutgers University at 732-235-2866.

Address: Institutional Review Board
Rutgers University, the State University of New Jersey
Liberty Plaza / Suite 3200
335 George Street, 3rd Floor
New Brunswick, NJ 08901

Email: human-subjects@ored.rutgers.edu

I have carefully read and fully understand the above, and affirm that the information I have provided about my age, background, substance use and alcohol use is accurate and truthful. I have received a copy of this consent form.

_____ _____

Date **Name and Signature of Participant**

RESEARCH STAFF:

I have explained the objectives of the study listed above and indicated any known risks to the above participant. I have assured the participant that I will answer any inquiries concerning the procedures involved. The participant has also been informed that he/she is free to withdraw from this study at any time without penalty.

_____ _____

Date **Name and Signature of Investigator**