Department of Veterans Affairs

RESEARCH CONSENT FORM

Version Date: 5 April 2018

Participant Name: _____ Date: _____

Title of Study: CSP#590: A Double-blind Placebo-Controlled Study of Lithium For Preventing Repeated Suicidal Self-Directed Violence in Patient With Depression or Bipolar Disorder

Local Site Investigator: _____ VA Facility:v _____

Principal Investigator/Study Chair for Multisite Study: Ira Katz, MD, PhD

PART ONE: SCREENING FOR ELIGIBILITY

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, 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

Why the research is being done and why you are being asked to participate:

The VA is doing everything it can to improve its care and learn how to prevent suicides. VA is doing this research to learn if lithium, a medicine used for treating bipolar disorder and depression, can prevent repeated suicide attempts in Veterans. There is some evidence that lithium may be helpful in preventing repeated suicide attempts but this has not been proven. This study is being done to determine whether or not lithium is effective in preventing repeated suicide attempts.

SUBJECT'S IDENTIFICATION

VA Form **10-10-86**

MAR 2006

VA CIRB template Nov 2012

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: May 1, 2018

LSI Approval Date: N/A

LSI Verification Date: N/A

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The complete study has two parts. Part One is to determine if you are eligible for Part Two, which is the actual study. Part One consists of an interview, filling out questionnaires, and a consultation with your mental health and an update to your primary care provider. If you meet the criteria for the study and you still want to participate, you go to the second part**.** In Part Two, half of the participants will get lithium and half will get a placebo (an inactive sugar pill). The placebo is necessary to see whether the benefits and possible harms could have happened anyway without the medication. All participants will be followed for one year to observe the benefits and harms of lithium or the placebo.

You are being asked to consider participation in Part One because you have recently survived a suicide attempt, a near attempt, or other self harm behavior and because VA staff involved with your care let us know that you were interested in being contacted about this study. **Your participation in Part One does not obligate you to go on to Part Two, the actual study.**

How many people will participate?

We do not know how many Veterans we will need to screen for eligibility but the full study (Part Two) will include 1862 Veterans. 29 VA Medical Centers will participate; and about <insert number> patients will participate from this VA Medical Center.

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Who is sponsoring the study and who is conducting it?

The research is organized and sponsored by the VA Office of Research and Development. The lead researcher at this VA Medical Center is <insert site PI name>.

DURATION OF THE RESEARCH

The entire study will take 4 to 5 years to complete. Each person in the study will be in Part One from one day to several weeks, and in Part Two, the full study, for one year.

If you agree to participate in Part One of this research, it would take about two to three hours of your time. If the results from this evaluation indicate that you are eligible for the full study, you would have the choice to continue or refuse testing required for Part Two of the study. **You will have no obligation to agree to continue with Part Two.** If, after reviewing all the details of the full study, you agree to participate, we would ask you to return for another visit and sign another consent form.

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STUDY PROCEDURES for Part One: Screening for Eligibility

If you decide to take part, you will be asked to complete an interview and questionnaires that cover your thinking and behaviors, mental health treatment, medications, use of alcohol and drugs, home and social supports and your understanding of the research study. You have the option not to answer any questions that may make you feel uncomfortable, but some responses are needed to see if you are able to participate in the study. We only ask questions to help us determine whether you are eligible. In addition, all interviews will be conducted in private. Any telephone discussions will be conducted once you inform us that you are in a location where you feel comfortable talking. You will also have information collected about your age, race, ethnicity, military history and contact information so that we can reach you. All this takes about two hours, and can be done in more than one session, in person and by telephone.

All procedures described here are done for the purpose of research, not usual clinical care. After these are done we ask you to return to discuss our findings to see if you met the criteria and want to participate in the full study (Part Two).

POSSIBLE RISKS OR DISCOMFORTS

The interview and questionnaires may include questions that cause you discomfort. Although we encourage you to answer as best you can, you don't have to answer any questions that make you feel uncomfortable.

POTENTIAL BENEFITS

There are no benefits that can be guaranteed from your participation. You may possibly benefit from participation if the interview or the tests lead to new information that could help you and your doctors in your treatment.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

This screening process is not a treatment. If you choose not to participate, you will continue to receive all necessary treatment that your doctors think you need. You and your doctors may choose to use lithium or any other medications for your treatment.

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CONFIDENTIALITY

Taking part in **Part One** will involve collecting private information about you. This information will be protected in the following ways:

Interviews will be conducted in private. Any telephone discussions will be conducted following arrangements to protect your privacy.

Written notes related to your participation will be kept in locked files in locked offices. Electronic information derived from the interviews and tests will be kept in encrypted computer files in password protected computers in locked offices.

Information from the interview may be shared with the doctors responsible for your health care.

Information about you may be combined with information from other people taking part in the study to allow us to write about the combined data we have gathered. No talks or papers about this study will identify you.

We will not share your records or identify you unless we have to by law. 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 Food and Drug Administration, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

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To further help us protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services.

With this Certificate, the investigators cannot be forced (for example by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

A description of this study is on http://www.ClinicalTrials.gov and 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 website at any time.

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COSTS TO PARTICIPANTS AND PAYMENT

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

Payment Offered for Participation:

You will not be paid for participation in this study. However, if you must pay for transportation, parking, or other expenses related to participation, the study will reimburse you. If you travel less than 50 miles round trip you will receive $50, and if you travel 50 miles or more round trip you will receive $70. If you do not travel, but are being reimbursed for other expenses/time you will receive the lesser of the two amounts, $50. Reimbursement will be made available by <insert local info>. Payments will be made through Austin Financial Services Center and will generate Internal Revenue Service Form 1099 regardless of the amount. Your SSN will be used for this purpose in reimbursement.

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.

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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./Mr./Ms. _____ at _____ and

After hours:

Dr./Mr./Ms._____ at _____.

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

Participation in this study is voluntary. If you choose to participate in **Part One**, participation in **Part Two** remains voluntary.

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Refusal to participate involves no penalty or loss of benefits. 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. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

You may discontinue taking part in this study at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received.

If you do withdraw from the study, the research team may continue to review the information they already collected. They cannot collect further information except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The investigator may end the study if new information becomes available on lithium for suicide prevention. Should this happen, the research team will let you and your doctors know, and they will share the information they have obtained with you and your doctor to guide treatment planning.

Your participation in this study may be terminated if you do not follow study procedures.

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PEOPLE TO CONTACT ABOUT THIS STUDY

If you have any questions, complaints, or concerns about this study, you may contact the study investigator at your VA Medical Center <insert info> or the study coordinator.

The investigator is Dr./Mr./Ms. _____at_____

The <insert info> is Dr. /Mr./Ms._____at _____.

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 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

After Part Two of this study ends, your study data will be stored indefinitely at the Cooperative Study Program, Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC).

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

_____ (insert name and title of person obtaining consent) 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 also give permission for the research team to contact family members, friends, or others who would be likely to know your whereabouts prior to randomization if we are unable to contact you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

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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