

**UNIVERSITY OF CALIFORNIA LOS ANGELES  
CONSENT TO PARTICIPATE IN RESEARCH**

**DGC Innovative Treatment Network (ITN)  
(*STAND Clinical Care*)**

**INTRODUCTION**

The Screening and Treatment for Anxiety and Depression (STAND) Program's Clinical Care study is investigating evidence-based treatments for depressive and anxiety symptoms. You have been asked to participate in this study because you are eligible to receive treatment through the STAND Program for depressive or anxiety symptoms and meet our preliminary study criteria to provide regular assessments for the duration of the study. This study is funded by the UCLA Depression Grand Challenge (DGC), a campus-wide initiative aimed at cutting the burden of depression. Clinical services are provided through the Innovative Treatment Network Clinic. This research study is conducted by Michelle Craske, PhD, from the Department of Psychology, and Nelson Freimer, MD, from the Department of Psychiatry, at the University of California, Los Angeles (UCLA).

**Research studies are voluntary and include only people who choose to take part.**

Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

**WHY IS THIS STUDY BEING DONE?**

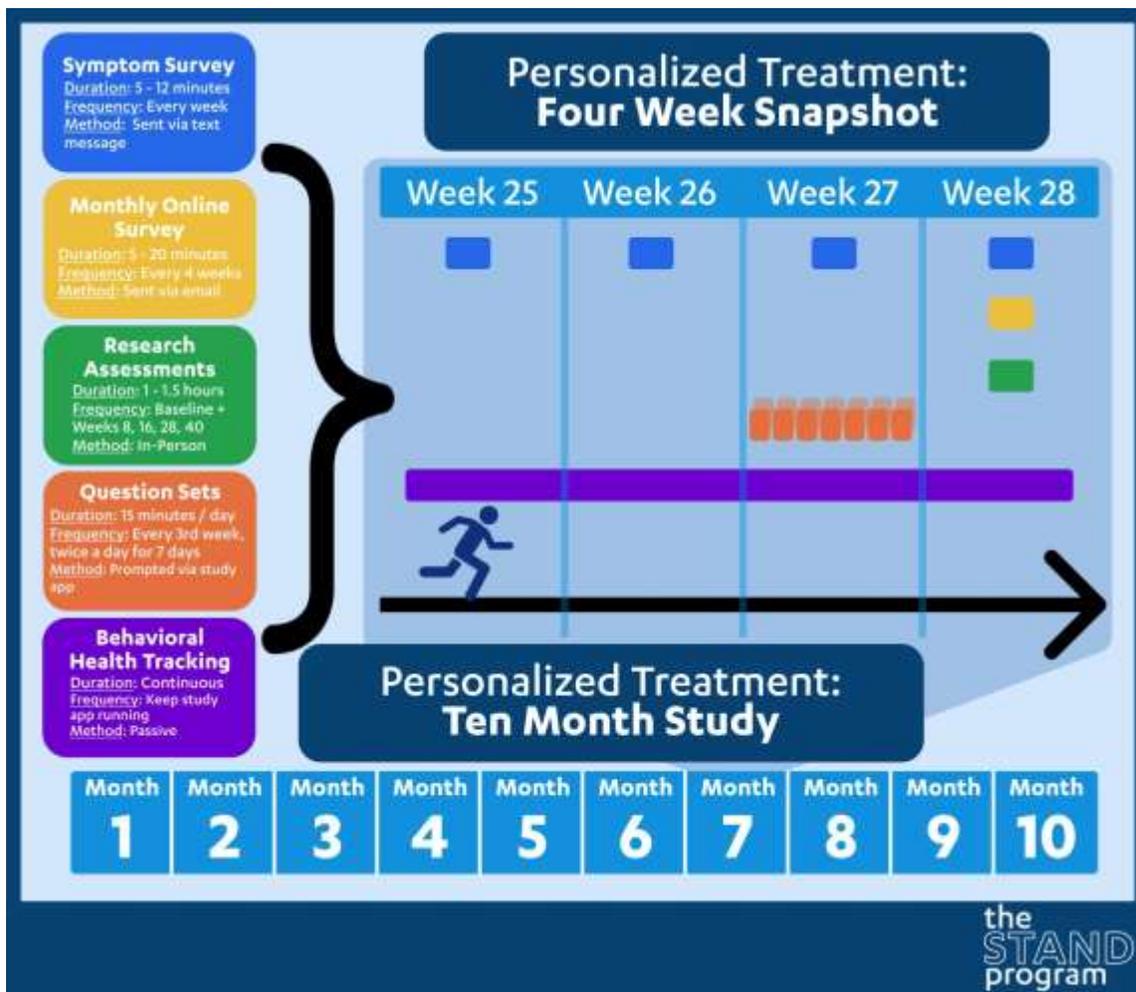
The STAND Program's Clinical Care is designed to provide gold-standard treatments for depression and anxiety in a scalable, personalized manner. Over time, newer treatments that evolve from ongoing investigations within the UCLA DGC will be evaluated. The STAND approach involves three tiers of treatment provided by both clinical psychologists and psychiatrists, and corresponding research assessments. The purpose of this study is to establish the feasibility of our tiered-treatment approach and integrated research clinic, identify baseline predictors of treatment response, and longitudinally measure mood-related symptoms using mobile health technologies. Findings from this study may enable us to develop and implement better ways of tracking symptom changes over time, of monitoring treatment response, and of providing personalized care.

