

**UNIVERSITY HOSPITALS
CLEVELAND MEDICAL CENTER**
CONSENT FOR INVESTIGATIONAL STUDIES
(v.09.2016) Form#2 Blood Drawing

Project Title: Pulmonary immune responses to *Mycobacterium tuberculosis*

Principal Investigator: Richard F. Silver, M.D.

Introduction/Purpose:

This study is designed to increase medical knowledge about the ability of white blood cells to migrate into the lungs of individuals who have been exposed to the *Mycobacterium tuberculosis* (*M. tuberculosis*), the bacteria that causes tuberculosis. For comparison studies involving lung cells, white blood cells are being obtained from the peripheral blood of several select groups. You have been asked to participate in this study because either:

- _____ A. You are a healthy, 18-50 year old non-smoker with latent tuberculosis infection (LTBI) as indicated by a positive tuberculosis skin test (PPD test or tuberculin test), or a positive tuberculosis blood test Interferon-gamma (IFN- γ) release assay (IGRA) test).
- _____ B. You are a healthy, 18-50 year old non-smoker and have **not** previously had a positive skin or blood test for tuberculosis.
- _____ C. You are a healthy, 18-50 year old non-smoker and you have previously been vaccinated with the tuberculosis vaccine BCG but do not have evidence of latent tuberculosis infection.

Please initial on the line below to indicate that you agree that the above checked statement best describes your volunteer status. _____

Print Name of Participant _____

The cells collected from your blood will be used in laboratory studies of tuberculosis. The bacteria that cause tuberculosis will be used only in the laboratory studies and you will not be exposed to it through your participation. The sponsor of the study is the National Institute of Health and the US Department of Veterans' Affairs Office of Research and Development. Approximately 500 volunteers will be enrolled from Case Western Reserve University (CWRU) and other Cleveland area medical and educational institutions, for participation in this study. There is a possibility that the investigators may become aware of new findings that may affect your willingness to continue participation. You will be informed of these new findings so that you may choose to continue or discontinue your voluntary participation.

Study Procedures

Blood drawing procedures will be performed in Dr. Silver's laboratory at the CWRU School of Medicine, or in the Dahms Clinical Research Unit (DCRU) of University Hospitals Cleveland Medical Center (UHCMC). Your blood will be obtained by insertion of a small needle into a vein in your arm. You will be told prior to the procedure exactly how much blood will be taken, but it will not exceed 8 ounces (240cc, or half of the amount of blood taken in a standard blood donation).

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You will be seated during the procedure; an area of skin on your arm will be washed with a small amount of alcohol. A tourniquet will be tied around your arm to make the veins in your arm easier to see and use in collecting the blood sample. A needle will be inserted into the vein and blood will be removed into one or more heparinized syringe(s) or directly into a vacuum-style blood collection tube. The tourniquet will then be removed and a bandage will be placed over the area where the needle was inserted.

It is essential that you inform the investigators if you are known to be anemic or have a low blood count, if you have recently had any episodes of bleeding or given blood for any reason in the past 6 weeks, or if you have been sick in any way in the past 2 weeks. If you have had any of these conditions, you will not be able to participate in the study at this time.

COLLABORATION AND SAMPLE SHARING:

The CWRU/UHCMC investigators participate in multi-center collaborations that also address the immune response to *Mycobacterium tuberculosis*. With your permission, they may share samples of your cells and/or results of studies performed with these cells with these collaborators. Investigators outside of CWRU and UHCMC will only obtain minimal information regarding your status as a subject (such as your age, race, and *Mtb*-infection status). They will not receive any identifying information such as your name, initials, date of birth, address or phone number. Please indicate below if you are willing to allow use of your samples in these collaborative studies in this way.

☐ Yes, I *will* allow CWRU/UHCMC investigators to share my cells samples and/or results of studies performed with these samples with other investigators.

☐ No, I *will NOT* allow CWRU/UHCMC investigators to share my cells samples and/or results of studies performed with these samples with collaborating investigators.

Genomic Research and Broad Sharing of Genomic Data:

As part of their research collaborations, CWRU/UHCMC participate in some projects that involve approaches known broadly as “genomics”. Genomic studies examine genetic differences across the entire set of human genes (the human “genome”). As part of this study we will be collecting information about your health and/or your individual genes. Our studies will specifically examine responses of your complete set of genes in terms of how they may provide potential protection from or susceptibility to the development of tuberculosis. In addition, if you agree, this data will entered into external scientific databases so that it can be broadly shared with other researchers

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performing genomic studies. For example, the National Institutes of Health (NIH, an agency of the U.S. government) requests that data obtained through NIH-funded studies be entered into the agency's "database of Genotypes and Phenotypes" or "dbGaP." Databases like this serve as preserved collections of all kinds of genomic data from studies conducted in the U.S. and around the world. The aim of assembling this information into organized collections is to allow qualified researchers to look for genetic connections for a range of topics in the future. Making data broadly available in this way means that your contribution and the data generated in this study could eventually be helpful in advancing other areas of scientific research also.

