IRB NUMBER: 09-99-30.
IRB APPROVAL DATE: 9/9/2019
IRB EFFECTIVE DATE: 9/9/2019
IRB EXPIRATION DATE: 7/8/2020

# UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
## CONSENT FOR INVESTIGATIONAL STUDIES
**(v.09.2016) Form#5 Bronchoscopic Challenge**

**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 _____

To stimulate local immune responses, a small amount of the skin test material PPD will be placed into a localized portion of one of your lungs. PPD stands for "purified protein derivative" and is a sterile commercial preparation composed of proteins that have been purified from cultures of *Mycobacterium tuberculosis*. PPD is not infectious and does not contain living bacteria. The PPD used in this study is approved for other uses but is not approved for use in bronchoalveolar challenge. PPD is considered experimental in this study and is therefore, regulated by the U.S. Food and Drug Administration (FDA). The cells 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 chose to continue or discontinue your voluntary participation.

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## Study Procedures

THE PROCEDURE OF URINE PREGANANCY TESTING:

If you are a female, you will be given a small specimen up to take into a private restroom in order to give a urine sample. You will be asked to urinate into the cup and to bring the specimen back to a nurse or physician prior to participating in the bronchoscopy procedure.

GENERAL INFORMATION FOR ALL BRONCHOSCOPY PROCEDURES:

You have been invited to participate in this research study because you are a healthy, 18-50 year old non-smoker fitting our research criteria as indicated by the checked statement above. Subjects are asked to undergo a series of two bronchoscopy procedures for research purposes only. These will include an initial procedure in which PPD is placed in your lungs and a follow-up procedure 48 hours later. You may change your mind at any time and decide not to participate in any further procedures. If however, you are already certain that you do not wish to participate in this number of bronchoscopies, you should not enter into this challenge portion of the study. In addition, if you have previously developed a very large reaction to skin testing with PPD, meaning one in which the hardened area on your arm was larger than 1 inch (25 mm, or the size of a quarter) across, you should not undergo this procedure. Likewise, if your skin blistered or broke open after receiving a tuberculin skin test in the past, you should not undergo this procedure.

Bronchoscopy procedures will be performed in the Dahms Clinical Research Unit (DCRU) of University Hospitals Cleveland Medical Center (UHCMC). For each of the bronchoscopies, it is essential that you do not eat or drink for at least 6 hours prior to the procedure. Before he procedure, your nose, throat, and breathing tubes will be numbed with an anesthetic medication (called Xylocaine, or lidocaine) similar to that used by dentists. You will receive this medication by as an inhaled gas by nebulizer, as a solution to gargle, and by direct placement of a gel into your nose with a cotton-tipped swab applicator. IT IS ESSENTIAL THAT YOU INFORM THE INVESTIGATORS IF YOU HAVE EVER HAD AN ALLERGIC REACTION OR ANY ADVERSE RESPONSE TO LIDOCAINE OR SIMILAR ANESTHETIC MEDICATIONS.

The fiberoptic bronchoscope is a flexible instrument that is about as wide as a pencil and about 20 inches long. It has a light at one end and a channel through which medication or fluid can be placed into the breathing tubes and then suctioned away. The bronchoscope will be passed through your nose or mouth, across your voice box, and into your breathing tubes. You will not be able to speak while this instrument is in place. You may experience some coughing and the sensation of difficulty breathing. You will be closely monitored to assure that your breathing is adequate; extra oxygen and medication to relieve coughing and shortness of breath will be at hand. **You may signal the doctor that you want to stop the procedure at any time if you are too uncomfortable to continue.**

After each procedure, you will be watched in the DCRU for at least 30 minutes to assure that you are well. If you have experienced any side effects from the numbing medications or the procedure itself, you will be asked to remain in the DCRU until these symptoms have resolved. The physician performing the bronchoscopy procedure will decide when you may be discharged following the procedure. In order to prevent choking, you must not attempt to eat or drink until the effects of the numbing medications wear off (generally one to two hours after the completion of the procedure).

