Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: Sept. 13, 2016

Participant Name: _____ Date: _____

Title of Study: Improving Treatment Engagement and Outcomes among Justice-Involved Veterans

Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Daniel M. Blonigen

INTRODUCTION

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

This research study is looking at a new treatment (Moral Reconation Therapy, or "MRT") to reduce criminal thinking. The purpose of this study is to evaluate MRT as a way to reduce return to criminal behavior and improve overall health outcomes by having Veterans attend a series of group sessions and activities. These sessions and activities will focus on topics such as building trust with others, repairing damaged relationships, and setting realistic goals in your life. With this research we hope to find out if the intervention is effective for Veterans by comparing a group of Veterans who attend MRT sessions with a group of Veterans who do not attend the sessions. The way we will learn about differences between the 2 groups is by doing interviews with the participants. If the research is successful, our study team will work towards distributing MRT training materials to other VA sites and treatment programs.

Who conducts this study? This study is conducted by Dr. Daniel Blonigen (VA Palo Alto). You may contact him at 650-493-5000 ext. 27828 if you have any questions. You can also speak to the study staff if you have any questions or concerns. This research is being conducted at three VA sites (Palo Alto, CA; Bedford, MA; and Little Rock, AR) and is funded by the VA. About 122 Veterans from each VA site will be in the study.

DURATION OF THE RESEARCH

Your individual participation in the project will take at most 1 year.

STUDY PROCEDURES

SUBJECT'S IDENTIFICATION

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If you choose to participate, the research study staff will ask you to meet with a member of the research team and answer questions about your background including your substance use and health. This session will take about 1 hour. After you complete this session, you will be assigned by a computer to one of the 2 groups; you will have approximately a 50% chance of being in the group that receives MRT, and approximately a 50% chance of being in the group that does not receive MRT and continues with treatment as usual. Neither you nor the study staff can decide which group you will be assigned to – this is called randomization. If you are randomly chosen to be a part of the MRT group, you will be asked to attend MRT groups twice per week for 12 weeks in addition to your usual treatment. MRT groups will last 1 hour each. These groups will include activities aimed to reduce criminal thinking. If you are in the group that does not attend MRT sessions, the rest of your care is the same as if you were not in the study. Also, if you are assigned to the group that does not receive MRT, we ask that you not seek out MRT treatment elsewhere during the study period of 1 year. Both groups will be asked to do another interview by a research study staff at 6 and 12 months after the first interview. These interviews will also last about 1 hour. You have the right to refuse to answer any question that makes you uncomfortable during any of these sessions.

The first interview and all MRT group meetings will take place at the VA. Six and 12 month follow-up interviews may take place at the VA or over the phone, whichever is more convenient for you. In the event you are in a jail or prison at those times, we will still attempt to contact you in these settings to conduct the 6- and 12-month interviews. Because you may have moved, or could be hard to contact after leaving the treatment program, we ask that participants in the study provide us with some additional ways to find you. We ask that you give us the names, addresses and phone numbers of 3 people who would know your whereabouts, and can be reached to give us this information. We also ask that if you have a probation officer, that you give us their name and contact information. Regardless of where you are, if we cannot speak to you directly, we will not tell anyone else what the study is about. Research team members will only ask for you, and if necessary, say that the call is about a “health survey”, but nothing more about the subject matter of the study.

We will ask for your social security number to access your VA medical records to obtain information on your medical history including the type and amount of health care services you receive from the VA. In addition, your MRT sessions will be videotaped so that research staff can check the quality of the intervention that you received. The tapes will only be used to make sure that you received the intervention that you should have received and will not be shown to anyone outside the research team. Your identity will not be made known. All tapes will be kept secure according to VA data storage rules, and will be stored for as long as the federal guidelines state.

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If you are assigned to the MRT group in this study, you may also be asked to complete an extra phone interview to share your thoughts on the MRT group sessions and ways to improve these groups. Up to 36 Veterans will be included in this portion of the study. We will ask that this final interview be audio-recorded in order to transcribe and code the interview. Your identity will not be made known. The information from this interview will be transcribed into a written version that can be studied by the researchers. The transcription will be performed by a professional medical transcription agency specifically chosen for this study.

Your safety and the safety of others in the treatment program will be monitored by the project staff throughout your time in this study.

As a research participant, you will be expected to:

- Keep your study appointments. If you plan to miss an appointment, please contact the research staff to reschedule as soon as you know you will miss the appointment.
- Complete your interviews as instructed.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks. The procedures in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur. Nonetheless, precautions will be taken to further reduce any risks to you in this study. Specifically, you are encouraged to have any questions answered and concerns addressed to your satisfaction prior to being asked to provide consent.

It is possible that a few of the questions asked of you (e.g., alcohol and drug use; criminal history) may cause you some discomfort. However, such questions should not cause you any more discomfort than the questions that are typically asked of other Veterans in mental health treatment. These questions are not anticipated to cause you any harm.

