University of California, San Diego
Consent to Act as a Research Subject

Novel Behavioral Intervention to Target Social Reward Sensitivity and Attachment

You are being asked to participate in a research study. Before you give your consent to volunteer, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Investigators:
This study is being conducted by Charles Taylor, PhD, Assistant Professor of Psychiatry at the University of California, San Diego. Phone number: (858) 534-9446.

Purpose of the Study:
This study is being conducted to examine the effects of a behavioral treatment designed to improve positive emotions, behaviors, and underlying brain systems. Participants will be individuals who experience difficulties with anxiety or depression. You have been asked to participate in this study because your responses to our screening questionnaire indicated that you are experiencing symptoms of anxiety or depression. There will be approximately 150 participants in this study.

Description of the Study:
This study has several parts. You will be asked to participate in one or more parts of the study. The clinical interview, computer-based, and behavioral portions of the study will be conducted at the Altman Clinical and Translational Research Institute located at 9452 Medical Center Drive, La Jolla CA, 92037. The brain imaging session will be conducted at the UCSD Keck Center for Functional MRI.

If you decide to participate in the study the following is a summary of what will happen to you:

Screening procedures:
To determine if you are eligible to participate, you will be asked to complete a clinical interview. A clinical interview is an assessment tool that helps researchers make an accurate diagnosis of a variety of psychiatric conditions. During this interview, you will be asked questions about your anxiety, mood, and history of other psychological symptoms, which will take approximately one hour.

If you are a female and capable of child-bearing, we will ask you for verbal confirmation that you are not pregnant. If you are pregnant or think you may be pregnant, you should not take part in this research. In addition you will be asked questions to determine if you are eligible to undergo MRI, such as whether you have a cardiac pacemaker; metal fragments in the eyes, skin or body; heart valve replacement, brain clips, venous filter, history of sheet metal work or welding, aneurysm surgery, intracranial bypass, renal or aortic vascular clips; prosthetic devices such as middle ear, eye, penile implants or joint replacements; hearing aide, neurostimulator, insulin pump, IUD, pregnancy; vascular shunts or stents; metallic implants, plates, pins, wires or

screws; permanent eyeliner or eyebrows, or tattoos since MRI may not be appropriate under some of these conditions.

If your responses indicate that you are eligible, you will be asked to participate in the study. If you are not eligible to participate, the information obtained from you during this screening will not be included in this study and will be shredded to protect your confidentiality.

Study procedures:
Part 1:
During this part of the study, you will be asked to complete questionnaires and provide the investigators with basic information about you as well as information about your mood and anxiety. This portion of the study should take about 30 minutes. Next, an interviewer will ask you some questions about symptoms of anxiety and other psychological symptoms that you may have experienced.

The interview will be video recorded and later rated by a clinical research assistant to make sure that all interviews are being performed the same way with each participant. The interview portion of the study will take about one hour. If your responses during this interview indicate that you are eligible to participate, you will continue to Part 2.

Part 2:
Next, you will be asked to complete several additional questionnaires and computerized tasks. During these tasks you will see pictures or words on a screen, and you will be asked to either do nothing or, in some cases, to push a button or move a joystick according to the rules of the task. The task(s) will be explained to you in detail beforehand so that you will know how to perform the task. These questionnaires and computer tasks will take approximately 90 minutes. You may take breaks in between the computer tasks if you so choose. You will also be asked to complete several tasks that measure your level of anxiety and mood in different situations (e.g., talking with a stranger). The behavioral tasks will take about 60 minutes and will be videotaped to make sure behavior ratings of you and research personnel are being performed the same way with each participant.

During the computer and/or behavioral tasks, some basic physical functions (e.g., heart rate, breathing rate) may be measured with a non-invasive device. Additionally, electrodes may be attached to your face to measure eye and other facial movements as well as to your neck, hand, wrist, and/or palm to monitor skin conductance and heart rate. The electrodes will be attached using gel/lotion and paper tape. Brain activity may be measured during these tasks using surface electrodes that are mounted in an elastic cap, which you will wear during the experiment. The cap has open plastic rings that are filled with gel/lotion and then surface electrodes will be placed in those holes. All electrodes will be removed after the assessment is complete. Setting up these devices and fitting and adjusting the electrodes and cap will take approximately 30 minutes.