Traditionally used identifying information about you (such as your name, initials, address, or phone number) will NOT be included in these databases. De-identified genomic data generated in this study may be deposited in databases that will be publicly accessible via the Internet. Researchers with an approved study may obtain permission from the NIH to access and utilize your de-identified genetic, genomic and/or health information deposited in the dbGAP database. Strict safety measures are in place to protect the privacy of your information. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you or your family. The risk of this happening is very small but may grow in the future. Researchers will always have a duty to protect your privacy and keep your information confidential.

You can participate in this research study even if you do not want to have a sample taken for genetic studies. If you do not wish your data to be shared in this way, you may still take part in this research study and your data will not be submitted to an external database. Please indicate below whether you consent to the sharing of your data in this way.

☐ **YES, I DO** consent to having my genetic, genomic and/or health information submitted to an external database and broadly shared with other researchers

☐ **NO, I DO NOT** consent to having my genetic, genomic and/or health information submitted to an external database and broadly shared with other researchers

Risks

Your participation in this study may involve the following risks, the insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

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Benefits

There will be no direct benefit to you by your participation in this research study. Your participation in this study may aid in our understanding of lung immunity, specifically that related to *Mycobacterium tuberculosis*.

Alternatives to Study Participation

Because of the nature of this research the only alternative is to not participate in this study.

Financial Information

There is no cost to you or your insurance for participation in this protocol. You will be paid \$5.00 for each ounce (30 mL) of blood drawn. If you withdraw, or are withdrawn from the study, you will be paid for the portions that you completed. To receive payment you must agree to complete a W-9 form, which requires you to provide an address and social security number to the accounting department. The IRS may consider this payment to you taxable income. You will be issued a 1099-Misc form only if payment exceeds \$600 from all studies in which you are participating within a fiscal year.

Research-Related Injury

In the event that a research activity results in injury, you/your medical insurance may be charged for the cost of diagnosing and treating your condition. You may be responsible for co-pays or deductibles. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". To help avoid injury, it is very important to follow all study directions.

Confidentiality

Samples collected for this study will be identified by a study code number only, and not by your name or identifying information. The key to these codes will be maintained in Dr. Silver's locked office. Presentations or manuscripts reporting results of this project will not include any information that would allow you to be identified as a study participant.

Student/Employee Rights

Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor the will results be shared with your supervisor.

Termination of Participation

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The sponsor or the investigator of this study, without your consent, may discontinue your participation in this study. You will however, be compensated for the portions of the study that had been completed prior to the termination of your participation.

Privacy of Protected Health Information

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled “Pulmonary immune responses to *Mycobacterium tuberculosis*” and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, Dr. Richard Silver, and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally, the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you:

- Your age, gender, address, phone number, and ethnicity
- Results of tuberculosis skin testing (also known as tuberculin or PPD testing) and Quantiferon blood test
- The possible reasons for you having a positive tuberculosis skin test if known (such as occupational exposure to tuberculosis patients, having received a tuberculosis vaccine, etc)
- Limited medical information obtained specifically to confirm that you are an appropriate subject for inclusion in this study (including any history of prior smoking, of asthma or other lung disease, of adverse reactions to topical anesthetics, and of treatment with immunosuppressive medications)

This PHI will be used to confirm that you are an appropriate subject for participation in this study, and to allow the investigators to accurately determine how to classify you within the various categories of volunteers who are being studied in this project. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: the Principal Investigator and other staff from the Principal Investigator’s medical practice group and research staff; Members of the Data Safety Monitoring Board for this research study; University Hospitals, including the Center for Clinical Research and the Law

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Department; Case Western Reserve University, including the Research Staff of the Department of Medicine; the Institutional Review Board of the University Hospitals Cleveland Medical as well as any Institutional Review Board accrediting body; Government representatives or Federal agencies, when required by law, specifically the Food and Drug Administration, the Department of Health and Human Services, Office of Human Research Protections, the National Committee for Quality Assurance, and the Joint Commission for Accreditation of Healthcare Organizations.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study.

To revoke your permission, you must do so in writing by sending a letter to:

Richard F. Silver, M.D.
Division of Pulmonary, Critical Care, and Sleep Medicine
Biomedical Research Building, Room 327
Case Western Reserve University School of Medicine
10900 Euclid Avenue
Cleveland, OH 44106-4941

If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

Summary of your rights as a participant in a research study

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If you withdraw or are withdrawn by the Principal Investigator or study sponsors (with or without your consent), any completed portions of the study will be compensated as noted under the Financial Information section of this consent. If information generated from this study is published or presented,

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your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages. Because of the nature of this research the only alternative is to not participate in this study.

Disclosure of your study records

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Richard Silver can also be contacted at (216) 386-1151 or through the University Hospitals Operator at (216) 844-1000. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center's Research Subject Rights phone line at (216) 983-4979 or write to: The Chief Medical Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

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X	
	Date
X	
	Printed Name of Participant

Study personnel (only individuals designated on the checklist may obtain consent)

X	
	Date
X	
	Printed name of person obtaining informed consent