If you agree to participate, you may withdraw from the study at any time, and you may refuse to any answer any specific questions. All information will be confidential and used only for the purposes of the research study. You may contact the site PI or a research assistant with any questions at any time.

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Risks of the usual care at the VA you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

POTENTIAL BENEFITS

We cannot and do not guarantee or promise that you will receive any benefits from this study. However, the information we get from this study might help us treat future patients.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

The alternative to participating in this study is not to participate. Your decision whether or not to participate in this study will not affect your medical care.

CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Records will be kept locked in filing cabinets, on computers protected with passwords, only study staff will have access to this information.
- Information about study participants may be discussed at meetings with the other sites, but you will not be identified by name.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you by name or any other information.

As noted above, we will ask for your social security number to access your VA computer records to obtain information on your medical history including the type and amount of health care you receive from the VA. If you choose to not share your Social Security Number you will not be able to participate in this study; however, this decision will not affect your medical care or eligibility for services. The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, or our local Research and Development Committee may look at or copy portions of records that identify you.

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In attempting to contact you, the research assistant will explain to any other person whom they reach that s/he is trying to locate you regarding a health survey. We will not include your name on any interview forms. Instead, these documents will be given ID numbers that are not linked to you. The list that contains names, contact information, and ID numbers will be kept on computer files that can only be seen by project staff, and all data with personal information will be stored in locked file drawers.

This informed consent will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others as dictated by VA regulations and state law. This form does not prevent you or a member of your family from releasing data about yourself or your involvement in this study, if you so choose.

CERTIFICATE OF CONFIDENTIALITY:

The Principal Investigator (Daniel M. Blonigen, Ph.D.) has received a Certificate of Confidentiality from the National Institute of Health (NIH), which will help protect the privacy of research participants. The Certificate protects against the involuntary release of information about participants collected during the course of covered studies. The researchers involved in the studies cannot be forced to disclose your identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. The Certificate does not mean that NIH approves or disapproves of the project. It only adds special protection for research information that identifies you. However, the participant or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the participant or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review Daniel M. Blonigen's records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: suspected child or elderly abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:* You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Payment Offered for Participation: Regardless of your assignment to the MRT intervention or usual care, you will be asked to complete an interview when you enter your treatment program and two follow-up interviews (in-person or by phone) 6 and 12 months later. You will be reimbursed $25 after completion of the first interview. For the 6 and 12 month follow-up assessment, you will be reimbursed $50. If you are selected to take part in the phone interview to answer questions about MRT, after finishing the sessions, you will be reimbursed $25 after completion of that interview. There are 2 ways that you can be paid: one is being paid by the research assistant with a gift card immediately after completion of each interview. Alternatively, you may receive a check through VA's Austin Financial Services Center. If you receive the check, your SSN will be used to generate a form 1099 from the Internal Revenue Service, which may be used for tax purposes.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY: Dr. Daniel Blonigen at 650-493-5000 ext. 27828

AFTER HOURS: VA Crisis Communications Line at 1-800-273-8255

Emergency and ongoing medical treatment will be provided as needed. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

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If you decide to withdraw after starting the study, data that has already been collected prior to your withdrawal will be continued to be used for research purposes and be kept according to the research study data retention policy. However, no further information will be collected about you.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The investigators may also withdraw you from the study and the study intervention may be stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the investigators and/or study staff.
- The investigators decide that continuing your participation could be harmful to you.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

Any withdrawal from the study on the part of investigators will not affect the standard care that you are already receiving in the Domiciliary Program or any other VA health care to which you are entitled.

PERSONS TO CONTACT ABOUT THIS STUDY

- **Questions, Concerns, or Complaints:** If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Principal Investigator (Daniel Blonigen, Ph.D.). You may contact him at (650) 493-5000 extension 27828. You should also contact him at any time if you feel you have been hurt by being a part of this study.
- **Independent Contact:** If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact your local Privacy Officer and Human Protections Administrator, Kristin Frazier at (650) 493-5000.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may

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call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

The data that you provide for this study will be retained after the study is completed and may be used to re-contact you about participating in future VA research projects. This data will be stored in locked filing cabinets at the Menlo Park Division of the VA Palo Alto HCS and on servers that are firewalled and password-protected. Once the study is completed, only research staff on the current project will have access to your data. Approximately 3-5 years after your participation in the current study is completed, if additional research funding is obtained, we may re-contact you via phone and ask you to participate in another phone interview to learn more about your health and well-being at that time. All those who participate in the current study will be eligible to participate in this future study.

Would you like to be contacted for future VA research studies?

☐ YES

☐ NO

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms _____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

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Participant Name: _____ Date:_____

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Principal Investigator: _____ VA Facility: _____

Principal Investigator for Multisite Study: Daniel M. Blonigen

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date

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