Part 3:
Next, you will complete the MRI session. If you are pregnant or think you may be pregnant, you should not take part in this research. If you are a female and capable of child-bearing, we will administer a urine pregnancy test before the MRI session. The test result must be negative for

you to participate in the MRI session. Dr. Taylor and his research team will make sure that your urine collected for this study will be properly discarded. It will not be used for any other research. In this session a picture of your brain will be obtained using a Magnetic Resonance Imaging (MRI) scanner. This session will take approximately 2 hours and will be scheduled at the UCSD Keck Center for fMRI. For the MRI scan, you will be placed in a large donut-like machine for about 1 hour. Your head will be placed in a special helmet-like "head-holder" and you will be asked to hold still while we take pictures of your brain. The MRI technician will position you in the scanning machine, provide hearing protection including ear plugs and headphones, ensure that you can fully view the display screen, and give you the response device (i.e., button box or joystick). You will be asked to perform several computer tasks while in the MRI scanner. During these tasks you will see pictures or words projected onto a screen or onto special goggles, and you will be asked to either do nothing or, in some cases, to push a button or move a joystick according to the rules of the task. The task(s) will be explained to you in detail before you enter the scanner so that you will know how to perform the task.

Part 4:
This is the treatment part of the study. You will be randomly assigned to one of two treatment groups or a waitlist group. The random group assignment ensures that each participant has the same probability (~33% chance) of being assigned to any group.

Treatment Groups:
If you are assigned to one of the treatment groups, you will come into the clinic once per week for either 5 or 10 treatment sessions. Each session will last about 1 hour, plus an additional 30 minutes during the first session for introductions and treatment orientation. During each session you will be presented with educational materials and prescribed exercises designed to increase positive thoughts, behaviors, and emotions. You will also be given instructions for completing activities throughout the week based on the information provided each session, including rating forms to assess your emotions and reactions to the exercises. These sessions will be video recorded to make sure that the treatment protocol is being administered the same way to each participant.

Waitlist Group: If you are assigned to the waitlist group, you will not complete any exercises in Part 4 for a 10-week duration. After completing Part 5 you will be given the opportunity to complete the treatment protocol.

Part 5:
After completing Part 4 (treatment groups) or approximately 10 weeks after completing Part 3 (waitlist group), you will attend a final assessment session during which you will complete the same assessments that you completed during the initial session (Part 2), including the brain imaging session (Part 3). Each session will last about 3 hours. If you were assigned to the waitlist group, you will be given the opportunity to complete the treatment protocol after Part 5.

Part 6:
If you were in the treatment groups you will be asked to complete Part 1 again approximately 3 and 6-months after you complete the treatment. You will have the option of completing the

follow-up assessments in person at our research clinic, or being emailed a de-identified link to a follow-up survey that will be uploaded to a secure, encrypted server when you complete it. The total amount of time to complete all study parts will be approximately 14 hours over the course of 4 assessment sessions. If you are assigned to the treatment groups, you will have an additional 7-12 hours of study time to complete, including weekly treatment and possible follow-up sessions.

Risks or Discomforts:
Participation in this study may involve some added risks or discomforts. These include:

1. You may experience temporary discomfort because you will be asked to answer some personal questions about your anxiety, mood, and other psychological symptoms (for example: “Have you been feeling depressed during the past few weeks?”). You will also be asked to view words, sentences, or pictures that are negative (for example: read the word "embarrassed" or "stupid"), or complete tasks (e.g., talking with a stranger) that may cause temporary discomfort. We will do everything possible to minimize any risks or discomfort you may experience as a result of the study. If you feel any discomfort as a result of participating in this study, you may stop at any time, and you should also contact the investigator for further consultation. The investigator will also provide you with a referral list with contact information for mental health resources in the community.
2. You may feel some discomfort from wearing the electrode cap as it may put some pressure on your forehead or chin (chip strap). You may also experience some temporary discomfort with the removal of the tape that holds the electrodes in place. You may experience some temporary skin irritation from the gel/lotion use to attach the electrodes to the skin, and/or the tape used to hold the electrodes in place. These risks will be reduced by using a hypoallergenic, bacteriostatic, saline-based gel and the option of foam padding for your forehead and/or chinstrap.
3. Risks associated with MRI: The magnetic resonance scanner is a long narrow tube that is open on both ends. A small number of individuals experience claustrophobia once inside. You will be able to signal the investigators with a squeeze ball device at any time to pause or stop the study or simply to ask questions.
    - The scanner produces loud banging noises while acquiring images. You will be given a set of earplugs to help with the noise.
    - There are no known effects from exposure to magnetic fields. However, some patients might become anxious or claustrophobic (a feeling of anxiety) during scanning. If this happens to you, you can stop the procedure at any time. You may also experience some discomfort and fatigue or muscular aches from lying on your back for one hour in a confined space during the imaging. While in the scanner, it is possible that you might become dizzy, or experience a small twitching sensation. This is not unexpected and should not be painful, but you should tell the researchers about it.
    - If you have any metal clips, plates or a pacemaker in your body, you should tell the investigator. MRI may not be appropriate under some of these conditions: a cardiac pacemaker; metal fragments in the eyes, skin or body; heart valve replacement, brain clips, venous filter, history of sheet metal work or welding, aneurysm surgery, intracranial bypass, renal or aortic vascular clips; prosthetic devices such as middle ear, eye, penile implants or joint replacements; hearing aide, neurostimulator, insulin

pump, IUD, pregnancy; vascular shunts or stents; metallic implants, plates, pins, wires or screws; permanent eyeliner or eyebrows, or tattoos.