If you are determined to be eligible for the study and you are determined to be suitable for Clinical Care (meaning your current symptoms fall above a certain cut-off), treatment will be personalized to your presenting needs and preferences, and might include: psychological therapy, psychological therapy with pharmacotherapy, or other appropriate treatment modalities. Any treatment option considered will be evidence-based. We will provide you with up to 6 months of psychotherapy. Note that most patients complete a course of treatment, on average, in 16 weeks.

Participation in the research clinic includes completing assessments for 10 months (see Figure). This includes completing brief symptom reports sent every week and longer surveys sent every month. By participating in this study, we will ask you to download an

app onto your phone and set a password lock on your phone in order to protect your privacy and the confidentiality of research information. Data will be collected using sensors already installed on your phone. For example, we will collect data about your sleep patterns based on measures such as light levels, wake/lock state of phone, activity measures. More details about this app and the types of data collected are provided below.

The Clinical Care is a part of the STAND Program, which also includes other studies, such as the STAND Online study. Participants, enrolled in the STAND Program’s Online Therapy study, will receive another form of treatment, suited for their needs – Online Therapy with Certified Support, with available support matched to symptom severity (Tier 1 or Tier 2) or will complete mood and symptom tracking through the Tracking Study (Tier 0). STAND Clinical Care is Tier 3 of the STAND Program.



If – after enrolling in the STAND Program’s Clinical Care - you are determined at any time to be eligible for online therapy with or without certified support (meaning your current symptoms fall below a certain cut-off), you might be offered access to an online cognitive behavioral therapy (CBT) program for anxiety and depression. Your access to this free, 6-week program will additionally include the option to meet one-on-one with a certified STAND coach (a trained and certified graduate student) once per week (either in person,

by phone, or by video chat using a secure mobile application) for support sessions. This is also part of the procedures for STAND Online Tier 1 and Tier 2. Data will be monitored from participants in all tiers and treatment modifications or psychotherapy booster sessions may be offered based on symptom scores. In these cases, you would not additionally be asked to complete the research assessments associated with participation in the STAND Online Therapy study, but rather you will remain with your Clinical Care research assessment schedule.

### **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

Up to 1000 patients will be offered care through the STAND. Only people who are eligible to receive one of the treatments offered by the clinic will be eligible to participate in the study.

### **WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?**

#### **Before you begin the study:**

For participants who meet criteria for STAND Online **Tier 1** or **Tier 2** based on the Mental Health Tracker or at entry of this study, an initial evaluation may be conducted with trained research staff to ensure eligibility (if required, no more than one hour).

Participants, who are known to meet criteria for the **STAND Program's Clinical Care**, or for whom eligibility for STAND Program studies is unclear, will complete evaluation assessments and meet with a clinical fellow for an evaluation to determine eligibility.

