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DEPARTMENT OF PSYCHIATRY
UCSD SCHOOL OF MEDICINE
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February 17, 2026

This following document is linked with the following ClinicalTrials.Gov information

**NCT Number** NCT05899348

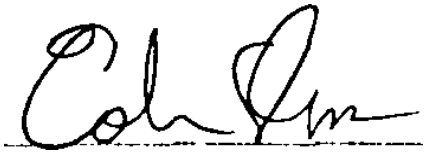
**Unique Protocol Id** 1R61MH129379-01A1

Title: iTEST: Introspective Accuracy as a Novel Target for Functioning in Psychotic Disorders

Note that for documents that are approved by the UC San Diego Human Protections Program the title of the study was listed as "A **Clinical Trial of iTEST: A Blended Intervention Targeting Introspective Accuracy"**

The last modified document date for the Study Protocol was 5/30/2023 and for the Informed Consent Document was 5/30/2023.

Best wishes,



Colin A Depp, Ph.D
Professor of Psychiatry, UCSD

# UNIVERSITY OF CALIFORNIA, SAN DIEGO
## CONSENT TO PARTICIPATE IN RESEARCH

**1. Study Title and Number**

#806997 Clinical Trial of iTEST: A Blended Intervention Targeting Introspective Accuracy

**2. Principal Investigator**

Colin Depp, PhD, Psychiatry Department with UCSD Health

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

Dr. Colin Depp: 858-822-4251
Primary Study Coordinator: Avery Quynh: 937-317-0790

- 24 Hours Emergency Numbers:
  - San Diego Crisis Line- 888-724-7240
  - National Suicide Prevention Lifeline- 988

**4. Study Sponsor**

The National Institute of Health, the study sponsor, is paying UC San Diego to conduct this research study.

**5. Study Overview**

This research study is being conducted to find out whether a new intervention that combines individual coaching with responding to game-like tests on a mobile device could improve the ability to accurately assess one's own abilities. This intervention is specifically designed for people who have been diagnosed with schizophrenia or schizoaffective disorder.

We are inviting you to participate in a research study because you have been identified as a person who may have a diagnosis of schizophrenia or schizoaffective disorder, and you are between the ages of 18 and 65.

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 investigator 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 see if an ability called introspective accuracy, which is the ability to accurately gauge one's performance, can be improved through coaching combined with electronic tasks delivered on a mobile device. The coaching component of the study is focused on identifying goals that are important to you and teaching you techniques to compensate for everyday problems like low motivation or forgetting.

If you choose to participate you will first undergo several procedures to determine if you are eligible for the study. That screening will take about 30 to 40 minutes and concerns your diagnosis, symptoms, and basic information about you.

If eligible for the study, you will come to a baseline assessment that will include further measures of cognitive performance, functional abilities and symptoms. This assessment should take about 3 hours. After that, you will meet with a coach for a total of 6 weeks. Each of these coaching visits will take about 60 minutes, weekly for 6 weeks. These visits will be in-person or remote. The focus of these coaching appointments will be in asking you about your goals and identifying solutions to everyday challenges you may have in achieving those goals. At the same time, you will be asked to complete a 15-20 minute exercise on a mobile device (either your mobile phone or one loaned to you by our group). You will be prompted to complete this exercise 6 days per week. The exercise consists of cognitive tasks like trying to remember words and then questions about your impression of how well you did on the task. The aim of the program is to increase your ability to accurately guess how well you did.

After 8 weeks, you will be scheduled for the first of three follow up assessments – at 8 weeks from your baseline assessment, 12 weeks, and then 16 weeks. Each of those visits should take about 90 minutes. Between week 8 and week 16, you will be asked to continue to complete the tasks on the mobile device and you will no longer meet with the coach on a weekly basis. Between week 8 and 16, the coach will contact you every other week by telephone to check in on how you are doing in general and then also any problems you may be having with completing the tasks on the device. Those telephone calls with the coach will take about 15 minutes each.

The most common risks or discomforts of this study are:

- Some of the questions we will ask you as part of this study may make you feel uncomfortable, or you may get a bit tired or anxious.