4. There is a risk of a loss of confidentiality.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Benefits of the Study:
There may or may not be any direct benefit to you from participating in this study. All participants will be provided with diagnostic feedback after the clinical assessment, which is an assessment tool that helps researchers make an accurate diagnosis of a variety of psychiatric conditions. All participants will also be given information on community clinics offering mental health services on a sliding fee scale. You may experience a decrease in symptoms or increase in positive emotions as a result of these procedures. The investigators may learn more about new treatments to benefit individuals experiencing elevated levels of anxiety or depression.

Alternatives to Participating:
The alternative to participation in this study is to not participate. There are alternative treatments for anxiety and depression. These include cognitive behavioral and talk therapy, as well as medications that have been shown to reduce symptoms.

Voluntary Nature of Participation:
Participation in this study is voluntary. Your choice of whether or not to participate will not influence your current or future relations with UCSD. If you decide to participate, you are free to withdraw your consent and to stop your participation at any time without penalty or loss of benefits to which you are allowed. If you decide that you no longer wish to continue in this study, you will be requested to notify the Investigator, Dr. Taylor, verbally or in writing. At that time, you will be asked to complete a final examination involving questions about your anxiety and mood to determine your health status.

There may be conditions under which the Investigator, Dr. Taylor determines that your participation in the study should end. These include any signs of change in your health status that may jeopardize your well-being (e.g., significant worsening of anxiety or mood symptoms). If your study participation is ended for these reasons, you will be referred to clinical resources in your community.

Costs and/or Compensation for Participation:
The only costs associated with this study are transportation costs to UCSD and the time required to complete the study procedures. You or your insurance will not be billed for the study procedures, such as the pregnancy testing or MRI.

You will receive compensation upon completion of the following: Initial clinical interview (Part 1 = $10), behavioral assessment session (Part 2 = $30), MRI sessions (Parts 3 and 6 = $75 each), Post behavioral assessment session (Part 5 = $30), follow-up session (Part 7 and 8 = $10 per session). You may also receive up to $25 each time you complete one of the tasks.

What if you are injured as a direct result of being in this study?:
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

Confidentiality:
Research records will be kept confidential to the extent allowed by law. All data will be kept confidential, and will be accessible only to research personnel, including the Investigator (Dr. Taylor), his co-investigators, and trained research assistants. Consent forms with identifying information will be kept in a separate locked filing cabinet from research materials. Research materials will be assigned a numerical code separate from any identifying information. This data will be kept in a locked office in the case of paper forms or on a password-protected computer at the research site in the case of electronic data. Data will be kept for at least three years after the conclusion of the study and study analyses are complete. Data may be reported in scientific journals, but will not include any information, which identifies you as a participant in this study. All of the information you provide will be associated with a number and data will be recorded based on that number.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior and in some cases, your genetic information, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments.
NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before

you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.
Research records may be reviewed by the UCSD Institutional Review Board and the National Institute of Health, the agency who is providing funding for this study. Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities. The clinician is also legally required to report serious threats of physical violence against a reasonably identifiable victim or victims to law enforcement and the victim(s). In the event that you report intention to injure or harm yourself (e.g., thoughts of suicide) the Investigator may also report this to appropriate medical or law enforcement personnel as required to assure your safety.

Questions about the Study:
If you have any questions about the research now, please ask. If you have questions later about the research, you may contact Dr. Charles Taylor at (858) 534-9446.

Please **check** a box below to indicate whether or not you would like to be informed about other studies you may be eligible to participate in:

☐ **YES**, you agree to be contacted about other studies. _____ (initial here)

☐ **NO,** you do not wish to be contacted about other studies. _____ (initial here)

Consent to Participate: Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you have about the study. Your signature also indicates that you agree to be in the study and have been told that you can change your mind and withdraw your consent to participate at any time. You have been given a copy of this consent form. You have been told that by signing this consent form you are not giving up any of your legal rights.

You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep. You agree to participate.

_____
Name of Participant (please print)

_____ _____
Signature of Participant Date

_____ _____
Signature of Investigator Date