- For all STAND Program tier studies, at your first in-person visit, you will be asked to complete the following:
  - Read and sign this consent form, along with other standard UCLA treatment forms, and a HIPAA authorization form that allows us to review your medical record to obtain information such as your age, sex, diagnosis and current medications. This information will be recorded in a separate file that will be coded, de-identified and kept confidential. We also might register you within UCLA Health system following your completion of these documents, in order to provide you with treatment services.
  - Consenting to participate in this study includes an agreement to establish care with an outside provider, if clinically indicated, by the end of the treatment session offered. We will transfer your care to this outside provider when deemed clinically appropriate (either at the end of this study, or the end of your STAND Program's Clinical Care therapy). By signing a Release of Information, you will agree that we may communicate with your outside provider before, during, and after the treatment session offered.

The remaining visits and assessments vary according to your STAND program tier.

#### **During the study – Tiers 1 and 2:**

- **Baseline Assessment** (about 1 hour)
  - Complete a series of online surveys and computer tasks.
  - Come in for an in-person orientation to STAND and schedule of assessments
  - Download an app onto your smartphone in order to collect information on your daily activities and sleep patterns, using passive sensors already in your phone. More details about this app and the types of data collected are provided below.
  - Provide a blood sample (about 40ccs, or 3 tablespoons of blood).
- **Access and complete our Online Therapy Program.**

We are offering access to a program called “This Way Up”, a six-week internet-based Cognitive Behavioral Therapy (CBT) program for adults with anxiety and/or depression.

**C** = Cognitive = Thoughts or way of thinking

**B** = Behavioral = Doing or how we respond

**T** = Therapy = A way of helping someone

The online program involves 6 lessons, which feature an illustrated story of two individuals, who are recovering from anxiety and depression. We recommend approximately 1 hour per week reading the lessons (total approximately 6 hours) from your home, or wherever you prefer. After completing each lesson, you can download and print lesson summaries that contain some take-home tasks to help you practice the new skills and facilitate your recovery. We’ve found that people who get the most out of our programs spend about 3-4 hours a week completing the homework tasks and applying the new skills they’re learning on a daily basis. The number of exercises in the homework varies from week to week. Below is the outline of the course.

Lesson 1: Introduction: Learn about the symptoms of worry and sadness.

Lesson 2: Identifying thoughts and low activity

Lesson 3: Challenging worry and negative thoughts

Lesson 4: Confronting your fears

Lesson 5: Mastering fears and thoughts together

Lesson 6: How to avoid relapse

You will have 6 weeks to complete the lessons. A new lesson will become available each week. To help you complete the lessons within this timeframe, we will monitor your progression through the program and will contact you by e-mail or phone if we notice you haven’t accessed the lessons in more than 7 days.

- **Research assessments throughout the treatment.**

In addition to the baseline assessment, you will be asked to:

  - Complete a set of online surveys and computer tasks (about 45 minutes).
  - Complete a brief survey once every two weeks.
  - Complete online surveys every four weeks.
  - Leave our custom app installed and running on your phone.
    - To help us verify the data collected through the app, we will ask you to respond to a number of questions using your smartphone about behavior, such as places you visited that day, distance travelled, or your mood. This

will occur twice per day for one week every three weeks that you are enrolled in the study. The questions will take approximately 15 minutes per day.

- These data will be monitored throughout the study and treatment modifications may be offered based on symptom scores.

You will be asked to complete approximately 20 hours of assessments over the 40 weeks of the study.

### **During the study – STAND Program Clinical Care (Tier 3):**

- **In-person evaluation assessments:**

*(initial evaluation totals 4 hours – may be split into 2 or more sessions, treatment planning/1<sup>st</sup> therapy session totals 1 hour)*

- Complete a clinical interview and mood rating scales
- Complete review of psychiatric, medical, medication, substance use, family and social history
- Provide a blood sample (about 40ccs, or 3 tablespoons of blood)
- Download an app onto your smartphone in order to collect information on your daily activities and sleep patterns, using passive sensors already in your phone. More details about this app and the types of data collected are provided below.
- Complete a series of online surveys and computer tasks either before or during your in-person visit
- Receive a review of your assessment schedule
- Receive a consultation with a Psychology Fellow and if needed, a Psychiatry Fellow from our teaching and research clinic

If you are deemed eligible for the STAND Program's Clinical Care, based on the evaluation of the clinical team, a treatment plan will be offered to you and you will be allowed to proceed with a treatment offered by the clinic.

