

Title: Targeting Dopamine-Mediated Social Reward Sensitivity to Remediate Social Disconnection (R61) Project

NCT06269146

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CONSENT TO PARTICIPATE IN RESEARCH

1. Study Title and Number

Title: **Targeting Dopamine-Mediated Social Reward Sensitivity to Remediate Social Disconnection (R61 Project)**

Study # 806035

2. Principal Investigator

Charles Taylor, PhD, Associate Professor of Psychiatry at the University of California San Diego and Dr. Franklin Schneier, MD, Research Psychiatrist and Co-Director of the Anxiety Disorders Clinic at New York State Psychiatric Institute are conducting this research and asking for your consent to participate.

3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number

If you have questions or research-related concerns, you may reach the UC San Diego study team at (858) 822-4357. You may also reach the Principal Investigator, Charles Taylor, PhD, at (858) 534-9446.

4. Study Overview

This research study is being conducted to examine the therapeutic potential of a medication, pramipexole, to improve social connectedness and functioning in people who experience anxiety or depression.

Pramipexole is a medication that increases dopamine signaling in parts of the brain believed to underlie motivation and behavior, and it has improved depression symptoms in some studies. We are testing this medication because it is thought to work in a different way than currently available FDA-approved medications for anxiety and depression, which tend to only be partially effective for improving social functioning.

We are inviting you to participate in a research study because your responses to our screening questionnaire indicated that you are experiencing symptoms of anxiety or depression with moderate disruption in your social functioning.

This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

The purpose of this research study is to understand how pramipexole affects social behavior and associated brain systems believed to support a person's ability to connect with others. Knowledge gained from this study

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

may help inform the therapeutic potential of pramipexole for reducing social disconnection and improving social functioning in people experiencing anxiety or depression. Participation in the study may or may not benefit you directly; it may result in new knowledge that may help others.

You will first undergo several procedures to determine if you are eligible for the study, including a clinical interview, medical examination, blood and urine tests, and ECG (also called an electrocardiogram). If you are eligible, the study is approximately 9 weeks, with a 6-week treatment period. During that time, you will visit our research clinic for brain imaging and behavioral tests, surveys, and other procedures designed to monitor your safety and measure the effect of the study drug or placebo. After the baseline visit, you will be assigned to receive one of two doses (1.0mg/day or 2.5mg/day) of the study drug (pramipexole) or placebo (an inactive substance), which you will take twice daily for 6 weeks. You will meet with a study physician weekly to monitor your safety and symptoms and adjust the medication dose. An overview of the study appointments, time commitment and compensation is shown in the table below.

Procedure	Schedule	Time Commitment	Compensation
Screening (this appointment)	1-2 weeks before starting study drug	4 hours	\$50
Baseline (fMRI* and assessments)	Week 0	5 hours	\$100
Treatment (6 weeks)	Week 0-6	3 hours (0.5 hours/week)	N/A
Post (fMRI and assessments)	Week 6	5 hours	\$100
Physician Follow-up	Weeks 7-8	0.5 hours/week	N/A
Physician Follow-up	Week 9	0.5 hours	N/A
Completing all study procedures	N/A	N/A	\$50
Total	9 weeks	~18 hours	\$300

*fMRI or MRI is also known as magnetic resonance imaging.

The most common risks or discomforts of this study are mild to moderate anxiety or distress when completing the clinical interview or behavioral assessments, and mild side effects associated with the study drug. These may include headache, nausea, feeling sleepy/drowsy, light-headedness, and/or difficulties sleeping. You will be monitored for any symptoms by the study physician and research team.

The most serious risks include those noted above, including mild to moderate anxiety or distress when completing the study procedures and mild side effects from the study drug.

A complete listing of possible risks and discomforts associated with this study can be found in Section 8 of this document.

