Participant Name: _____ Date: _____

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

Local Site Investigator: _____ VA Facility: _____

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

Part Two: Randomized Trial

INTRODUCTION

You are invited to take part in a research study that is 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 is the research being done?

The VA is doing everything possible to improve the mental health of Veterans. It is a tragedy when someone tries to take their own life, and the VA is trying to learn how to improve our efforts to prevent this from happening.

The purpose of this study is to learn if lithium, a medicine used for treating bipolar disorder and depression, is effective in preventing repeat suicide attempts. There are no medicines for preventing suicide for people with depression or bipolar disorder, but some studies indicate that lithium may work in people who have depression or bipolar disorder. However we do not know for sure whether lithium prevents suicides.

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Participants in the study have a 50:50 chance of receiving either lithium or placebo (sugar pill) in addition to the full array of VA mental health and suicide prevention treatment we have in the VA currently. The placebo is necessary to see whether the benefits and harms would have occurred anyway.

Why am I being asked to participate?

You are being asked to participate in this study because you have had an experience with a suicide attempt, a near attempt or another form of self harm. You also have bipolar disorder or depression. You are thus among those people we believe lithium is most likely to help. You have gone through the Screening Evaluation (Part One) and may be eligible for the study.

The research team will review this consent form with you, answer any questions, provide you with all the information that you want to help you decide whether or not you want to be in the study.

Is the treatment used in this study approved by the Food and Drug Administration (FDA)?

Lithium is approved by the FDA for treating an acute manic episode in bipolar disorder. It is also sometimes used for treating depression but this use is not approved by the FDA. Using lithium for suicide prevention is also not approved by the FDA. We are doing this study to see whether lithium is useful to prevent suicides.

Who is sponsoring the study and who is conducting it?

The VA Office of Research and Development is designing and paying for the study. The lead researcher at this VA Medical Center is <insert name of PI>.

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How many people will participate in the study?

1862 people from 29 VA Medical Centers will be involved. We think about <insert site info> Veteran participants will come from this Medical Center.

DURATION OF THE RESEARCH

You will need to have another evaluation to determine your eligibility for the study. This includes a physical exam, blood tests and electrocardiogram. This will take about two hours of your time. If you are eligible and decide to participate, your participation in the study will be for one year.

The entire study will take 4 to 5 years to complete and to make the results available to the people who have participated. We will review your medical records until the study has finished; however, we will not need to contact you after you complete one year of participation in the study.

STUDY PROCEDURES

Determining Eligibility (2 hours)

Before being randomized in the study, we will need to further confirm your eligibility (in addition to the assessments done in Part One). You will have a medical checkup, an electrocardiogram (heart tracing) and have a blood sample taken (about two tablespoons of blood) to check your kidney, liver and thyroid function. If you are a woman of childbearing age, you will be asked about birth control and will provide urine for a pregnancy test. Acceptable forms of birth control include methods of birth control which result in a low failure rate (less than 1% per year) when used consistently and correctly. These methods include implants, injectables, combined oral contraceptives, some intrauterine devices (IUDs), sexual abstinence or vasectomized partner.

All procedures described here are done for the purpose of research, not usual clinical care. After these are done we will discuss our findings with you to see if you met the criteria and want to enroll in the full study. This may happen on the same today or we may ask you to return at a later date.

Randomization of Study Medications (1.25 hours)

At the beginning of the study, you will be randomly (by 'toss of the coin') assigned to get lithium or a placebo, a pill that looks and tastes just like lithium but has no effect on your body. You have a 50:50 chance of receiving lithium or placebo. Neither you nor your doctor will know which pill you are getting. The lithium or placebo **(both called "study medication")** will be given for 1 year.

The number of pills will be adjusted until the right blood level is reached. Blood levels and adjusting the number of pills will be done every 5 to 14 days for about 6-8 visits.

You will bring in old pill packages at each visit and receive new ones or by express mail. The packages contain a 2 week supply.

Follow-up visits (45 minutes – 1.25 hours)

You will come in every 5-14 days until the medications are adjusted. This usually takes 6 to 8 visits. After that the study visits will be monthly for 1 year. You may need to be seen more if your health changes for any reason.

During the year follow-up, a few visits will require an electrocardiogram, and your blood will be taken monthly for the first 6 months, then every 3 months until the end of the study. If you are taking certain blood pressure medications, your blood will be taken at every visit. At each visit we will check on any side effects you are having, changes in your medications or health and ask you to fill out questionnaires about how you are feeling.

Some of the study can be done by phone. If blood tests or an electrocardiogram are necessary, we will try to arrange it so that it is convenient for you. There will be approximately twenty (20) study visits over the course of the one year.

Your medical condition or medications (even ones where you don't need a prescription) might change. If this happens, you and/or your physician should notify the study team. The study medication may need to be adjusted or stopped. In either situation, you may still continue in this study.

In addition to the study pills, you will receive your normal medical and mental health care which includes the special VA care for people who have tried to commit suicide or are at high risk. We strongly encourage you to use this care.