The most serious risks include :

- Despite every possible safeguard, there exists the slight risk that confidential information regarding your history, substance use or psychiatric diagnosis may become known outside of the research setting.

A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document.

There may be benefits to you from participating in this research. These include learning to improve your ability to accurately gauge your abilities, however, since this is a new intervention we cannot be certain that will occur. Possible benefits to others include the development of interventions to improve functioning in people with schizophrenia or schizoaffective disorder.

The alternative to being in this study is not to participate.

***More detailed information about this research study is provided below.***

**6. 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

**7. How many people will take part?**

There are two sites leading this research. We plan to study 30 people in San Diego and there will be another 30 people in Dallas, Texas.

**8. What happens if I take part in the research?**

Here is what will happen to you if you agree to be in this study: As you read this form, ask questions if something is not clear.

This study requires an initial visit that combines screening, consent process if eligible, and a baseline assessment. After that, there will be 3 additional lab visits. The first visit that combines screening and baseline tasks will take approximately 3.5 hours. This visit includes a screening process (1 hour) and then a series of tasks (2.5-3 hours) if you pass the screening. The last three lab visits will take 90 minutes.

As part of the intervention, you will also be asked to meet with a coach once per week for 6 sessions for one hour each and you will be asked to complete daily exercises (with one day off per week) for 16 weeks. These exercises will be delivered on a mobile device. You will be asked to use your own smartphone or will be given a smartphone device.

If you agree to participate, you will complete all of the following tasks:

**Screening (Approximately 30-40 minutes) :**

a. You will be interviewed about your current and past mental health symptoms. You will also be asked to complete a brief screening measure of symptoms and your reading level. We may ask for your permission to contact your doctor to confirm your diagnosis and medications. You will sign a separate authorization form allowing us to contact your doctor. If eligible, we will continue Visit 1 procedures during this visit.
b. We will ask for your permission to contact a close friend, family member or clinician of yours whom you see at least once per month to ask them some questions about your day-to-day activities and functioning. We will ask them these questions within a week after the screening appointment and again at 16 weeks after that appointment. That informant will be told you are in a research study at UCSD but other confidential information about you (e.g., your diagnosis) will not be shared. In order to participate in this research, providing the name and contact information for this person is required.

Informant name: _____

Informant relationship to me (e.g., friend, family member, clinician)
_____

Informant contact information: _____

**Visit 1 (Approximately 3 hours):**

a. You will complete interview-style questions regarding your mental-health history and any current symptoms, as well as your physical health and medical history.
b. You will complete computerized tasks about your ability to navigate everyday functional challenges.
c. You will complete several computerized tasks that involve looking at pictures or reading short phrases and answering questions about them. Your job will be different for each task, and specific instructions will precede each task.
d. You will be asked to complete a series of self-report questionnaires that assess your mental health history, different life experiences and capture current symptoms and feelings about yourself, others and your surroundings

**ITEST Coaching and Mobile Device Exercises:**

a. After the in-person lab assessment, you will be asked to meet with a coach for one hour. These appointments will be individual appointments between you and the coach and they will continue each week, for a total of 6weekly sessions. These sessions will focus on assessing your goals and identifying ways of reducing barriers to those goals. You will also be taught strategies for compensating for everyday cognitive problems like forgetting.
b. It is important to note that the visits with the coach and the lab visits are with different people. They can be scheduled on the same day or on different days, depending upon your preferences and can be remote or in our lab depending upon your preference.
c. You will be provided a mobile device or you can use your own mobile phone and will,

after meeting with the coach, complete exercises once per day 6 days per week. The mobile device will prompt you to complete these tasks and you can decide when during the day you would like to complete them. The exercises will take about 15-20 minutes and will involve brief tasks involving memorizing words or guessing emotions of faces. The goal of these exercises is to improve your ability to accurately guess how well you did in remembering or guessing faces, and not to improve your ability on the tasks. You will receive feedback about how closely your guess about how well you did matches how well you actually did on the task, and the goal of this set of tasks is to increase the accuracy of your guesses about your performance based on the feedback you receive. During the first session and later ones with the coach you will have the opportunity to gain practice and ask questions about what you are being asked to do. You will be asked to continue these exercises for 16 weeks.

d. You do not need to install an app on your phone – you will receive reminders to complete the training through web-based links that are sent by text message to your phone.

