Consent Form for Targeting Anhedonia in Cocaine Use Disorder

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Sponsor:
National Institute on Drug Abuse
Grant K08DA040006
PO: Will Aklin

NCT02773212
IND/IDE: 131221
Version: 8
Date: 4/18/2024

University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research
Targeting Anhedonia in Cocaine Use Disorder Treatment Study

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About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	This research is being done to test possible treatments that may help people quit using cocaine, and to better understand how emotions relate to using drugs and quitting drugs. There is no one treatment for cocaine addiction that works for everyone. Thus, we are testing two possible treatments. If you take part in this study, you will be randomly assigned (e.g. like the flip of a coin) to possible treatments:

	• Medication: One treatment is a medicine called "extended-release dextroamphetamine". This medicine is used to treat ADHD. Research suggests this medicine may also help people quit using cocaine, but this use is still experimental, meaning it is NOT approved by the FDA. To help us find out if this medication really works, the study is "blinded." This means that you and the researchers will not know if you are getting the medication or not. While you're in the study, you'll take pills twice a day. They might be the medicine, or they might be a placebo, which are pills that look like medicine but don't have any medicine in them. The placebo is used to keep people's expectations about medication from influencing the study results. Two in three (66%) of participants will get the medication, while one in three (33%) will get the placebo. Either way, you'll help us find out if this medicine helps people quit cocaine. • Rewards Program: The other treatment is a program that rewards you for breaking your addiction habits. In this treatment, you'll get gift cards when you meet goals, like not using cocaine for a few days, a week, or longer. Research suggests this treatment can help people quit using cocaine. Two in three (66%) of participants will get the rewards program, while one in three (33%) will simply do regular checkup visits. Some people will get the medicine, some people will get the rewards, and some people will get both. Everyone will get a treatment. No matter what treatment you get, you'll also get two talk therapy sessions to help you quit.
WHAT WILL HAPPEN TO ME DURING THE STUDY?	This study takes 7 weeks total to complete. In this week, which we call the "baseline week", you will complete this consent visit and a two-hour long testing session. At the testing session you'll do some tests of your emotional responses to happy and sad things before you start treatment. It will take about two hours. You'll wear sticky patches on your face, chest, and hands to track your emotions while you do things like looking at happy and sad pictures. These tests help us understand how emotions relate to drug use and quitting drugs. For the next 6 weeks you will be in treatment. During treatment you'll come in every Monday, Wednesday, and Friday. These "checkup" visits will be about 30-45 minutes. At each checkup, you'll talk about your drug use and any treatment side effects. You'll give a urine sample that we will test for drugs. You'll have

	your vitals checked, and you'll get your medication. During the 6 weeks of treatment you'll follow this schedule: Next week, which we call the "medication start week", you'll start to get either the medication or placebo. Either way you will get pills that you take twice a day by mouth. Over this week we will gradually increase the dose of the medication, to make sure you are not having serious side effects or bad reactions to the medicine. For a month after that, which we call the "treatment month", you will continue to take the medication and do checkups three times a week. During this month, if you have been assigned to the rewards program you will also get rewards as you meet treatment goals. Once a week you will redo the two hours of tests to see if your emotions are changing during treatment. You will also get two talk therapy sessions to help you plan and maintain a quit attempt. One therapy session will be in the first week and the second will be in the 3rd week of the treatment month. In the last week of the study, which we call the "medication stop week", we will gradually decrease the medication dose back to zero. During this week we will work with you to plan your next steps, such as helping you find treatment in the community that you can go to after the study ends. For more information, please see the "What procedures are involved?" section below.
HOW MUCH TIME WILL I SPEND ON THE STUDY?	Over 7 weeks, you will come into the clinic approximately 20 times. We expect the entire study to take about 26 hours of your time.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	Based previous studies of treatments for cocaine addiction, we believe they may help people who want to quit or cut down on their cocaine use. However, because people respond differently to treatments, no one can know for sure if a given treatment will help you. Thus, we cannot promise any benefits to you from taking part in this research. We also hope that the information we get from this study may help others with cocaine addiction in the future, because this study may help find which types of treatment work best for which people.
WHAT ARE THE MAIN RISKS OF THE STUDY?	The main risks of this study are possible side effects of the experimental medication. We will watch for side effects during your treatment and do what we can to relieve them. But you should know that some side effects can be serious, even life-threatening, or may