<u>One year after randomization – Month 12/End of study participation (1.75 hours)</u>

The end of study medication visit will include the following procedures: recording of all your current medicines, having and ECG done, Brief physical exam and the recording of vital signs (heart rate, temperature, breathing rate and blood pressure), completion of 5 questionnaires, review of any adverse side effects, collection of study medication cards and any unused study medication and your study medication diary.

After the visit, the research staff will inform your VA mental health provider (psychiatrist or nurse practictioner) whether you were taking lithium or placebo so the two of you can decide on further treatment with medications. If you were on lithium and decide to stop it, it is safer to gradually lower the dose over a few weeks, as there is information that stopping lithium suddenly may not be as safe.

30 Day Follow-up Visit (30 minutes)

Thirty days after 1 year of follow-up, there will be a final visit that is basically the same as the one you did when being screened for eligibility (Part One). You and the research staff will complete 4 questionnaires. You will also be asked about any ongoing adverse side effects.

After study participation has ended:

After you complete study participation (1 year) and until the study ends (up to 4-5 years), we will review your medical records to track how your health has been since your final study visit. To determine your health status, we will review your medical records and VA clinical databases.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur. These risks are different from any risks you might encounter from usual care. This form only covers risks from the research.

The possible risks and discomforts of participation include the inconvenience of the time for research visits. To the extent possible, interviews will be scheduled at your convenience or by telephone to minimize this.

Each blood test requires about a teaspoon of blood or about eight tablespoons over a year. This is not enough blood loss to cause any medical effects. However, the needle sticks may cause pain (like a pinch), or bruising, and, rarely, infections. Very rarely, patients become lightheaded or faint from having blood drawn.

The primary risks and discomforts of participation are from the study medication. Lithium has been used for over 30 years and is generally safe if used as instructed and blood levels monitored. It should be kept out of the reach of children or others with limited capacity to read or understand. You should not break, chew or crush the tablet. If you experience any troubling side effects you should immediately contact the research team.

Risks and Side effects

You may experience side effects during this study regardless of whether you are taking lithium or placebo. If people have side effects, they usually have them when they first begin lithium. These are usually mild and go away after days or weeks. The most frequent side effects include nausea, loose stools, thirst, change in urination patterns, shakiness, headaches, sweating, fatigue, decreased concentration, and skin rash.

Side effects that last are usually due to high levels of lithium in the blood. These usually go away with lowering the dose of lithium or changing the time it is taken. Also, some medications may interact with lithium. The study team will review your medications to check for known interactions. It is important that you notify the study team of any new medications prescribed before starting them so that the study team may be aware of any potential interactions with lithium. For some medications, the study drug dose may need adjusting and extra monitoring might be necessary.

Side effects:

Risks of the usual care 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.

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Symptoms that up to 75% of people experience who start lithium and which go away in 90 to 99% of people who continue lithium:

Mild nausea

Loose stools

Abdominal discomfort

Decreased appetite

Weight change

Thirst

Changes in urination patterns

Shakiness of the hand

Headache

Sweating

Fatigue

Decreased concentration

Rash

Dry Skin

Hair thinning

Fast or pounding heartbeat

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Adverse side effects that occur less frequently but may persist:

Decreased activity of the thyroid gland, or increased size of the gland. This may occur in about 25% of people so we will monitor your thyroid function throughout the study.

Lithium may cause worsening of pre-existing acne or psoriasis in about 50% of people who already suffer from these conditions. This worsening usually goes away once lithium is stopped.

Adverse side effects that occur in less than 1-2% of people taking lithium:

Lithium toxicity in which people get diarrhea, vomiting, drowsiness, weakness, lack of coordination, dizziness, confusion, trouble with walking or balance, blurred vision, ringing in the ears, and stupor, coma, seizures, blackouts, multiple organ failure, dangerous heart irregularity and death

You should let us know immediately if your health changes or when you start any new medications.

Certain illnesses and certain medications (particularly nonsteroidal anti-inflammatory drugs (NSAIDs), such as high dose aspirin, ibuprofen, and naproxen, medicines used for heart problems, and medicines used to treat high blood pressure) may change your lithium level even though you are taking the same amount of lithium. Increased lithium levels may increase side effects or lithium toxicity, and decreased lithium levels may be less effective.

Lithium is dangerous when blood levels go too high. We will be closely monitoring your lithium blood levels, so it is unlikely that toxicity will occur if you follow directions carefully. You should contact the research team, your psychiatrist, or a doctor immediately if you have taken too much of your study medication.

Risks associated with suddenly stopping study medications:

For people taking lithium for bipolar disorder, stopping the medication too quickly can lead to recurrences of mania or depression, and increase the risk of suicide.

Before you discontinue your study medication for any reason, it is important that you contact the research team or your psychiatrist so they can help you do it safely.

They will give you instructions on how to safely stop taking the study medication.