THE FIRST BRONCHOSCOPY PROCEDURE:

During the first bronchoscopy procedure, the doctors will first obtain a baseline sample of the cells from your lung by performing a washing of a portion of your lungs. The bronchoscope will be advanced into one of your lungs until a small region of the lung can be sealed off from the rest of the breathing tubes. Two ounces of sterile salt water will be washed into this segment of your lungs and then suctioned out. This will be done up to 4 times.

The doctors will then perform the immune-stimulating "challenge" procedure by advancing the bronchoscope into a small segment of each lung until the tube is again sealed off form the rest of the lung. The doctors will place salt water into a segment of one lung. The same amount of salt water containing a diluted preparation of tuberculosis skin test material PPD will then be placed into the matching segment of the other lung. The entire procedure of the first bronchoscopy will last 15-20 minutes.

Beginning the night of the first bronchoscopy, you will be asked to complete a symptom diary in which you will record your temperature as well as the presence and severity of any symptoms from a list of potential symptoms on a nightly basis for one week.

THE FOLLOW-UP BRONCHOSCOPY PROCEDURE:

The follow-up bronchoscopy procedure will be performed 48 hours after your initial procedure. Immediately prior to undergoing this second bronchoscopy, you will undergo a set of chest x-rays as well as provide blood work for clinical monitoring, as described in detail in consent form 4 (Clinical Evaluation).

Curing the follow-up bronchoscopy, the doctors will perform washings of the same areas in each of your lungs in which solutions were placed during the first procedure. The bronchoscope will again be advanced until a small region of your lung can be sealed off from the rest of the breathing tubes. Two ounces of sterile salt water will be washed into this segment of your lung and suctioned out. This will be done up to 4 times on one lung, and then repeated in the matching segment of the other lung. The procedure will last for 15-20 minutes.

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## 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 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 may withdraw consent for research use of genomic data or health information at any time. In this event, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be.

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

GENERAL RISKS OF BRONCHOSCOPY WITH BRONCHOALVEOLAR LAVAGE:

Your participation in this study may involve the following risks. During the bronchoscopy procedures, you can expect to experience some coughing and shortness of breath; this will be minimized by the use of the numbing medicine, and, if necessary, by the administration of oxygen. Irregularity of your heartbeat may occur, which is temporary and will also be minimized by the oxygen. You may have a sore throat, hoarseness, and some coughing for up to 24 hours after the completion of the bronchoscopy. Rarely fever or lung infection may result following the procedure.

YOU SHOULD NOT PARTICIPATE IN THIS STUDY IF YOU HAVE PREVIOUSLY HAD ANY TYPE OF ALLERGIC REACTION OR OTHER ADVERSE RESPONSE TO LIDOCAINE OR SIMILAR MEDICATIONS. Allergic reactions to the anesthetic medication (Xylocaine or lidocaine) can include the development of skin rashes and anaphylactic reactions (characterized by wheezing, shortness of breath, and shock). In addition, potential dose-related toxic effects of lidocaine include twitching, seizures, and depression of respiratory and cardiac function. As a precaution, medications for the treatment of allergic reactions including anaphylaxis are kept at the bedside during all bronchoscopy procedures. In order to prevent dose-related toxicity from lidocaine, procedure orders for this study include specific limits on the amount of medication that you may receive during a bronchoscopy. If the doctors find that you are experiencing unusual discomfort that cannot be controlled with standard amounts of lidocaine, the bronchoscopy will be stopped even if you are willing to continue. If this occurs, you will still receive full compensation for undergoing the bronchoscopy procedure.

The risk of participation is also greater for subjects who have a history of symptomatic asthma or other chronic lung diseases. Potential subjects with a history of prior asthma symptoms may participate in this study only if they are not currently on any medications for asthma (including “rescue inhalers” such as albuterol) and have not required any treatment for at least five years. You should report any history of

prior respiratory symptoms or diagnoses to the investigators so they can determine if it is safe for you to participate in this study.