	not go away. The possible side effects will be explained in more detail later in this form. There may also be other side effects we don't know about yet. For this medication there are some **serious but rare** side effects that you need to know about. These do not happen often, but they are serious when they do. These are: • Heart related problems, including stroke, heart attack, increased blood pressure and heart rate. • Mental problems, such as hearing voices, believing things that are not true, or mania, suspicion or aggression. • Circulation problems in fingers and toes, such that fingers or toes feel numb, cool, painful, or change color to pale, blue or red. This medication also has a number of **more common but less serious side effects.** The ones we most commonly see in our study are decreased appetite, restlessness, anxiety and trouble sleeping. You should not suddenly quit this medication, as this can produce withdrawal symptoms (e.g. depression, irritability, craving). You should not take this medication while pregnant, lactating, or planning a pregnancy. For details and a list of risks you should know about, please see the "What are the potential risks and discomforts?" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	If you decide not to take part in this study, there is other care available to you. Although there is no FDA-approved medication for cocaine addiction, there are other treatments (such as counseling) that are available. Dr. Wardle will discuss these other treatments with you if you choose not to take part in this study. You do not have to be in this study to be treated for cocaine addiction.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Dr. Wardle at 312-413-5564 or email at mwardle@uic.edu. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

Who may participate in the study?

You have been asked to participate in this research because you told us you were interested in getting treatment to help you quit or cut down on your cocaine use.

Approximately 55 subjects may be involved in this research at UIC. Approximately 25 participants have already taken part in this research at our prior location at the University of Texas Health Science Center in Houston, Texas.

What procedures are involved?

This research will take place in the ART Lab in the Behavioral Sciences Building at 1007 W. Harrison St., 3rd Floor, Room 3011A (this is our reception/waiting room).

The total amount of time you will be in the study is about 7 weeks. Over those 7 weeks you will need to come into the clinic around 20 times. Visits can vary from 30min up to 2.5hrs depending on what you are scheduled to do during that visit. All together, we expect the study will take approximately 26 hours of your time.

Special considerations for COVID-19 - Don't come to your appointment if you have cold or flu symptoms. Call or text us and we will reschedule you. You will need to wear a mask to the appointment (we can give you one if you don't have one). We will check your temperature at each appointment and reschedule you if you have a fever. Our staff will wear protective equipment (such as masks and gloves) when working with you. We will use a secure video chat software called WebEx to talk with you from another room when we can, such as for your therapy sessions. This reduces your risk of getting COVID by reducing the amount of time you are close to other people in the clinic. However, for some tests we still need to be within 6ft. of you (such as taking your blood pressure).

If you agree here is what you will be asked to do as part of the study:

- Intake Evaluation: You have already completed the intake evaluation. If you agree to take part in this study, the information collected during your intake becomes part of your records for the current study.
- Consent and Initial Drug Use Calendar: Today, you will do the consent process, and if you decide to take part in the study we will also do a drug use calendar with you, to understand your typical patterns of use before starting treatment. We expect the visit today to take approximately 1hr, and you will be paid $5.00 for this visit, whether you decide to take part in the study or not.
- Baseline Testing Session: You will then do the Baseline Testing Session. This is a two-hour session that can be done any day of the week. You will be asked about your recent drug use and provide a urine sample to test for drugs. Then, we will attach small sticky sensors to your cheek and forehead to monitor electrical activity in your skin during the

tests. You will then complete some tests on the computer (similar to computer games). These will test your emotions. As part of these tests, you will view a number of pictures, including both pleasant pictures (e.g. puppy dogs, ice cream cones) and unpleasant pictures (e.g. war scenes, attacks). You will be paid $20 for doing these tests, and you can also win small amounts of money during some tests (ranging from $5.00 – $12).

