Department of Veterans Affairs	Informed Consent Form	COMIRB APPROVED For Use 24-Jan-2017 23-Jan-2018
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Subject Name: _____ Date: _____

Title of Study: Veterans Affairs Rheumatoid Arthritis (VARA) Registry

Principal Investigator: Liron Caplan, MD, PhD VAMC: 554

VA Investigator: Liron Caplan, MD, PhD COMIRB# 06-0956

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about rheumatoid arthritis (RA). You are being asked to be in this research study because you have RA. In this study, we will take a single blood sample that will be stored in a tissue bank. We would also like to keep some of the left-over tissue taken during any procedure that you have undergone or will undergo (discussed below in "What happens if I join this study?") We would also like to store your health information from other medical providers (also discussed below). We will also health record information, such as the severity of your RA, each time you visit our clinic for routine care. We may ask you if we can collect additional blood samples when you visit clinic in the future, but we will collect these serial samples no more than once every year.

Why are we doing this? Your blood and/or tissue sample contains heredity (genetic) information about you. Scientists hope to develop genetic and/or other blood tests that may help predict which patients will develop RA, or develop the most severe forms of arthritis. These genetic and blood tests may also eventually help select the most effective treatments for RA. Your blood sample will be part of a collection from thousands of patients with RA collected from VA Medical Centers. This collection of blood samples is called the VARA Registry. These blood samples and information on the severity of your RA will be used by scientists conducting future research on inherited factors in rheumatoid arthritis.

Up to 1000 people from the Denver VA Medical Center will participate in the study.

What happens if I join this study?

If you join the study, you will undergo a single blood draw using standard techniques. The blood draw will be performed by personnel in the Denver VA outpatient laboratory and will be done at the time of your Rheumatology clinic visit. The blood draw will take approximately 2 tablespoons of your blood that will be stored in two tubes. Standard techniques will be used to limit discomfort related to the blood draw. Also, if you have undergone or will undergo any medical procedure at the VA, we may keep a sample of the tissue collected during that procedure to put in the blood and tissue bank. We will only store left-over tissue not used for the test/procedure. This would include storing blood

and tissue from other blood and tissue banks, such as the Department of Defense Serum Repository. Lastly, we would like to store your health information from other medical providers, such as hospitals and doctors outside of the VA system, including the Department of Defense.

To protect your confidentiality, your name will not appear on these blood and/or tissue samples. Your blood and/or tissue samples will be transported to an Omaha VA laboratory located at the University of Nebraska Medical Center (UNMC) where the tissue bank is located. All data related to the study will be kept in a secured database at the Dallas VA to insure confidentiality. All blood and tissue samples will be stored in a confidential and secure manner and will be accessible only to study personnel. Any future proposal using the VARA Registry blood and tissue samples will require prior approval by a Scientific Ethics and Advisory Committee and a representative Institutional Review Board or IRB. No research will be conducted involving your blood and/or tissue sample or patient information until after the research is reviewed and approved by these two committees. The researchers who use your blood sample and genetic information will not have your name. This process will insure that your information is being properly protected.

We will also record information on how severe your RA is each time you visit our clinic for routine care. You will be asked to fill out a questionnaire, and we will perform a physical exam. The questionnaire may require an extra five to ten minutes to complete. We will also record the results of tests that your care provider orders for you as part of your routine care.

We do not intend to delete your identifiable private health information or destroy your blood and/or tissue sample unless you indicate you no longer wish to participate in this study. If you change your mind and no longer want your blood/tissue(s) to be used for research, please contact Liron Caplan, MD, PhD at (720) 857-5103 and your sample will be destroyed.

The anticipated time required to complete the consent process, blood draw, and questionnaire is 30 to 45 minutes, depending on the wait time at the outpatient laboratory.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include those associated with a blood draw. Approximately 2 tablespoons (1 tablespoon = 15 ml or 1 ounce = 30 ml) of blood will be removed by putting a needle into your vein. This is the standard method used to obtain blood for tests. You will feel pain when the needle goes into the vein. A bruise may form at the site. A total of 2 tablespoons will be taken for research purposes over the course of this study.

Other possible risks include that your protected health information will not remain confidential. However, many security measures are in place to ensure that this does not happen. Your blood sample will be stored in a locked freezer that only authorized personnel have access to. Your blood sample will be labeled with a code that does not identify who you are. Clinical information about you (including results of tests) that link you to your blood sample will be stored in a secured database that is accessible only to study personnel.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about rheumatoid arthritis. This study is not

designed to treat any illness or to improve your health. Also, there are risks as mentioned in the Discomforts or Risks section above.