Because all of the risks involved in participation in research bronchoscopy would be of even greater risk to a developing fetus than an adult subject, women who are or may be pregnant should not participate in this research procedure. You therefore should notify the investigators and withdraw from study participation if you are or may be pregnant. As an additional precaution, all female subjects will be required to provide a urine sample for an on-site pregnancy test within 48 hours of the time of their participation in this procedure.

RISKS OF BRONCHOSCOPIC CHALLENGE WITH PPD:

The goal of this procedure is to use PPD to cause a local inflammatory response in a portion of one of your lungs. Study of the cells that are involved in this response may help clarify how the immune system protects against the development of tuberculosis.

The procedure of bronchoscopic antigen challenge has been used for many years in the study of asthma. However, this research project is the first to use PPD in bronchoscopic challenge procedures in humans. The exact response of your lungs to challenge with PPD therefore cannot be known with certainty. At the time of placement of PPD into your lung, it is possible, although very unlikely, that you could experience an immediate allergic reaction (known as anaphylaxis). This could lead to wheezing, shortness of breath, and shock. In order to be prepared for this possibility, emergency medications to treat this reaction will be available at your bedside at the time the challenge procedure is performed. It is also possible that in several days following the placement of PPD into your lung, the resulting inflammatory response could become stronger or o a larger portion of your lungs than anticipated. If tis were to occur; you could develop more persistent cough, fever, chest pains, shortness of breath, or coughing up blood. If any of these symptoms were severe or persistent, it is possible that the investigators would place you on anti-inflammatory medications (such as cortisone or prednisone) that are known to suppress immune response to PPD. This medication would be provided by the investigators. **It is possible, but extremely unlikely, that the complications of an unusually strong response to PPD could result in permanent respiratory impairment or death.**

All precautions will be taken to minimize the risk of your participation, and only physicians experienced in performing fiberoptic bronchoscopy will participate in this study. In the event that you are concerned about any symptoms that develop following the bronchoscopy, you may reach Dr. Silver through the UHCMC operator at (216) 844-1000.

RISKS OF URINE PREGNANCY TESTING:

There are no physical risks involved in the procedure of giving a urine sample for pregnancy testing; however there are potential risks involved in the results of either a positive or negative urine pregnancy test. A positive urine pregnancy test could be inaccurate. If you are found to have a positive test, you be will be advised as to appropriate follow-up studies that would be required to confirm that you are

pregnant. You will also be excluded from further participation in this study unless further studies (usually a blood test for levels or pregnancy-related hormones) indicate the urine pregnancy test was inaccurate and that you are not actually pregnant. The unexpected findings of a positive pregnancy test could be emotionally stressful for you, as could waiting for the results of the confirmatory follow-up testing. Being a part of this study while pregnant may expose the unborn child to significant risks. If you are a woman of childbearing potential, a pregnancy test will be done, and it must be negative before you can enter this study.

## 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 for your time and effort for being in this research project. You will receive an additional $10 for undergoing urine pregnancy testing (if applicable). You will be paid $150.00 for undergoing each research bronchoscopy. You are free to change your mind for any reason and decide not to undergo the second bronchoscopy. If you do this, you will still receive $150 for the bronchoscopy procedures that you have completed. In addition, if any bronchoscopy in which you participate must be terminated for any reason prior to the completion of the research procedures, you will still receive full compensation of $150 for you participation.

You will also receive financial compensation for other procedures in which you participate that are in association with the bronchoscopic challenge, including blood drawing, clinical monitoring studies (blood work, chest x-rays, etc) and completion of the symptom diary, as detailed in the Clinical Evaluation consent form.

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, in 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

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 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.

[5]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, 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.

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## 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.

| | |
|---|---|
| X | |
| Signature of Participant | Date |
| X | |
| Printed Name of Participant | |

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

| | |
|---|---|
| X | |
| Signature of person obtaining informed consent | Date |
| X | |
| Printed name of person obtaining informed consent | |
| | |