- Medication Start Week: After the Baseline Testing Session, you will do the "Medication Start Week". During this week you will:
  - **Start Checkups**: During this week you will start to come in the ART Lab three times a week (Monday/Wednesday/Friday) for checkups. Each checkup should take between 30-45 min. At each checkup you will be asked about your recent drug use, give a urine sample to test for drugs, talk about your medication, side effects, and any health changes, have your vitals checked, and get your assigned medication. If you are female, we will also check your urine samples for pregnancy every 2 weeks throughout the study. You will keep doing checkup visits through the rest of the study. You will be paid $5.00 for each checkup.
  - **Gradually Start Medication**: During this week we will gradually start the medication you will get during the study. If you are getting the medication, you will start receiving extended-release dextroamphetamine. This is a stimulant medication that is FDA-approved to treat Attention-Deficit/Hyperactivity Disorder (ADHD or ADD). Research suggests it may also help people quit using cocaine, although it is not FDA-approved for this. The dextroamphetamine dose will be increased gradually up to 60mg/day. If you are not in the medication groups you will get placebo pills. Neither you nor your doctor will know if you are receiving dextroamphetamine or placebo, as both will look the same. All the study pills will contain a marker that will appear in your urine. The marker will help us know whether you take the pills. We will also give you special pill bottles that count the number of times the bottle is opened. Always bring your pill bottle and any pills you didn't take to your checkups.
- Treatment Month: After the "Medication Start Week", you will begin the 4-week "Treatment Month". During this month you will:
  - **Continue Checkups and Medication**: Throughout the Treatment Month you will continue to come in three times a week (Monday/Wednesday/Friday) for checkups, and you will continue to get your assigned medication. Each checkup will be the same activities, and is expected to take 30-45 min. You will continue to get paid $5.00 for each checkup.
  - **Get Rewards Program (if assigned):** If you were assigned to the rewards program, you will also get rewards (gift cards) during the treatment month as you achieve treatment goals. Each time your urine sample is negative for cocaine you will get a reward. The details of the reward program will be explained to you if you are assigned to it. The rewards will be given during your regular checkups, and don't require any additional time or visits.
  - **Get Individual Therapy**: In the 1st and 3rd week of the Treatment Month you will get a 1 hour-long session of individual therapy designed to help plan and maintain a quit attempt (total of 2 sessions). These sessions may be scheduled on the same day as a regular checkup, depending on your availability. We will record these

sessions, both for monitoring to ensure the therapy is done right, and to find out what parts of therapy sessions are most useful.

- **Repeat Testing Sessions**: Once a week during the Treatment Month you will re-do the 2-hour Testing Session (totaling 4 Testing Sessions during the treatment month). These will be just like the Baseline Testing Session described above. These may be scheduled on the same day as a regular checkup, depending on your availability. You will be paid $20 for doing the tests, and can win additional small amounts of money (ranging from $5 – $12) on some tests at each session.

- Medication Stop Week: After the Treatment Month, you will do the "Medication Stop Week". During this week you will:
  - **Continue Checkups**: You will still come in three times a week (Monday/Wednesday/Friday) for checkups. Each checkups will be the same activities as before, and should take 30-45 min. You will be paid $5.00 for each checkup.
  - **Gradually Stop Medication**: During this week we will gradually reduce the amount of medication you are receiving until you are receiving none.
  - **Get Referrals:** In the last week, you will also meet again briefly with your therapist (15-30 min.) to wrap up and make a plan for where you will go for any further treatment you might need.

Below is a table that summarizes what you will be asked to do as part of the study:

What?	During which parts of the study?							Payment
	Baseline Week	Medication Start Week	Treatment Month				Medication Stop Week	
			Week 1	Week 2	Week 3	Week 4		
Consent and initial drug use calendar - 1hr	Any day							$5
Testing Session - 2hrs each	Any day		Any day	Any Day	Any Day	Any Day		$20 plus winnings per session for 5 sessions (total $100+)
Checkups - 30-45min each - give urine sample and answer questions about drug use - get vitals checked - answer questions about medication and health - get medication		M/W/F	M/W/F	M/W/F	M/W/F	M/W/F	M/W/F	$5 per clinic visit for 18 visits (total $90)
Pregnancy Test (for women) – no extra time		M		M		M		No extra payment
Rewards Program (if assigned) - no extra time			M/W/F	M/W/F	M/W/F	M/W/F		Varies – you will get more information if you are assigned to this treatment
Individual Therapy (1hr Weeks 1 and 3, 15-30 minutes last week for referrals)			Any Day		Any Day		Any Day	No extra payment

What are the potential risks and discomforts?

There are certain risks of participating in this study. We will discuss these known risks with you now. This study may also include risks that are unknown at this time.

- Emotional discomfort from questionnaires and tasks: Some of the questions asked during the study (e.g. drug use) may be considered sensitive information. Answering these questions may cause frustration or distress for some people. You do not have to answer any questions you do not want to answer. Some of the pictures that you will see as part of the behavioral tasks contain negative content that may be mildly upsetting to some people. Please let us know now if you have particular phobias or triggers, or if you are still feeling upset after viewing the pictures.

- Confidentiality: Any time you provide sensitive information, there is a possible risk of breach of confidentiality. Please see following section entitled "CONFIDENTIALITY" for further information on how we protect your confidentiality, and the limits of confidentiality in this study.