We cannot promise any benefit to you or to others from you participating in this research. However, possible benefits include that while you are in this study, you may experience a decrease in symptoms or improvement in social functioning because of this study; however, this is not guaranteed to happen. All participants will be given information about community clinics offering mental health services, including those on a sliding fee scale. The investigators may learn more about a medication that may benefit others experiencing anxiety or depression in the future.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

Other options instead of participation in this study are alternative treatments for anxiety and depression. These include cognitive behavioral therapy as well as medications that have been shown in research to reduce symptoms. The alternative to being in this study is not to participate.

More detailed information about this research study is provided below.

5. Whom can I talk to if I have questions?

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

- UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

6. How many people will take part?

We plan to study approximately 200 people here. The research will include approximately 236 people across all locations.

7. What happens if I take part in the research?

Here is what will happen to you if you agree to be in this study:

Throughout this form the words, “drug” and “treatment” are used, often these terms refer to experimental drugs and treatments. As you read this form, ask questions if something is not clear.

Part 1: Intake/Screening

Session 0 Part 1

You will be asked to complete questionnaires and a clinical interview, remotely or in-person, to determine your eligibility. This involves answering questions about your demographics, health characteristics, anxiety, mood, and history of other psychological symptoms. This session, Part 1, of the screening will take up to 2 hours to complete.

Session 0 Part 2

If your answers to the clinical interviews and questionnaires indicate you are eligible, you will proceed to complete the following during an in-person visit:

- Review medical history
- Review of medications you are taking or have recently taken
- Physical exam including height and weight
- Vital signs: body temperature, pulse, and blood pressure
- ECG: Sticky patches are placed on your chest. These patches are connected to a machine that shows the electrical activity of your heart.
- Urine sample: You will be asked to provide a urine sample that will be used to check for:
 - Drugs of abuse. The results of these tests will be kept confidential
 - Pregnancy (if you are of childbearing potential)

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

- Blood draw for safety labs: A needle will be used to draw blood (approximately 20 ml or 4 teaspoons) from a vein in your arm. Blood will be taken to establish and monitor your health and to potentially exclude you from study treatment if we decide it would be unsafe for you to participate.
- Blood draw for blood biomarkers: Biomarkers can be used to predict how beneficial a treatment may be for a given person. Approximately 6ml (1 teaspoon) of blood will be drawn to assess your blood biomarkers. The blood sample for the biomarkers will be collected during the screening visit at the same time as the safety lab sample.

This session, Part 2 of the screening, will take up to 2 hours to complete.

The entire screening session, Part 1 and 2, will last up to 4 hours. The screening visit could be done on the same day or on separate days. If eligible, you will continue to Part 2: Baseline Visit on a different day.

Part 2: Baseline Visit

If you are eligible after the screening visit, you will be asked to come for the baseline visit. The baseline visit will take about 5 hours in total, split over 1-2 visits due to scheduling logistics.

This visit includes completing questionnaires, behavioral tasks, and an MRI scan. The behavioral tasks are intended to measure your responses to different situations (e.g., talking with a stranger; making choices to complete an activity alone or with someone else). The tasks will be explained to you in detail beforehand so that you will know how to complete them. Some of the behavioral tasks will be video recorded to make sure behavior ratings of you and research personnel are being performed the same way with each participant. These video recordings are not an optional part of the study.

During the behavioral tasks you will be asked to:

- Have a conversation with another person that involves taking turns answering questions that will be provided to you. You will be asked to complete some questionnaires during and after the conversation.
- Make decisions about whether to complete an activity alone or with someone else. Each option will be paired with a small amount of money within a range of \$0.10 to \$0.30. A random selection of your decisions will be used to determine your earnings at the end of the task. You could earn a maximum of \$5. You may keep any money earned at the end of the experiment.

You will also be asked to complete an MRI scan. MRI machines use a strong magnet to make pictures of the inside of your body. During the MRI scanning, you will lie on a long narrow couch for 1 hour while the machine gathers data. You will hear tapping noises that are from the MRI scanner. 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 a display screen, and give you the response device (i.e., button box). 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, and you will be asked to either do nothing or, in some cases, to push a button according to the rules of the task. The tasks will be explained to you in detail before you enter the scanner so that you will know how to perform them. Please note that the MRI data collected for this study is not valid for clinical or diagnostic purposes. We are therefore unable to share MRI data with participants.