- **Engagement in Treatment.** You will be asked to attend regularly scheduled appointments with your assigned Psychology Fellow, Psychiatry Fellow, or both. Treatment in the clinic will be provided for up to 10 months. Note that most patients complete a course of 16 sessions of psychotherapy, on average, within 20 weeks.
- **Research assessments throughout the study (10-months).**
  - In-Person Research Assessments (2-3 hours each) at 16 and 40 weeks
    - You will be asked to complete assessments according to this schedule regardless of your personalized treatment plan, or changes in your treatment plan.
  - Complete a brief survey via text message on your smartphone once every week
  - Complete online surveys via email every four weeks and on some other weeks.
  - Leave our custom app installed and running on your phone.
    - To help us verify the data collected through the app, we will ask you to respond to a number of questions using your smartphone about behavior, such as places you visited that day, distance travelled, or your mood. This

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will occur twice per day for one week every three weeks that you are enrolled in the study. The questions will take approximately 15 minutes per day.

- These data will be monitored throughout the study and treatment modifications may be offered based on symptom scores. If you have finished your active treatment, there is a chance that based on these data we may invite you to return to the Research Clinic for an additional treatment session, which would be discussed with you and your outside provider.

During your participation, we kindly ask that you are willing and able to receive regular communication via e-mail or text from the study team over the course of your participation in this study, including phone, e-mail or text supportive and motivational messages, as well as appointment and assessment reminders.

You will be asked to complete about 35 hours of assessments over the 40 weeks of the study.

#### **More details about STAND Program Tier Studies:**

**Behavioral Health Tracking:** Completing assessments is an important aspect of participating in the research study. These data help us monitor your progress through treatment, make informed decisions about your treatment, and they provide us with valuable information necessary to evaluate and improve the treatment we offer. If you decide to proceed with assessment and treatment, we will kindly ask that you are willing and committed to completing these assessments and leave the app installed and running on your phone. If you are not willing to comply, you may withdraw your consent to participate in this study.

Upon enrollment, you will be asked to download an app onto your smartphone, which will pick up information from the sensors already in your smartphone. The app will run in the background unless forcefully closed. We will ask you to keep the app open at all times so data may be collected. This data will be sent to study staff as part of the research study daily. The minimum amount of information we are asking for your permission to passively gather is described in the table below.

What we're trying to understand	Examples of information gathered	Sensors/plugins used to gather information
<b>How you interact with your smartphone</b>	Screen interactions, how close you hold the phone to your face, how you use other apps	Applications, Device Usage, Gyroscope, Installations, Magnetometer, Proximity, Rotation, Screen
<b>Your movement</b>	Your speed, direction, balance, physical activity, mode of transportation (still, walking, running, biking, in vehicle)	Accelerometer, Activity Recognition, Gravity, Linear Accelerometer
<b>Your environment/surroundings</b>	The lighting around you, brief samples of sounds in your environment, temperature and humidity, air pressure, time zone	Ambient Noise, Barometer, Light, Temperature, Time zone
<b>Locations you visit</b>	GPS coordinates of places you've been along with information from <a href="#">Google's Fused Location API</a> (if available)	Location, Google Fused Location
<b>Your call and text habits</b>	The frequency and duration of calls and the number of text messages sent and received. Please note that information about your contacts is de-identified. No person or entity involved in the study can see the names or numbers of your friends and family or what you say to them over text or calls.	Communication
<b>Capabilities &amp; functioning of your Smartphone</b>	Battery level, processor usage, running applications, network connections	Battery, Network, Processor, Telephony, WiFi

In addition, the app may prompt you to answer brief daily questions on occasion. This may occur 1-2 times per day, for 7 days in a row, once every three weeks while you are enrolled in the study. Answering these prompts will help the researchers relate the information passively gathered through the app(s) to the context of your life. Here are some examples of the topics we may ask about:

- Your mood
- Your daily routines
  - Times you wake up, go to sleep, work, attend school or engage in other daily routines
  - The places you visit and reasons for going to certain locations
- Your relationship to people you've contacted. For instance, if you called your best friend, the app would ask who this number belongs to. You would indicate the person's relationship to you, and the app would then know in the future the nature of your relationship. However, no one, including the researchers, would ever see your best friend's number or name, and we cannot access content of the phone call. The research team would simply know that you called your best friend.
- How you've been feeling physically

**Study Conditions:** Upon entry into the study, you will be randomized into one of two study conditions. If you are randomized into the first study condition, all of your survey scores will be monitored throughout the study and you may receive follow-up from our clinical team in response to survey scores if it is indicated that additional treatment options are needed. If you are randomized into the second study condition, a subset of your survey scores will be monitored throughout the study and you may receive follow-up from our clinical team in response to these survey scores if it is indicated that additional treatment options are needed.

**Academic Records:** If you are a registered UCLA student, by consenting to participate in this study, the researchers will have permission to access your student record for the duration of your enrollment at UCLA. The researchers will use your student record, including academic and demographic information, to examine academic performance and enrollment status in all study participants. No further action is required on your part for us to collect these data.

**Blood Samples:** Blood will be drawn at your first visit. Approximately 40 ccs of blood (about 3 tablespoons) will be taken to collect genetic material by a trained phlebotomist or nurse. The blood will be taken from your arm by a needle, similar to a routine blood test in a clinical laboratory. Samples will be stored at UCLA.

**Stool Samples:** You can opt in to participate in this assessment. If you agree to participate, you will be asked to provide a stool sample near your initial evaluation visit, and then again one month after providing your first sample. You will be given a collection kit and instructions for how to provide the sample, and the time requirements to return the sample to us. You cannot have taken antibiotics or probiotics within one month of sample collection; you will be asked to delay your sample collection until 30 days have passed since taking antibiotics or probiotics, if you have recently taken either. You will be provided compensation for any samples you provide.

**Risk Responses:** If any of your responses are potentially concerning (e.g., you are suicidal and with a plan to harm yourself), your information is forwarded to our clinical team for confidential review. A clinician will contact you to determine if you have safety concerns that require immediate help. If you receive treatment by an external provider (i.e., not associated with STAND), you might be asked to provide us with your written permission to share this information with your current provider.

#### **HOW LONG WILL I BE IN THE STUDY?**

This study will require multiple visits to UCLA, with the total number dependent on your personalized treatment plan. Duration of research assessments, regardless of treatment tier, is expected to last approximately ten months.

#### **WHAT KIND OF RISKS OR DISCOMFORTS COULD I EXPECT?**

**Known risks and discomforts:** The possible risks and/or discomforts associated with the procedures described in this consent form include the following:

**Risks associated with mood and cognitive assessments:** The risks of answering questions about your mood, feelings or thinking include fatigue, anxiety or discomfort.

**Risks associated with venipuncture:** Blood samples will be obtained by venipuncture. This method involves inserting a needle into a vein in the arm and withdrawing a sample of blood as is done routinely to obtain blood for physical examinations. Venipuncture is accompanied by minor discomfort at the site of the needle entry and may result in slight bruising and a feeling of faintness. In this study, a trained technician or nurse will obtain at least 40 ccs (about 3 tablespoons) of your blood at your first study visit. Aseptic techniques, including sterile disposable blood collection apparatus, and adherence to standard medical precautions reduce potential risks.

**Risks Associated with loss of privacy in genomic research:** It is possible that other investigators conducting other research might request that data collected for this study be shared for further research. If you agree that your data may be shared with other investigators, your name or other personal identifying information would not be revealed. While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance. We consider this highly unlikely since we will not give these companies access to your genetic information or individual identifiers such as name, date of birth, etc. If they did obtain your genetic information, there would be theoretical possibility that this information could be used in ways that could cause you distress.

Any specimens (e.g., blood) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.

**Risks associated with smartphone app installation:** Your smartphone battery may drain more quickly than usual while the study apps are installed on your device. While the study apps have been designed to use a minimal amount of data, there is a small chance you could experience an increase in data plan usage during the study period.

**Risks associated with stool sample collection:** There are no anticipated physical risks or discomforts.

**Overall risks of loss of confidentiality:** One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled "How will you keep my information confidential?" for more information.