Who is paying for this study?
This research is being paid for by the VA. There is no outside funding for this study.

Will I be paid for being in the study?
You will not be paid to be in the study.

Will I have to pay for anything?
There will be no cost to you for participation in this study. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be withdrawn from the study?
The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?
The Eastern Colorado Health Care System will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans and non-veterans. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, you may call Liron Caplan, MD, PhD at (720) 857-5103.

Who do I call if I have questions?
The researcher carrying out this study at the VA is Liron Caplan, MD, PhD at (720) 857-5103. You may ask any questions you have now. If you have any questions later you may call Liron Caplan, MD, PhD at (720) 857-5103. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call Colorado Multiple Institutional Review Board (COMIRB) office at (303) 724-1055. If you want to verify that this study is approved, please contact the VA Research Office at (303) 399-8020, ext. 2755. Information can also be found at http://www.clinicaltrials.gov.

Who will see my research information?
We will keep all research records that contain your identifiable health information, confidential to the extent allowed by law. Questionnaire data will be entered into a computer at the Denver VAMC and stored in a VA database on a secure VA server protected with passwords at the Dallas VAMC. Only study personnel will have access to this information. Paper copies of the questionnaires will be kept in a locked filing cabinet at the Denver VAMC.

Your blood and/or tissue sample(s) will not contain your name or other identifiable information and will be transported to an Omaha VA laboratory located at UNMC where the tissue bank is located. Blood samples will be stored in a confidential and secure manner and will be accessible only to study personnel. Study personnel will not have your name, address, phone number or any other information that will identify you. This process will insure that your information is being properly protected. Your blood sample will be stored indefinitely, according to VA requirements.

We will try to keep your medical records confidential, but it cannot be guaranteed. Records that identify you (including your medical records) and the consent form signed by you, may be looked at by the following people:

- Federal agencies such as the Food and Drug Administration (FDA) and the General Accountability Office (GAO) that protect research subjects like you, may also copy portions of records about you
- People at the Colorado Multiple Institution Review Board
- The investigator and research team for this study
- The sponsor (group paying for the study) or an agent for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. However, we will always keep the names of the research subjects, like you, private.

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

We will ask you to sign a different form that talks about who can see your research records. That form is called a HIPAA Authorization form. It will mention companies and universities who will see your research records.

You have the right to request access to your personal health information from the Investigator.

The HIPAA Authorization form that you will also be asked to sign will state when or if it expires. However, you may withdraw this authorization for use and disclosure of your personal health information by providing written request to the Investigator. If you withdraw the HIPAA Authorization form, the Institution, the Investigator, the research staff, and the research Sponsor will no longer be able to use or disclose your personal health information from this study, except so far as that they have already relied on this information to conduct the study.

A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. But, if you request disclosure, we can release the information. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). This study has been granted a Certificate of Confidentiality from the National Institutes of Health. This means we will also not scan the copy of your consent form or make a note that you have signed this consent form in your electronic medical record at the VA. Per VA Health Services Research and Development, we will still be entering some research data into your electronic medical record.

Is there other information I need to know?
Please read each sentence below and think about your choice. After reading each sentence, check "yes" or "no." If you have questions, please talk to your doctor or nurse.

I give permission for my blood and left-over tissues to be stored in a central tissue bank at an Omaha VA laboratory located at the University of Nebraska Medical Center (UNMC), to be examined in the future for inherited factors in the development of Rheumatoid Arthritis and to be used in future studies, such as to develop improved methods for Rheumatoid Arthritis treatment.

☐ Yes ☐ No ____Initials

A representative of the VA study personnel associated with this study may contact me in the future to take part in more research.

☐ Yes, I am interested in being contacted to participate in future studies. ____Initials

☐ No, I am not interested in being contacted to participate in future studies. ____Initials

Agreement to be in this study

I have read this form or it has been read to me. A member of the research team has explained the study to me and answered my questions. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told that I do not have to take part in this study. My refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Liron Caplan, MD, PhD at (720) 857-5103 during the day and at (303) 399-8020 after hours (ask for the rheumatologist on call). If any medical problems occur in connection with this study, the VA will provide the necessary medical care.

I choose to participate in this study. A copy of this consent form will be placed in my medical record.

Subject's Signature: _____ Date: _____

Print name: _____

Consent form explained by: _____ Date: _____

Print name: _____

Investigator: _____ Date: _____

Print name: _____

If Applicable: Witnessed by:_____Print Name:_____Date:_____