Reproductive Risks:

Lithium can cause birth defects and it is not safe to take during pregnancy. If you are pregnant, plan to become pregnant, or are nursing, you cannot take part in this study. You must notify us immediatlely if your method of birth control changes and/or you believe that it may have lapsed and you are at an increased risk of pregnancy.

A pregnancy test will be performed at each study visit for those participants of childbearing potential. The test will be performed by urinalysis. If you are able to become pregnant, you will have a pregnancy test before starting this study. While taking the study drug, you should not become pregnant. During the study you need to take measures to prevent pregnancy by using a medically accepted method of birth control.

If you become pregnant, you need to stop taking the study medication and tell your doctor and the research team immediately. You will be asked to sign a separate consent form and HIPAA so that we may follow you during the pregnancy up and and including the pregnancy outcome.

POTENTIAL BENEFITS

Lithium may or may not be effective for suicide prevention. You may not benefit from taking study medications.

The VA and society as a whole may benefit from this research by learning more about how to prevent suicide.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

Participation in this research is completely voluntary.

Whether or not you participate, you will receive safety planning and other services for Veterans at risk for suicide, treatments (including medications) for depression, bipolar disorder, and other mental health conditions, and treatment for any medical conditions you have.

This treatment may include receiving lithium under the direction of your current doctor.

CONFIDENTIALITY

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

Interviews will be conducted in private. Any interviews or discussions over the telephone will be conducted following arrangements you choose to protect your privacy. Written notes related to your participation in this study will be kept in locked file cabinets 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 your research participation will be shared with the doctors responsible for your medical and mental health care. Results from the electrocardiogram and the blood tests except for the lithium levels will be included in your medical records.

During the study, we will monitor your VA medical record to see if you have had any suicide attempts or self-harm events. If you are also receiving care from a non-VA clinic or hospital, we will ask your permission to obtain those records to confirm any suicide events that you or your study doctor tells us about.

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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.

We will do everything we can to keep others from learning about your participation in the research. To further help us protect your privacy, we 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.

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A description of this clinical trial will be available on http://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 completed results. You can search this website at any time.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants*:* You will not be charged for any treatments or 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 site specific info>. Payments will be made through Austin Financial Services Center and will generate Internal Revenue Service Form 1099 regardless of 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.

If at some point you have thoughts of self-harm or are in emotional distress and need to speak to someone, please call the Veteran's Crisis Hotline at: 1-800-273-8255 and Press 1. They are available 24 hours a day 7 days a week.

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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.

For those who participate in this research, there are more than minimal risks associated with taking study medication. If you experience injuries that may be related to study medication, you should contact the research team or your doctors. Treatment for injuries related to study medication will be provided without charge to you.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

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PARTICIPATION IS VOLUNTARY

Participation in this study is voluntary. Refusal to participate will involve 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.

You may choose to discontinue study medication while remaining in the research study. If so, the research team will work with you to decrease the number of pills you are receiving each day. Suddenly discontinuing lithium may lead to worsening of symptoms in bipolar disorder, and possibly an increased risk for suicidal behavior. Tapering the medication gradually is safer than abrupt discontinuation.

If you do withdraw from the study, the research team may continue to review the information they already collected and your medical records. They cannot collect further information directly from you. They may continue to review VA clinical and administrative records to find out if you have repeated self-harm or suicidal behavior unless you withdraw your consent for them to do so either verbally or in written form.

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RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

The investigator may terminate this study at any time. Possible reasons include: additional information on the benefits versus the risks of lithium for suicide prevention; discontinuation of funding for this research; or problems with your ability to follow study procedures. 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.

PERSONS 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 or the <insert info> during regular business hours.

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.

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SIGNIFICANT NEW FINDINGS

Sometimes during the course of a research study, new information becomes available about the condition or medicine that is being studied that might change a person's decision to stay in the study. If new information about the treatments to prevent suicide, or about the benefits and risks of lithium, becomes available the study team will tell you about it and talk with you about whether or not you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

FUTURE USE OF DATA

After this study ends, your study data will be stored indefinitely in a research Data Repository at the Cooperative Study Program, Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC).

If you agree, the Cooperative Studies Program Coordinating Center in Boston, MA will make your study data available for use for other approved research studies by investigators not associated with this study. Researchers using the study data will not have access to your identifying information such as name, address, and Social Security Number.

Researchers may link this data with the electronic medical records data from VA national data resources including the Suicide Prevention and Application Network (SPAN) and National Data Systems (NDS), but Data Repository personnel, will ensure that your data will be de-identified to the extend possible prio to release to other researchers.

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Any use of your research data, from this study, by other researchers must comply with existing regulations and be approved by appropriate oversight bodies including a VA Institutional Review Board (IRB), a committee that protects the rights of research subjects. The oversight bodies may require that you be contacted for your consent prior to the use of your data in a new study if it decides such consent is required for your protection.

If you would like to be included, please read the following statement and circle one answer below. Please initial in the space indicated below your answer. You can change your mind about participating at any time. No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.

I give permission to allow researchers to store my data in the Data Repository.

YES **NO**

Please Initial: _____

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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 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 Print Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date

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