### **ARE THERE ANY BENEFITS IF I PARTICIPATE?**

**Possible benefits to me:** The possible benefits you may experience from being in this study might include improvement in depressive symptoms. However, a response to treatments offered cannot be guaranteed in any patient and neither the degree of response nor the duration of response to one of the treatments offered can be reliably predicted at this time.

**Possible benefits to others in society:** This study aims to further medical knowledge and may improve future treatment of depression and anxiety.

### **WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?**

Your participation in the study is entirely voluntary. If you decide not to take part in this study, or if you withdraw from this study before it is completed, the alternatives listed below are available. If you do not have or cannot afford a private psychologist or psychiatrist, we will recommend low cost treatment centers that may be able to help you.

- Psychotherapy
- Receiving pharmacotherapy to treat depression and anxiety, including:
  - antidepressants such as fluoxetine (Prozac®), sertraline (Zoloft®), citalopram (Celexa®), escitalopram (Lexapro®), paroxetine (Paxil®), venlafaxine (Effexor®), nefazodone (Serzone®), bupropion (Wellbutrin®)
  - older antidepressants such as tricyclics (i.e. Nopramin®, Pamelor®, Vivactil®) or monoamine oxidase inhibitors (i.e. Parnate®, Nardil®)
- Taking part in another study

### **CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?**

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions, if you choose to receive treatment elsewhere (e.g., become a participant in another treatment study) or if you miss scheduled visits. For example, if you become ill during the research, you may have to drop out, even if you would like to continue. The investigators, Drs. Michelle Craske and Nelson Freimer, will make the decision and let you know if it is not possible

for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate. The researchers or the study sponsor might also decide to stop the study at any time. You will be provided information about available resources if this occurs.

Note that if you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to that point will remain part of the study and may not be removed from the study database.

## **HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?**

This section of the consent form describes how your information will be protected and handled.

**Privacy:** We take your privacy very seriously. As part of our commitment to your privacy, you have been assigned a unique study ID that will follow you throughout the course of the study. Study data containing your name or other information that could directly identify you is kept in secure, password-protected, and locked locations and will only be accessed by individuals who have been trained to protect your privacy.

There are also steps you can take to protect your privacy. You will likely be answering questions and completing tasks in this study that relate to your mood and mental health. Because this information can be sensitive, the study team will ask you to password protect your personal phone on which the apps will be used.

We may release identifying information in some circumstances. Specifically, the researchers are legally required to report known or reasonable suspicion of abuse to a child, elder, or dependent adult and serious threats against a reasonable identifiable victim or victims. Information will be released only to responsible agencies and others we are mandated by law or the university to report to (e.g., potential victims of violence).

**Data storage & security:** Your information will be stored on multiple secure databases. These databases are secured by multi-tiered information technology security infrastructures. Access to these databases is on a “need to know” basis and only for the execution of research and supporting job functions. Study databases have strict security provisions, including but not limited to multiple firewalls, separate servers, and data encryption protocols. The researchers intend to keep the research data and records until analysis of the information is completed. In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time (see below).

**Data sharing & broad consent:** By signing this consent form, you will give us permission to share your information with people other than the researchers who are conducting this study.

The data that we will share will remain de-identified, meaning they will not contain identifying information. These data will be available to other investigators through one or more ‘controlled-access’ databases. This means that people who want to see that data

have to be approved by the Principal Investigator before they can have access. These other investigators may be at other research centers (academic or commercial) around the world. You will not be informed of the details of any specific research studies that might be conducted using your data, including the purposes of the research, and it is possible that you might not have chosen to consent to some of those specific research studies. Results from these studies may not be disclosed to you.

Data used, created, or collected in the research study may be shared with the following groups:

- The study team members.
- Other investigators working at other research centers (academic or commercial) who are working on this study and who agree to protect the data.
- Study monitors and auditors, for example from funding agencies, who make sure that the study is conducted properly.
- Readers and reviewers of scientific journals that may publish the results of this and other studies that involve your data. Note that publications and/or presentations that result from this study will not identify you by name.
- Data Archive repositories, for example The National Institutes of Health (NIH) and NIMH have developed a federation of data repositories called the NIMH Data Archive (NDA) to store the collection of de-identified data from participants in research studies related to mental health. The extensive information collected by these studies provides a rare and valuable scientific resource to the largest possible number of qualified investigators in an effort to achieve rapid scientific progress.