- Sensors and monitoring: About half of people experience mild discomfort or irritation to the skin when we clean the sites to apply the sensors used during the Testing Sessions, but this should be temporary (lasting a few minutes to a few hours, depending on the sensitivity of your skin). In a small number of people (approximately 1 in 100) this irritation can last longer, or produce marks that last for up to a week. Please let us know now if you have unusually sensitive skin or allergies to any common skin products or adhesives. All electrical equipment is appropriately protected, making any electrical hazard from the monitoring extremely unlikely.

- Study Medication: Dextroamphetamine has a modest risk of side-effects. These are divided into two groups: effects that are very serious when they occur, but quite rare, and effects that are more common but less serious. There also risks to suddenly stopping the medication, and risks during pregnancy.
    - **Serious but rare side effects** include: 1. Heart related problems, including stroke, heart attack, increased blood pressure and heart rate. To reduce this risk, we did a full physical examination before we give you the medication, and we'll check your heart rate and blood pressure regularly during the study. Let study staff know right away if you have any signs of heart problems, such as chest pain, shortness of breath, or fainting while taking the study medication. 2. Mental problems, such as hearing voices, believing things that are not true, or mania, suspicion or aggression. To reduce this risk, we have asked you about your mental health history before we give you the medication, and we ask about these symptoms regularly during the study. Let study staff know right away if you are experiencing changes in your thinking or behavior while taking the study medication. 3. Circulation problems in fingers and toes, such that fingers or toes feel numb, cool, painful, or change color to pale, blue or red. To reduce this risk, we have done a full physical examination before we give you the medication, and we ask about these symptoms regularly during the study. Let study staff know

right away if you experience these signs, or have any unexplained wounds on your fingers or toes while taking the study medication.

- **More common but less serious side effects** include: allergic reactions, blurred vision, fast or irregular heartbeat, decreased appetite, restlessness, anxiety, tremors, headache, trouble sleeping, dizziness, stomach upset, weight loss, dry mouth, diarrhea or constipation, impotence, changes in sex drive, frequent or prolonged erections.
- **Suddenly stopping dextroamphetamine** may cause depression, irritability, and changes in sleep, appetite and craving. At the end of the study we will help you taper off of the medication to avoid these effects. Please note, even if the study medication works for you, after the study ends, the medication may not be available to you through your doctor or insurance program. There is a risk that you will relapse to using cocaine after stopping the study medication.
- **Risks during pregnancy** may exist with dextroamphetamine. Therefore, pregnancy testing will be done every two weeks during the study. Female patients of childbearing potential must not be pregnant or lactating, and if sexually active, must be using acceptable methods of birth control to be enrolled in the study. Acceptable methods include: (1) surgical sterilization (such as tubal ligation or hysterectomy), 2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) intrauterine device (IUD). If you become pregnant while taking part in this study or if you have unprotected sex, you must inform the study staff immediately.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?

Based on experience with these treatments in individuals with cocaine addiction, we believe they may help people who want to quit or cut down on their cocaine use. However, because people respond differently to therapy, no one can know in advance if it will be helpful for you. Thus it is possible you may not benefit from this research.

It is also hoped that knowledge gained from this research may benefit others with cocaine addiction in the future, because this study will help find which types of treatment work best for which people.

What other options are there?

If you decide not to enter this study, there is other care available to you. Although there is no FDA-approved medication available for cocaine addiction, there are other treatments (such as counseling) that are available in the community. Dr. Wardle will discuss these other treatment

options with you if you choose not to take part in this study. You do not have to be in this study to be treated for cocaine addiction.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team. As noted above, a possible risk of the research is that your participation in the research or information about you and your health might become known to someone outside the research team. We take several steps to protect against this. First, you will be assigned a number, which will be used instead of your name on all paper and electronic forms. However, we do keep a list that links your name with this number. We do this because sometimes the same person wants to take part in a few of our studies, and it is helpful for us to know if someone has been in one of our studies before. For example, we would not put people in the same treatment if they had side effects from it before. We store all paper forms in locked cabinets in a locked room in our clinic. We store all electronic information on our password protected and encrypted server, which is maintained by the University's IT services. Only authorized study staff have access to paper and electronic forms. We do keep your results in your research record indefinitely. The exception to this is the video recordings we will take of your therapy sessions using WebEx. At the conclusion of the study we will have these sessions securely transcribed, and we will delete the original video recordings. Until that time, they will be stored temporarily on our secure, password protected, encrypted servers. After that time, the transcriptions will be similarly stored on our secure, password protected, encrypted servers.

