Official Title:	A Phase I Single Site Open Label Clinical Trial for the Development of a Human BCG Challenge Model to Assess TB Drugs and Vaccines.
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Fred Hutchinson Cancer Center
University of Washington
Consent to Participate in a Research Study Called:

A phase 1, single site, open label clinical trial for the development of a human BCG challenge model to assess TB drugs and vaccines

MAIN CONSENT FORM

Principal Investigator:

James Kublin, MD, MPH.	Executive Director, CoVPN/HVTN, Fred Hutch	206-667-1970

Investigators:

Chetan Seshadri, MD	Associate Professor, UW Medicine	206-543-6709
E. Chandler Church, MD, MSc	Senior Fellow, HVTN/CoVPN Fred Hutch	206-667-6982
Thomas R. Hawn, MD, PhD	Professor, UW Medicine	206-616-4124
Jay Vary, MD, PhD	Associate Professor, UW Medicine	206-598-5065
David Sherman, PhD	Professor and Chair, UW Medicine	206-543-4547
M. Juliana McElrath, MD, PhD	Sr. VP, Fred Hutch/Professor, UW Medicine	206-667-6704

Emergency number (24 hours): Dr. Chetan Seshadri pager: (206)-559-0431

➢ Important things to know about this study

You are invited to participate in a research study. These are some of the things you should know about the study:

- Being in this research study is voluntary. Whether you join or not is your choice.
- The purpose of this study is to develop a challenge model using Tice® Bacillus Calmette-Guerin (BCG) which is a tuberculosis (TB) vaccine. A challenge model is a scientific method of measuring the immune responses in a person's body that protect them from a specific infection. We are developing this challenge model to evaluate the use of BCG for future studies of TB drugs and vaccines.
- In this study we are using the FDA approved TB vaccine, Bacillus Calmette-Guerin (BCG)
- In this study we are using the FDA approved antibacterial treatment Isoniazid (INH)
- You will have about 17 visits over about 6 months.
- We will collect blood at about 14 visits. You will receive study vaccine at one visit. If you are in group 1 you will receive an antibacterial drug at 3 visits. We will do a skin test at 4 visits, and a skin biopsy at 4 visits.

We will give you details about why we are conducting this study, the study procedures, and the risks and possible benefits of participating in this study. We will also give you any other information that you need in order to make an informed decision about joining this study.

Below is a more complete description of this study. Please read this description carefully.

➢ What is the purpose of this consent form?

Thank you for your interest in our research study. Please read this consent form or ask someone to read it to you. If you decide to join the study, we will ask you to sign or make your mark on this form. We will offer you a copy to keep.

It is completely up to you whether or not to join the study. Take your time in deciding. If it helps, talk to people you trust, such as your doctor, friends, or family. If you decide not to join this study, or if you leave it after you have joined, your other care at this clinic and the benefits or rights you would normally have will not be affected.

➢ Why have I been asked to take part in this research study, and who is in charge of it?

We invite you to join this research study because you are generally healthy and do not have human immunodeficiency virus (HIV) or TB, are 18 to 45 years old, and do not live or work with someone who is immunocompromised, including infants or pregnant people.

The researcher in charge of this study is Dr. James Kublin, (206) 667-1970.

Merck Sharpe & Dohme LLC is supplying the BCG vaccine for this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

➢ Why is this research study being done?

We are doing this study to develop a scientific method that will measure the body's immune response before, during and after an injection of the BCG TB vaccine taken with or without the treatment of Isoniazid (INH) which is an antibacterial drug that treats TB infection. We want to better understand the effects the BCG vaccine has on people's immune system.

➢ How many people will take part in this study?

About 10 people will take part in this study.

➢ What is the vaccine being used in this study?

The vaccine being used in this study is called Bacillus Calmette-Guerin (BCG). BCG is an FDA approved vaccine used to provide immunity, or protection against TB.

➢ What is the antibacterial treatment drug being used in this study?

In this study, we are using the FDA approved antibacterial drug Isoniazid (INH). INH is an FDA approved antibiotic that fights bacteria. INH is used to treat and to prevent TB.

➢ What will I have to do if I am in this study?

Before Entering the Study

To see if you can take part in this study, you will have a screening visit. The study staff will use information from the screening procedures to decide whether you can take part in the study.

Screening Procedures

If you want to join this study, we will screen you to see if you are eligible to join. You will be able to ask questions before deciding if you want to participate in this study. Screening involves a physical exam, and review of your health history. The study team will ask you about any medications you are currently taking including herbals, vitamins, and holistic/naturopathic medications. If you were born female and could become pregnant, we will test you for pregnancy.