**e.** After 6 sessions, your coach will contact you every other week by telephone and ask you about your well being and your experiences with the mobile exercises.

**Recording:** Participation involves audio recording portions of the assessment visit, such as the interview and the intervention sessions. The purpose of audio recording is for supervision of study staff and quality assurance. These audio recordings will only be reviewed by Dr. Depp and his colleagues, and will be used to ensure that the facilitators are following the intervention manual and the research assistants are accurately administering the assessments.

Audio recording during the assessment visits is not required for participation in this study; however, it is important that the study staff audio record the skills training and remote coaching sessions. You may refuse to be audio recorded or that the audio recording be stopped at any time during the assessment visits. You may erase the audio recording up to a few minutes before the recording is stopped. These audio recordings will be kept in a secure server with only an identification number and not your name, and all audio recordings will be destroyed according to an approved protocol. If you wish to opt-out of audio recording at any time, please inform the study staff.

_____

**Global Positioning Satellite (GPS) Data:** The mobile phone provided to you includes a software program called GPS logger that stores GPS data, which includes your location and movement. If you choose to your own mobile phone, we will ask you to install GPS logger. We are interested in understanding whether information such as the distance you travel on a daily basis is affected by your mood and other symptoms. The program collects this data automatically. However, if you change your mind at any point, you may contact Colin Depp (contact information below) and your GPS data will be deleted and will no longer be collected or used in our analyses. You may delete the program from your phone at any point.

**Mobile Assessment Weeks**

Mobile assessment weeks include completing the word memory task, as well as the

emotion task. Unlike during the IA training, however, you will not be receiving feedback for your answers. You will be completing these mobile assessments on Week 9, 13, and 17.

**Visit 2, 3 and 4:**

a. After 8, 12, and 16 weeks from the first visit, you will complete similar measures as you had done in Visit 1. Your job will be different for each task, and specific instructions will precede each task.
b. You will be surveyed about your experiences with and impressions of the intervention you participated in.
c. You will also be interviewed about any symptoms that you are currently experiencing.

**Transportation**: During your recruitment phone call you either consented or did not consent to using our Lyft concierge service to come to this visit. If you would like to continue using this service please note that:

If you are unable to meet in our research office space due to physical disability or financial reasons, we will use the UCSD Lyft Concierge service to pick you up, provided that you live within a 25-mile radius. You will **NOT** be required to pay for the Lyft rides as the research study will cover the costs of these rides.

You will be providing your name, pick-up location, drop-off location, and phone number to the research staff, which will then be used by the Lyft driver to take you to your location. This information will only be given to the Lyft drivers after consent over the phone (during the phone screening procedures) and by providing written consent by initialing below. Your phone number and the driver's phone number will be masked during the active ride through a third party system. Neither you nor the driver will have access to each other's real phone numbers. Your personal health information (PHI) will not be shared with Lyft. You are being asked to fill out this section only if you have used/will continue to use the Lyft services.

If you choose to use your own mode of transportation, you are subject to any associated charges or fees with your own transportation, however, you will not be required to pay for parking at our research office for the duration of your visit.

**9. What are the risks and possible discomforts?**

Participation in this study may involve risks or discomforts. These include the following:

1. It is possible that increased awareness of your strengths and weaknesses on cognitive tasks may accompany increased depression or anxiety
2. Becoming tired, anxious or uncomfortable during visits.
3. Personal information regarding mental health may be disclosed to individuals outside of the research team if suicidal ideation is indicated, possibly risking some loss of some privacy. Study staff may be required to report to proper authorities if suicidal or homicidal intent is disclosed. You may be asked to provide your current location, to better serve your safety, if the need arises.