During the MRI tasks you will be asked to:

- Play a game in which you will be instructed to press a button when you see a certain target image appear in order to win positive social feedback or avoid negative social feedback. The feedback presented will be pictures of faces.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

- Answer questions about your own preferences and characteristics or those of another person (e.g., someone famous). Some responses will remain private and some will be shared with someone else (e.g., person you had a conversation with earlier in the study).
- Lie still while we take a picture of the structure of your brain.

Since the MRI scanner is a magnet, metal objects will be attracted to the scanner. It is very important that you tell the researcher about any metal objects, devices or implants that are in or on your body before you enter the scanner room. All metal objects must be removed before entering the magnet room. In some cases, having those devices may mean that you should not have an MRI scan.

Part 3: Treatment Phase

At the end of your baseline appointment, you will be “randomized” into one of three study treatment groups described below.

You will be randomized to receive one of two doses of the study drug (pramipexole) or matching dose of placebo (an inactive substance) for 6 weeks. Pramipexole has been approved by the Food and Drug Administration (FDA) to treat signs and symptoms of certain conditions (e.g., Parkinson’s disease and moderate to severe restless leg syndrome); however, it is not FDA approved for anxiety or depression and has not been tested for improving social functioning.

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have 1 in 3 chances of being placed in a specific group. Two-thirds will receive some dose of pramipexole and one third will receive placebo.

In this study you might receive a placebo. A placebo is a pill that looks like the study drug but has no real medicine in it. A placebo is often used in research studies so that the doctor and you do not know your study group. The study is done this way because knowing whether you are getting the study drug or placebo can change the results of the study. In case of an emergency, we can find out if you are getting the placebo or the medication.

During the 6 weeks in which you are taking your assigned study drug or placebo, you will meet with a study physician weekly, for about 0.5 hours each week, to monitor your safety and symptoms and adjust the medication dose as needed. These meetings and your medication dispensation will occur at our research clinic at weeks 0, 2, and 4. If the study physician cannot be on site for some reason, they will connect with you by phone or video call. The study physician will also check on your safety and symptoms remotely by phone or video call at weeks 1, 3, and 5 of treatment. You may be asked to attend an unscheduled in-person visit if the study clinician determines it appropriate to ensure your safety.

The drug and MRI scans in this study may affect a baby, before or after the baby is born (for example, birth defects or problems that emerge during infancy or childhood). The medication pramipexole has been associated with higher rates of failure in early pregnancy in rats, as well as changes in breastmilk. Therefore, those able to become pregnant should not be in this study if they are:

- pregnant,
- breast-feeding, or
- trying to become pregnant.

To determine your eligibility for this study, a pregnancy test will be conducted before you enter the study. If the test is positive, you will not be able to participate in the study. Pregnancy tests will be repeated before each MRI during the study, once more during treatment, and at the end of treatment. It is important that you understand that even if a pregnancy test is negative, you could still be pregnant, because these tests cannot

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

detect very early pregnancies (that is, within the first few days). If you are unable to provide a urine sample for the pregnancy test at the MRI session, we will ask for your verbal confirmation that you are not pregnant.

If you are able to become pregnant, you should use birth control for at least 21 days prior to the first dose of the study drug, the entire time you are in the study and for 3 months afterwards. Hormonal methods (birth control pill, etc.), double-barrier methods (condoms with spermicidal, sponge with spermicidal, or diaphragm with spermicidal), or not having sex may be used. Your doctor will discuss these with you.

If you are able to cause a pregnancy, you should not have unprotected sex with someone who is able to become pregnant while on this study. If your partner(s) is/are able to become pregnant, you and your partner(s) should use birth control (described above) for the entire time you are in the study and for 3 months after taking your last dose of the study drug.