A physical exam may include but is not limited to:

- Checking your height, weight, temperature, pulse and blood pressure
- Looking in your mouth and throat
- Examining your lymph nodes
- Listening to your heart and lungs
- Feeling your abdomen (stomach and liver)
- Asking about any vaccines you have gotten recently

We will do blood tests to screen for Pregnancy, HIV, Hepatitis B surface antigen, antibody to hepatitis C, Syphilis, and latent Tuberculosis (TB). Results of these screening tests must be negative in order for you to participate in the study.

We will also collect urine to test for pregnancy, Chlamydia, and Gonorrhea.

If you test positive for active hepatitis B, hepatitis C, Chlamydia, Gonorrhea, active or untreated Syphilis, we are required by law to report your name and your positive test results to the Seattle-King County Health Department. This will be done in a private manner.

If you test positive for HIV, the study staff will counsel you on your HIV infection and notifying your partner(s). As researchers, we are not required to report positive HIV tests to the health department. We are required to notify your primary care provider if we find you are infected with HIV. Your primary care provider would be required to report your name to the local health department when you seek his or her care.

If you were born female and are sexually active in a way that could lead you to get pregnant, you must agree to use birth control from 30 days prior to your BCG vaccination until 4 months after your BCG vaccination. You should not become pregnant during the study because we do not know how the study procedures could affect a developing baby. We will talk to you about effective birth control methods. If you join the study, we will test you for pregnancy before the BCG vaccination.

During the Study:

Clinic visits

If you meet the study requirements, want to join the study and your study clinician agrees, here is what will happen:

You will come to the clinic for scheduled visits about 17 times over about 6 months. The length of the visits will vary. Visits can last from 30 minutes to 2 hours.

During the study, or even after your last scheduled visit, we may ask you to return to the clinic for extra visits and/or laboratory tests and medical exams. We would do this, for instance if your laboratory results are not normal, if your BCG vaccination site does not have a well healed scar, or if you have a health issue.

We would ask you to return so that we may follow-up on the results of your original tests and/or medical exams and repeat these procedures as necessary for your health and safety. If we confirm you have a health problem, you will be referred to a local provider for appropriate care.

Being Assigned to a Group

There are 2 groups of participants in this study. We will give one group INH and the other group will not be given INH in order to measure the effect of INH on the immune response to BCG vaccine as well as the effect of INH on BCG itself. In this study, we use a computer program to decide which group you

will be in. If you join this study, you will not be allowed to choose the group you are in. You will have a 1-in-2 chance of being in either group.

The two groups are:

- Group 1 (INH): This group will take INH in either three 100mg tablets or one 300mg tablet for three days (Study Days 4, 5, and 6) after the BCG vaccination.
- Group 2 (Control): No INH will be taken.

Procedures:

In addition to giving you the BCG vaccine and NIH treatment, we will:

- Ask questions about your medical history, and medications you are taking.
- Do pregnancy testing if you were born female and can become pregnant
- Do physical exams, and vital signs
- Assess BCG vaccination site
- Collection of BCG vaccination site gauze/dressing
- Collect urine and blood samples.

Receiving the BCG Vaccination:

One intradermal (under the skin) injection of BCG will be given to all participants in the upper arm/shoulder or forearm region. Following the injection, we will ask you to remain at the clinic for about 30 minutes to monitor any injection site reactions or problems. Intradermal administration of BCG is an off-label use of the FDA approved BCG. The FDA approved application of BCG is via the percutaneous route that requires a special pronged device. BCG is administered most frequently outside of the U.S. via the intradermal route or subcutaneous routes.

If your BCG vaccination site does not have a well healed scar, then you will be asked to return to the clinic twice per/week from the day it is identified as abnormal until it has resolved.

Receiving INH (only for Group 1)

If you have been assigned to Group 1, you will take INH: oral tablets of either three 100mg tablets (total 300mg) or one 300mg tablet for three days after receiving BCG (Study Days 4, 5, and 6).

Self-monitoring and health status recorded on Memory Aid device

You will be asked to complete a daily electronic questionnaire called a memory aid, to help record any reactions you may experience during the study. The study team will send you a link daily to access the memory aid. You will be instructed on how to use the initial and on-going memory aids and how to measure and record any symptoms. It will be optional to record your oral temperature as well as the medications you are taking throughout the study. You will also be asked to record side effects and reactions to BCG such as: pain, tenderness and drainage, fevers, nausea, and vomiting. You will be asked to record your health status information using the memory aid from Day 1 until the end of the study at Day 114.