To help us protect you and the information we will be collecting from you, this research has been given a Certificate of Confidentiality by the U.S. government. This Certificate means that the researchers cannot be forced, even by courts or the police, to disclose any information about you. No information about you, or provided by you, during the research, will be disclosed to others except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care), with the exception of the situations described below:

1. Study information which identifies you and the consent form signed by you may be looked at by the following regulatory groups, which monitor the conduct of our studies:
- The Food and Drug Administration (FDA)
- The funding agency, the National Institutes of Health
- UIC Office for the Protection of Research Subjects
- The Data Safety Monitoring Board for this study

2. You may still disclose, or agree in writing to allow researchers to disclose, information about you. For example, if you would like an employer or insurer to know something about you that is documented in this research, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

3. If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to the state's child protective services, adult protective services, and/or the nearest law enforcement agency.

4. If you tell us that you are seriously thinking about hurting yourself, or hurting someone else, we may report this to medical personnel or to appropriate authorities.

We my share data collected as part of this study with other researchers who are interested in similar questions. We will only share your data with other researchers either when that data cannot be used to identify you in any way, or when there is a written agreement in place that the data will be used solely for research, that no individuals will be identified in any publications, that data will be secured by equivalent electronic safeguards, and that once data analysis is complete, the data will be returned to us or destroyed. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if I am injured as a result of my participation?

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of an UIC employee.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research study?

There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will be paid for taking part in this research study. For each of the five 2-hr Testing Sessions, you will receive $20, plus your winnings on the tests, which can range from $5 - $12 per session. For the consent visit today and each of the 18 regular clinic visits (3 times per week during the Medication Start Week, four-week Treatment Phase, and Medication Stop week) you will receive $5.00. Thus, if you complete all study visits, your minimum total payment will be $195.00, plus your winnings from the Testing Sessions. If you are randomly assigned to be in the Rewards Program, you will also have the chance to earn rewards (gift cards) each time you provide a urine sample that is negative for cocaine. Finally, you will receive bus or parking passes to cover transportation costs each time you need to come into the clinic. We can also send an Uber for you once a week during the study, to help you get in if you are having trouble coming to a visit.

You will receive your payments at the end of each visit. **At each visit you can get up to $25 of your payment in cash. Any amount left over $25 will be paid in gift cards.** Because your payment in the study may exceed the threshold for tax reporting, we will need to collect your social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS).

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC. For your safety, however, you should consider the investigator's advice about how to leave the study. As described above, suddenly stopping dextroamphetamine may cause depression, irritability, and changes in sleep, appetite and craving. If you chose to withdraw early we will offer to help you taper off of the medication over 1 week to avoid these effects. You may also request to have your information removed from our database at any time by contacting Dr. Wardle, at phone number 312-413-5564, and your information will be removed.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- You are determined to be ineligible;
- You are unable to follow study guidelines;
- Your medical condition changes or you have side effects of the medication;
- New information becomes available that indicates that participation in this study is not in your best interest
- If the study is stopped.

In the event you withdraw or are asked to leave the study, you will still be compensated for visits you have already attended, as described above.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

What other things should I know?

Our study physician, Dr. Christopher Holden, is also the Director of the UIC Recovery Clinic, and the Medical Director of the Substance Abuse Residential Rehabilitation Treatment Program

at the Jesse Brown VA. If you were referred to the study from one of these clinics, you should know that Dr. Holden is a researcher on this study, and as a researcher, is interested in both your clinical welfare and in the conduct of this study. Before entering this research study or at any time during the research study, you may ask for a second opinion about your care from a health care provider who is not associated with this research study. You do not have to participate in any research study offered by your healthcare provider. A decision to not participate will not affect your clinical care with Dr. Holden now or in the future. You should also know that we sometimes refer participants to these clinics for treatment, if they offer services that are appropriate for that person (e.g. if an individual needs additional treatment after completing the study). If you are uncomfortable being referred to clinic run by someone affiliated with the study, we are happy to provide a different referral. Your decision to accept or decline a referral does not affect your ability to participate in this study.

Remember:
Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject
I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

_____ _____
Signature Date

_____
Printed Name

_____ _____
Signature of Person Obtaining Consent Date (must be same as subject's)

_____
Printed Name of Person Obtaining Consent