***Risks of increased awareness potentially leading to increased depression or anxiety:*** It is theoretically possible that becoming aware of cognitive strengths and weaknesses as a result of

participating in this study may lead to increased depression and anxiety. We will monitor depression and anxiety throughout the trial and we will notify you at the time of assessment if symptoms increase by 25% from your baseline (Visit 1 assessment). We will provide referrals to mental health providers and resources, and you may decide if you wish to continue participating in the study.

***Risks of Loss of Confidential Information:*** Despite careful safeguards, information regarding your history, drug and/or alcohol use, or psychiatric diagnosis may become known outside of the research setting.

Dr. Depp and his associates are not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. If Dr. Depp or his associates determine reporting to authorities, or other health agencies is necessary because of imminent serious danger to yourself or others, then they would only disclose information in your records, such as your current location and potential risks, to the extent necessary to prevent such imminent danger.

***Risks of Interviews/Questionnaires/Quality of Life Assessments that Discuss Sensitive Issues:*** Some of these questions may seem very personal or embarrassing. You may skip any question that you do not want to answer. If the questions make you very upset, we will help you to find a counselor, refer you to an appropriate clinic for follow up, or you can contact:

Dr. Colin Depp: 858-822-4251
Primary Study Coordinator: 937-317-0790

- 24 Hours Emergency Numbers:
  - San Diego Crisis Line: 888-724-7240
  - National Suicide Prevention Lifeline: 988

***Possible Unknown Risks:*** In addition, there might be risks that we cannot predict at this time. 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 that might impact your decision to participate.

**10. 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 or documents 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, National Institute of Mental Health
- Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected

Information from this study is available only to study investigators, authorized personnel and collaborators, and Institutional Review Board of UCSD. The Institutional Review Board of UCSD is an entity that oversees the protections and rights of research participants. Because this study

takes place at two sites, including the UCSD and the University of Texas at Dallas, data collected will be shared across sites. However, data shared across sites will not contain personally identifying information about you . The data collected (including any interviews, questionnaires, or information related to medication-taking patterns) in other IRB-approved studies by members of this investigative team that you may be enrolled in or have previously participated in may be combined with data collected in this study (provided that you had consented to be contacted for future research previously). The reason to use data already collected about you from prior research studies by our team is to reduce the time for data collection about you in this study. To guard your privacy, only a special code number will appear on questionnaires, and all records, forms, and information will be kept in locked file rooms and cabinets. Each sample is labeled with a unique non-identifiable study ID. All personal identification data will only be accessible to authorized research personnel. The record linking your identifying information (name, address, etc.) and the code will be kept separate from the rest of the study information. Such data will be kept under lock and key in a secure lab space. If held digitally this information will be encrypted, password protected and only accessed on a secure virtual private network through the university.

We will assist you in password protecting your personal smartphone, and the study smartphones are password protected. No personally identifying information will be stored on the study phones. Should you lose the device, the password protection of the phone ensures no one else has access to the data. De-identified data from the mobile devices will be stored on a web-based internet database. This data will be kept separate from the data collected during the office visits. No personal information is linked to any of the data that is downloaded from the web-based internet database.

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 by May 2028. This is only an estimate and the actual time to complete the study may be longer or shorter depending on several factors.

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 (see the separate authorization form for more information). Your permission as described in this informed consent and authorization form does not have an automatic expiration date.

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 abuse 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.

**Information Available to Others:**
In addition, information from this study will be de-identified and shared with other researchers and collaborators. All data stored in those databases will be coded, and investigators will not be able to link the data back to you. We will collect and keep a link between the code and your identity in a different location. You may decide now or later that you do not want to share your information with any of our collaborators. However, if data has been stripped of identifying information, it may be impossible for researchers to remove one's data from the database. If so, contact the researchers who conducted this study, and they will tell the respective collaborators, which can stop sharing the research information to the best of their ability. This will not affect your participation in the current study.

To conduct this study, we use a third-party automated text-messaging company to administer our surveys, NeuroUX (https://www.getneuroux.com/). Therefore, if you opt to use your own device, your telephone number will be used to establish your text message surveys with NeuroUX.

**11. Will I need to pay to participate in the research?**

There will be no cost to you for participating in this study.