If you become pregnant or think you might be pregnant during study treatment or within 3 months after completing study treatment, you must inform the Study Doctor immediately. Your Study Doctor will want to follow the pregnancy and collect information about the outcome of the pregnancy.

Part 4: Post-Treatment Visit

After completion of the 6-week treatment phase, you will complete the same assessments that you completed during the Baseline Visit (Part 2), including questionnaires, behavioral tasks, and an MRI scan, as well as a medical exam, ECG, and routine blood and urine pregnancy test (if you are of child bearing potential), and a test to measure the amount of pramipexole in your blood. The blood tests will involve collection of about 3 tablespoons of blood.

Part 5: Discontinuing the Study Medication

At the end of the treatment phase, you will be given instructions for gradually discontinuing from the study drug or placebo over two weeks. To monitor your symptoms, the study physician will call you one week and two weeks after the completion of the 6-week treatment phase. The study physician's final follow-up call with you will occur at the end of the study, when you are off the drug for one week. At the end of this session, you will be debriefed and referred for additional care as appropriate.

8. What are the risks and possible discomforts?

Participation in this study may involve risks or discomforts.

Side Effects from the Study Drug

The most common side effects associated with pramipexole are:

- Headache
- Nausea
- Feeling sleepy/drowsy
- Light-headedness
- Difficulties sleeping

In clinical trials of patients taking pramipexole for restless legs syndrome, the following symptoms occurs at a greater rate in the pramipexole group and affected at least 2% or 2 out of 100 patients: Nausea, constipation, diarrhea, dry mouth, fatigue, flu symptoms, headache, and sleepiness; and the following symptoms occurred in at least 5% or 5 out of 100 patients: nausea, diarrhea, heartburn, flu symptoms, fatigue, insomnia, abnormal dreams, nasal congestion, pain in extremity.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

In the largest clinical trial in depression, symptoms that occurred in at least 5% or 5 out of 100 patients and that were more common on pramipexole than placebo were headache, nausea, sleepiness, dizziness, insomnia, infection, fatigue, loss of appetite and vomiting. Abrupt discontinuation could potentially cause discomfort from withdrawal symptoms.

Cases have also been reported of experiencing increased urges to gamble, sexual urges, urges to spend money, and binge eating while taking pramipexole.

- Allergic Reactions:

With any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious, and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing call 911 immediately.

We will closely monitor you during the study and will treat any discomforts or side effects that you have the best we can. If your side effects are severe, we may lower your dose or stop giving you the study drug or placebo.

Risks Associated with the Study Tests

Interview, questionnaires, and computerized and behavioral tasks: 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 (e.g., pictures of angry faces) 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.

Risks of Magnetic Resonance Imaging (MRI) Studies: The magnetic resonance imaging (MRI) machine is a powerful magnet. This magnet may cause any metal in your body to move. If you know of any metal in your body, you will need to tell the researcher right away. Otherwise, there are no known risks of MRI. Some people with claustrophobia (fear of closed spaces) may find the MRI scanner too confining. In that case, you can ask to be removed from the scanner and this will be done immediately. The MRI scanner makes a loud beeping sound. We may ask you to wear protective earplugs during scanning.

You may experience some discomfort and fatigue or muscular aches from lying on your back for one hour in a confined space during the scanning. 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.

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

Blood Sampling: A blood sample will be collected from you for the screening medical tests and analysis of study drug concentrations, which may cause discomfort and bruising at the place where the needle goes into the skin. Fainting, and in rare cases skin infections, may occur.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

Urine Sampling: Participation in this study will require that your urine be tested for drugs including cocaine, methadone, cannabinoids, opiates, amphetamines, benzodiazepines, and barbiturates. These tests are necessary to make sure study procedures would be appropriate for you. The drug test may result in a positive result. The drug test results will not be made available to you. Efforts will be made to keep your personal information confidential. The drug tests are not labeled with any identifying information. Awareness of a positive drug test may have serious personal or social consequences which may include difficulty obtaining health, life, and/or disability insurance or employment, and difficulty traveling to some foreign countries.