Blood draws

You will have blood draws for screening laboratory tests, clinical safety tests, and measurement of immune response to BCG throughout the study.

When we take blood, the amount will depend on the lab tests we need to do. It will be some amount between 6.5mL and 138mL (a little more than 1 teaspoon to about a half cup) depending on the visit.

Your body will make new blood to replace the blood we take out. To compare, people who donate blood in the US can give a total of about 500mL in an 8-week period.

Skin biopsy

A 4 mm (about the size of a grain of rice) skin biopsy will be taken at the BCG vaccination site 4 times during the study to measure the level of BCG in the skin. A study clinician will perform the procedure known as punch biopsy of the skin. A punch biopsy is a surgical procedure performed following the administration of local anesthesia (lidocaine). A small piece of skin at the BCG vaccination site will be removed. The area of the biopsy will be closed using gel foam. We will ask you not to swim in chlorinated water until the gel foam has sufficiently closed the biopsy area.

If you do not agree to this skin biopsy, you will not be able to participate in the study.

Photographs

We will take photographs of the BCG vaccination site after the BCG vaccination at 7 different clinic visits. If there are any abnormalities or the vaccination site does not have a well-healed scar, we will continue to take photographs once per week until it has resolved. We will take a final photograph of the BCG vaccination site for all participants at Visit 17 or if you leave the study early. We will not photograph your face or other identifiable markings. These photographs will be stored confidentially in the research record.

PPD Skin Test

Purified Protein Derivative (PPD) is a skin test to determine if you have TB. A small shot that contains PPD is given under the top layer of your skin. You may feel a slight sting. A bump or small welt will form, which usually goes away in a few hours. After 2-3 days you must return to the clinic to have the area checked to see if you have had any reaction to the PPD.

The test will be performed up to two times during the study. The first test will be at Visit 14 and checked by the clinician at Visit 15. If the first PPD skin test is negative, then the second PPD skin test will be done 2 weeks later at Visit 16 and checked by the clinician at Visit 17. If either test is positive, we will draw your blood to distinguish between a true TB infection or false positive result due to BCG vaccination.

Abnormal BCG Vaccination Site Procedures

If an abnormal vaccination site is identified as not having a healed scar, or has an open and draining ulcer, then you will be asked to return to the clinic twice per/week until it has resolved.

Withdrawal Procedures

If you decide to withdraw from the study early, we will ask you to complete visits 14-17. These visits will be scheduled according to when your dose of BCG was given. If you cannot complete visits 14-17, you will be asked to complete the end of study visit 17 procedures.

The table below shows the schedule of clinic visits during the study.

Clinic Visit	**1** (Screening Visit)	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**
Day	**-42 to -1**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**8**	**15**	**28**	**56**	**84**	**98**	**100**	**112**	**114**
Week	**0**								1	2	4	8	12	14		16	
Study Drugs		**BCG**				**INH****	**INH****	**INH****									
Informed Consent	X																
Medical History	X																
Height, weight: BMI	X																
Blood Draw	X	X	X	X	X	X			X	X	X	X	X	X		X	X
Urine Collection	X																
Pregnancy Test (blood)	X																
Pregnancy Test (urine)		X															
Physical Exam & Clinical Assessment	X					X*			X*	X*	X*	X*	X*				X
Injection		X															
INH Administration						X	X	X									
Skin Biopsy					X				X	X		X					
Injection Site Evaluation		X	X	X	X	X	X	X	X	X	X	X	X				
Health Status & AE / SAE Review		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Medication Review	X					X	X	X	X	X	X	X	X	X	X	X	X
Memory Aid eCRF			X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Photographs of Injection site						X			X	X	X	X	X				X
PPD skin test / Assessment														X	X	X	X
Dressing / gauze Collection			X	X	X	X			X	X	X	X	X				
Compensation	$50***	$75	$50	$50	$100	$50	$25	$25	$100	$100	$50	$100	$50	$50	$25	$50	$50

* Only if applicable if indicated based on review of interim medical history and previous clinical assessments
** Only if you are in Group 1
*** $50 for the completion of the screening visit, this visit could occur over multiple days.

➢ What if I choose to leave this study?

You are free to leave the study at any time and for any reason. Your care at this clinic and your legal rights will not be affected, but it is important for you to let us know.

If you withdraw from the study during the follow up stage, we will ask you to come back to the clinic for the End of Study visit procedures within 7 days, but ≤ 30 days, after the dose of BCG.

➢ Can the researchers take me out of this study?