The smart-phone device will be supplied at no cost while you take part in this study if requested. You may also opt to use your own cell phone for the study. The cost of getting the smart phone ready and giving it to you is also provided at no cost. If you lose or damage a borrowed device, you will not be held responsible for the cost of the device or any other costs.

If you choose to use your own device in the study to receive text message surveys or answer phone calls associated with the study, you are subject to any standard text message rates, roaming fees or any fees associated with your own cell-phone provider plan.

**12. 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 return the smart-phone device.

If you stop participating, we will ask you for permission to use your existing data with us.

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 investigators may stop the study or take you out of the study at any time, even if you would like to continue. This could happen because the study is cancelled, failure to comply with study procedures or the investigator's clinical judgment deems discontinuance is in your best interest.

If you decide later that you do not want the information collected from you to be used for future research, you may tell this to Dr. Colin Depp or the study staff, who will use their best efforts to stop any additional data collection. However, in some cases, such as if your information has already been tested, the data from these tests are no longer linked to your identity and cannot be removed from the research database.

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

The data 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 in other research. In addition, data that have been de-identified will be uploaded to National Data Archive of the National Institute of Mental Health for other researchers to access and use.

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.

**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 $220.00 for in-lab assessments. You will be provided $20 for completing the screening portion of Visit 1 and compensated $50 for completing the rest of that visit. For Visit 2, 3, and 4 you will be compensated $50 for each.

During the weeks when you complete assessments on your mobile device, you will also be paid $5 for each of the 6 assessments you complete. The number of days completed is factored into the compensation and so you can receive up to $30 to complete all 6 assessments on the device. Thus, over the 4 assessment weeks, you can receive up to $120 for completing all assessments.

Combining in-lab and mobile assessments, the maximum possible amount you will receive is $340.

You will not be compensated for meeting with the coach or for completing the exercises on the mobile device. If you choose to stop attending meetings with the coach or completing the

mobile exercises, you may continue to participate in the other aspects of the study and continue to receive compensation as above.

**15. What else is important for me to know?**

You will not be provided any clinically relevant information that may pertain to your health. You will be provided a summary of the research findings for the study overall (not individual results) upon request. If the study results in a published paper, the paper will be posted to the laboratory website for reference by the public.

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.

If you report to study personnel that you are actively experiencing severe suicidal ideation, there is a safety plan protocol in place to address these experiences. The protocol encompasses varying degrees of assistance depending on the level of immediate danger to oneself. Assistance starts with providing community resources like the crisis lines. For more symptomatic participants we will offer a one-on-one phone call or meeting with our in-house clinicians to go through safety planning and personalized solutions. For participants who are in immediate danger, we will mediate care with a clinician and a crisis-line member (if needed), and an appropriate action plan and solution will be facilitated.

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.

**16. Additional Choices to Consider**

A) In section 8, we discuss consenting to collecting location data (GPS), and providing access to our Lyft concierge service. These extra procedures are optional, meaning that you can participate in the study even if you refuse the procedures. Please indicate your choice by initialing the appropriate line below:

_____I **AGREE** to participate in GPS data collection as an optional procedure.

_____I **DO NOT AGREE** to participate in GPS data collection as an optional procedure.

_____I **AGREE** to participate in the Lyft Concierge Service as an optional procedure.

_____I **DO NOT AGREE** to participate in the Lyft Concierge Service as an optional procedure.

We would like to offer the opportunity to receive general results of the research study. You may also change your mind about this choice. Please initial your choice below:

_____**YES**, send me a summary of the research results.

_____**NO**, do **NOT** send a summary of the research results.

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

**UNIVERSITY OF CALIFORNIA, SAN DIEGO**

**CONSENT TO PARTICIPATE IN RESEARCH**

**Signature Block for Adults Able to Provide Consent**

**Participant**

*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.*

Printed Name of Participant

Signature of Participant Date

**Person Obtaining Consent**

*I document that:*

- *I (or another member of the research team) have fully explained this research to the participant.*
- *I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

**Witness (if applicable)**

*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.*

Printed Name of Witness

Signature of Witness Date

**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.

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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