ECG: There is generally no risk with having an ECG. The sticky patches may pull your skin or cause redness or itching.

Risks of Loss of Confidential Information: There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will remove all personal identifiers from forms and keep study records in locked cabinets behind locked doors or on secure, encrypted and password-protected servers maintained by the University.

Risks Associated with Reproduction, Pregnancy: Procedures involved in this research might be dangerous for pregnant individuals and/or fetuses. You should not become pregnant or cause a pregnancy while in this research. Methods of birth control allowed for this study are described in Section 7 above. If you are breastfeeding, you should not breastfeed a baby while taking part in the study as the study drug could harm the baby.

Risks of Incidental Findings: Although the testing you will have in this study is being undertaken for research purposes only and should not be considered a substitute for normal medical care, it is possible that the doctors may notice something that may be serious or could affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

Delay in initiating other potentially beneficial treatments: The time from the initial evaluation to completion of study procedures is anticipated to be approximately 9 weeks. Participating in this study could therefore delay initiation of treatments such as cognitive behavioral therapy or other medications that have been shown in research to reduce symptoms. A study physician will be in contact with you every week from the time of consent through the completion of study procedures to evaluate your symptoms and ability to continue in the protocol.

Possible Unknown Risks: In addition, there might be risks that we cannot predict at this time. These unknown risks may be temporary, mild, and last only while you are actively participating in the research, or they may be serious, long-lasting, and may even cause death. You will be informed of any new findings that might affect your health or welfare, or might affect your willingness to continue in the research.

9. How will information about me be protected?

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people might include:

- Members of the research team and other staff or representatives of UCSD whose work is related to the research or to protecting your rights and safety.
- Representatives of the study sponsor or product manufacturer
- Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

Research records will be kept confidential to the extent allowed by law. Consent forms with identifying information will be kept in a separate locked filing cabinet from research materials or on a HIPAA-compliant secure server for electronic copies. 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.

As mentioned, part of this study will require that videos be taken of your face and/or parts of your body. These videos will be subject to the same confidentiality conditions described above. Even so, someone who knows you well may be able to identify you from the videos and know you are participating in this study. To minimize this risk, we only allow study personnel to view the videos and they only view them for study purposes.

This consent form and some details of your study participation will be noted in your UC San Diego Health record. If you do not currently have a UC San Diego Health record, one will be developed for you. People involved with your medical care and insurance at UC San Diego or other organizations may become aware of these details. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your UC San Diego Health record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

You will be asked to sign separate UC Health Insurance Portability and Accountability Act (HIPAA) Research Authorization form to use and disclose (share) your health information that identifies you for the purposes of this research study. Your permission as described in this informed consent and authorization form does not have an automatic expiration date.

The results of this study may be published once the study is completed. However, we will keep your name and other identifying information confidential. We expect this study will be completed in 3 years. This is only an estimate and the actual time to complete the study may be longer or shorter depending on a number of factors.

Information about you is protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases.

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. In addition, if researchers are made aware that a subject has certain communicable diseases including sexually transmitted diseases/infections (STDs/STIs), hepatitis, and HIV, this must be reported. If any

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

10. Will I need to pay to participate in the research?

There will be no cost to you for participating in this study. The only costs associated with this study are transportation costs to the research site and the time required to complete the study procedures. Neither you nor your health insurance will be charged for any of the study tests, procedures, or activities.

11. What if I agree to participate, but change my mind later?

You can stop participating at any time for any reason, and it will not be held against you. Your choice will not affect any treatment relationship you have with healthcare providers at UC San Diego Health or any services you receive from them. No matter what you decide, there will be no penalty to you. You will not lose medical care or any legal rights.

If you stop early, please contact us immediately. We will ask you to answer some questions regarding your symptoms and health to ensure your safety, as well as your reasons for discontinuing. We will also ask you to return any unused study drug or placebo for your safety. We may invite you to complete the post-treatment assessments (even if you do not complete the 6-week treatment phase) so we can determine any effects the study drug or placebo may have had. You can decide not to complete these assessments.