The researchers could take you out of this study at any time. This would happen if:

- They think it is in your best interest not to continue in the study.
- If you are a female who becomes pregnant.
- You are not able or willing to follow study procedures.
- The whole study is stopped.

If you withdraw from the study for any reason, previously collected information will remain in the study records and will be included in the analysis of results. This information could not be removed from the study records.

➢ What are the risks and inconveniences of this study?

In this part of the consent form, we describe the side effects we expect from the tests, procedures, and treatments in this study. BCG TB vaccine and/or INH could cause side effects we do not know about yet. We carefully watch everyone in the study for side effects.

If you join this study, we will tell you if we discover new side effects that could affect you.

This form lists side effects of *individual* drugs. Other side effects could occur when we use these drugs *together*.

Side effects may be mild or very serious. Medicines could be given to help lessen side effects. In some cases, side effects can last a long time or never go away.

Risks of the BCG Vaccine

The BCG vaccine continues to be the most widely distributed vaccine worldwide, generally provided to infants immediately after birth, so it is safe and well tolerated.

Typically, most people will develop a small swelling (nodule) at the vaccination site that can break open, release pus or blood-tinged discharge, and form an ulcer the size of a dime. The ulcer will heal over a period of weeks and forms a scar that remains for life. Occasionally, lymph nodes around the vaccination site can become tender to touch. "Flu-like" symptoms that are common to many vaccines includes fevers, chills, loss of appetite, muscle aches, and generally not feeling, which can last 1-2 days.

A very small number of people (1 in 4 million) have an immediate allergic reaction to BCG. Symptoms include rash, swelling around the mouth, and difficulty breathing. These can be treated with emergency medications. If severe, they can cause death.

A very small number of people (1.56 to 4.29 cases per million) may have a disseminated BCG infection. These occur most frequently in people who are immunosuppressed, which is why people with immunosuppression should not participate in this study. This infection can be treated with medications.

You may develop a false positive tuberculin skin test (PPD) that will complicate the early diagnosis and treatment of latent (inactive) TB. However, a diagnosis of latent TB can be

confirmed by other methods, including a clinical examination, chest x-ray, and blood test (QuantiFERON®-TB Gold Test).

You may experience:

- Pain, swelling, redness, and/or itching caused by the intradermal injection,
- There is a slight chance of getting an infection at the intradermal challenge site.

Risks of Isoniazid (INH)

You may experience some side effects that include:

- Numbness and tingling in the arms and legs,
- Inflammation of the Liver / Hepatitis (symptoms include loss of appetite, nausea, vomiting, fatigue, malaise, and weakness),
- Nausea with or without vomiting
- Upset stomach
- Rash.

You will be closely monitored by study staff and necessary treatment will be administered to alleviate symptoms that may occur.

Risks of Skin Biopsy

This procedure generally is safe, but certain risks accompany any surgical procedure.

Risks associated with punch biopsy of the skin include:

- Local bleeding and bruising in the surrounding tissues,
- Pain associated with the surgery or the healing process,
- Excessive scarring at the surgery site,
- Allergic reaction to the numbing medicine (lidocaine), gel foam or the surgical instruments,
- Local infection in the surrounding tissues,
- Damage to structures beneath the skin such as an artery or nerve.

Risks of PPD Skin Test

You may experience:

- Pain, swelling, redness, and/or itching caused by the PPD injection,
- Allergic reaction to the agent,
- There is a slight chance of getting an infection at the site.

Risk of Blood Draw

- Pain, swelling, or redness, caused by the insertion of the needle,
- Nausea/light headedness and there is a slight chance of fainting,
- There is potential for an infection at the needle insertion site.

Risks of Lidocaine

May cause mild discomfort when injected, skin discoloration or an allergic reaction.

Possible Risks Related to Allergic Reactions

As with all vaccines or drugs, you could have an allergic reaction, like a rash, hives, or even difficulty breathing. *Allergic reactions can be life threatening.* When they occur, it is usually soon after the vaccination or study drug dose. Therefore, the study staff will give you treatment if you need it.

Risk of the Loss of Confidentiality

There is a chance of the loss of your confidentiality. Each member of the research team has completed human subjects protections, and HIPAA and confidentiality training. Your information will be stored in secure buildings under password protected computers to protect your identifiable information.

Reproductive Risks

Taking the BCG vaccine and INH may involve unknown risks to an embryo, fetus (unborn baby) or nursing infant. Therefore, you should not join this study if you are pregnant, if you are planning to become pregnant, or if you are breast-feeding.