**Data sharing with you:** We are unable to share your individual results from the study with you or your provider. This includes, but is not limited to, behavioral health tracking data obtained from your phone sensors.

**Emergency contact:** We ask you to provide us with your emergency contact. We will contact your emergency contact only if we have consistently failed to reach you using a variety of channels (phone, email) and if we are concerned about your safety. We will disclose to your emergency contact only that you are participating in a UCLA research study and that we have been trying to reach you but failed to do so. We will disclose that we are concerned about your safety if that is the case. We will not disclose the nature of the study or any other information you have provided to us.

**Mandated reporting:** We may release identifying information in some circumstances. Specifically, the STAND Program team members are legally required to report known or reasonable suspicion of abuse to a child, elder, or dependent adult and serious threats against a reasonable identifiable victim or victims. Information will be released only to responsible agencies and others we are mandated by law or the university to report to (e.g., potential victims of violence). We also might need to release information about you if you are in danger and need emergency care (e.g., imminent threat of suicide or serious self-harm). Any and all relevant information obtained during the course of the study can be used in mandated reporting if indicated (e.g., emergency contact).

**E-mail and texting policy:** By agreeing to participate, you provide your consent to receive appointment reminders and other communication regarding the STAND Program sent to you via texting or e-mail. Texting and email are not secure communication methods as unencrypted messages could be intercepted. The STAND Program team commits to using the minimum necessary standard when communicating with you using these methods (i.e., providing only essential information).

### **ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?**

**Financial obligation:** The study will pay for research-related items and/or services that are provided only because you are participating in the study. These research-related items and/or services are explained in other areas of this consent form.

You or your health plan may be responsible to pay for all the types of items listed below:

- Items and services that would have been provided to you even if you were not in the study
- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items and/or services

**Payment for participation:** You will not be compensated for participating in this study. Participants who agree to provide two stool samples and to complete a survey about dietary habits will be compensated with \$40 in cash for the first sample and survey and \$60 in cash for the second sample and survey upon delivery of the sample. In total, these participants who provide both stool samples and dietary surveys will receive \$100.

### **WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?**

**The Research Team:** You may contact the Principal Investigators, Michelle Craske at (310) 825-8403 or Dr. Nelson Freimer at (310) 794-9571, or contact our study team at [STANDcenter@mednet.ucla.edu](mailto:STANDcenter@mednet.ucla.edu) or (310) 872-4010 with any questions or concerns about the research or your participation in this study.

**UCLA Office of the Human Research Protection Program (OHRPP):** If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: [mirb@research.ucla.edu](mailto:mirb@research.ucla.edu) or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.

### **WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?**

**Rights of research subjects:** Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at any time.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

## HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

**Agreement to participate:** If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form, which includes the Research Participant's Bill of Rights, to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

**Consent to Audio/Video Recording and Observation:** By agreeing to participate, you agree to allow the observation in person, via one-way mirror or audio or video recording of therapy or research sessions for the purposes of teaching and clinical supervision. This includes in-person interviews and research visits, therapy sessions in Tier 3 and one-on-one sessions offered in person, by phone, or via video chat in Tiers 1-2.

Please indicate below if you additionally agree to allow these videos to be used in the future for the purposes of training and education:

Yes

No

Please indicate below if you additionally agree to allow these videos to be used for research:

Yes

No

Consent to optional research assessment:

Please, indicate below if you additionally agree to provide two stool samples for microbiome analysis and to complete a survey about dietary habits twice (a month apart). Compensation will be provided.

Yes

No

**Data Sharing:** By agreeing to participate, you are also agreeing to allow your data and/or specimens to be kept for use in future research to learn about, prevent or treat depression or other health-related problems.

**Future Contact:** By agreeing to participate, you are also agreeing to be contacted by UCLA researchers in the future to take part in other research studies, or to follow-up on your participation in this study.

**SIGNATURE OF THE PARTICIPANT**

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

\_\_\_\_\_  
Name of Person Obtaining Consent

\_\_\_\_\_  
Contact Number

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date