If you stop participating, we may not be able to remove the information we have already collected about you or specimens we have already collected from you. Your specimens and information about you are protected and are subject to the same confidentiality conditions described above.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

In addition, the study doctor may take you out of the study at any time, even if you would like to continue. This could happen due to the following:

- It is in your best medical interest to stop your participation (i.e., for your health and safety)
- You need treatment not allowed in this study
- You do not follow study instructions
- You do not adhere to the study requirements listed in Section 13
- The study is canceled

12. What will happen to information and/or biospecimens collected from me?

The data and specimens we collect with your identifiable information (for example, your name, medical record number, or date of birth) as a part of this study may be used to answer other research questions or may be shared with other investigators for other research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your data and specimens in other research.

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

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

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

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 behavioral information to the 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>.

While your privacy and confidentiality are very important to us and we will use safety measures to protect it, we cannot guarantee that your identity will never become known.

13. What are my responsibilities if I take part in this research?

If you take part in this research, we expect that you will:

- Give correct and accurate information about your medical history and current symptoms.
- Attend all study appointments.
- Inform the study doctor or staff about any health problems you have during the study.
- Inform the study doctor or staff about any new medicine or drugs you take during the study.
- Not take part in any other medical research studies.
- Not take any dis-allowed medicines or therapies.
- Not take any other drugs or remedies unless the study doctor has approved them beforehand. This includes prescription and over-the-counter drugs (including vitamins and herbs).
- Take the study drug as instructed.
- Not give your study drug to anyone else.
- Return unused study drug and packages at study completion or earlier (if discontinuing before study completion).
- Keep the study drug out of reach from children.

14. Will I be compensated for participating in the research?

If you agree to take part in this research, we will provide you up to \$300 for your time and effort. You will receive compensation upon completion of the following: Intake/screening surveys and clinical interview (\$25); intake/screening medical exam and tests (\$25); baseline session (\$50 for surveys and behavioral assessments; \$50 for MRI scan); post-treatment session (\$50 for surveys and behavioral assessments; \$50 for MRI scan); completing all study procedures (\$50). Therefore, a subject who completes all study visits and procedures would receive \$300 in compensation.

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

15. What else is important for me to know?

Because this is an investigational study, we do not provide individual research results to participants. However, if unanticipated findings are revealed through the medical tests, we will provide you with all results of the screening tests and will assist you in communicating these results to your primary physician or other health care provider, so long as you provide written consent for us to do so. This study will be registered with [clinicaltrials.gov](https://www.ClinicalTrials.gov) – the National Institutes of Health registry. Once the study is completed, results will be published on <https://www.ClinicalTrials.gov> within one year of study completion. These results will be searchable by entering the study title at the top of this consent form or by searching the Principal Investigator's name. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

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 Office of IRB Administration at 858-246-4777 or irb@ucsd.edu for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

17. Additional Choices to Consider

The study team would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

_____ YES, you may contact me

_____ NO, you may NOT contact me

Alternative Contact Person: We would like your consent to contact a person of your choosing if we have difficulty reaching you or in case of emergency. This person can be a family member, friend, or healthcare provider.

Alternate Contact Person Name

Alternate Contact Number

UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

Signature Block for Adults Able to Provide Consent

Participant	
<i>I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form.</i>	
Printed Name of Participant	
Signature of Participant	Date
Person Obtaining Consent	
<i>I document that:</i> • <i>I (or another member of the research team) have fully explained this research to the participant.</i> • <i>I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.</i>	
Printed Name of Person Obtaining Consent	
Signature of Person Obtaining Consent	Date
Witness (if applicable)	
<i>I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.</i>	
Printed Name of Witness	
Signature of Witness	Date

UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.
2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.
5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. Told of the types of medical treatment, if any, available if complications should arise.
7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.
9. Provided a copy of the signed and dated written consent form and a copy of this form.
10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

- UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777