If you join this study, you will have to use an effective method of birth control from the time this form is signed until at least 4 months after the last dose of BCG vaccine and INH. If you are already using a method of birth control, you will have to check with the study team to make sure it is acceptable.

If you became pregnant after joining this study, you would have to notify the study team immediately. You will be asked to complete the visits 12-15.

The effects of the BCG vaccine and INH on fathering a child are also unknown.

➢ Are there benefits to taking part in this study?

We do not expect a direct health benefit to you for participating in this study. Even though you are TB negative, we hope to see if INH is an effective treatment for those who have TB. We hope the information from this study will give us insight on the TB drugs and vaccines given to individuals who have TB. This will help us in the development of better drugs and vaccines to help other people with TB in the future.

➢ What other choices do I have besides this study?

You may choose not to participate in this study. Other services you receive at this institution will not be affected. If you choose not to join this study, you could join another study if one is available and you are eligible. You could also choose not to join any study.

➢ Will I receive any payment?

You will receive compensation per study visit based on which procedure(s) are being done. The compensation is as follows:

- $50 for the completion of the screening process
- $25 for scheduled visits without blood collection
- $50 for scheduled visits with blood collection
- $75 for completion of the BCG vaccination visit
- $100 for completion of visits with skin biopsy procedure
- $25 for any unscheduled visit without blood collection
- $50 for any unscheduled visit with blood collection

The compensation you receive for being in this study may be considered taxable income. This happens if we pay you more than $600 between January 1 and December 31 of the same year. The study staff may collect your name, address, and social security or tax ID number for tax purposes. This information may be shared with the accounting department at Fred Hutchinson Cancer Center and the US Internal Revenue Service (IRS). We will not share the name of this study or nature of the research with these groups.

➢ Protecting Your Privacy / Who has access to my research records?

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Fred Hutchinson Cancer Center Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center.
- Office for Human Research Protections, and other regulatory agencies as required.
- Merck Sharpe & Dohme LLC and the people who work for them

All reviewers will keep your records private. We cannot guarantee absolute privacy. If you have a medical condition that we are required to report by law, then some of your information may be shared. At this clinic, we have to report the following information:

- Hepatitis B and Hepatitis C, and sexually transmitted diseases
- We suspect you may be harming yourself or others or planning to do so

If your confidential information is released, you will be told.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

➢ How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevents health insurance companies or group health plans from:

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

➢ What are the costs to me?

You do not have to pay anything to be in this study.

➢ What happens if I am injured?

For a life threatening problem, call 911 right away or seek help immediately. Contact the study team when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Dr. Chetan Seshadri (UW Pager 206-559-0431 or cellphone 206-660-0118). They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds

to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You will not lose any legal right to seek payment for treatment if you sign this form.

➢ What will my information and samples be used for?

Your information and tissue samples (such as blood) will be used for the purposes of this study.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

Test results would not affect your care, so we do not plan to return results to you.

In addition, be aware that by agreeing to participate in this study, your information or tissue samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

➢ We invite you to donate tissue and blood samples for other research.

After we do tests on samples in this study, some samples may be left over. We invite you to donate these leftover samples for future research. This may include genetic research.

If you join this study, you will not have to donate samples for future research. You would be free to say "yes" or "no." Regular medical care would not change if you say "no."

If you donate samples, they would be stored in a secure location. If we want to use your samples for other research or share it with other scientists for research, an ethics review committee (IRB) would review the request. The IRB would decide if we need to ask you for permission to do the research.

Your donated samples will be used only for research. This research could be done by for-profit companies. Researchers would not report their results to you or your doctors. The research results would not be included in medical records. The results would not affect your medical care.

Research with these samples might help develop new products. If these products make money, there is no plan to share the money with the participants who donate their samples.

If your samples are released, your identity remains confidential. Your personal information stays with the study site that collected the sample from you. Each sample contains only 4 pieces of information:

- A participant ID number
- The type of specimen inside the tube
- A visit number
- A specimen collection date

If you donate samples for research, you could withdraw the donation at any time by calling Dr. Chetan Seshadri at 206-543-6709 (seshadri@uw.edu). You would have no penalty for

withdrawing the donation, and regular medical care would not change. We could not return donated samples, but we might be able to destroy them. We could not destroy samples if they are stored or shared without any label saying who donated them. In this case, it could still be used for research.

➢ What are my rights as a research subject?

- You do not have to join this study. You are free to say "yes" or "no".
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we will tell you.
- If you join this study, you will not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.
- If you decide to drop out, we would want you to tell the study team. You and the study team could talk about the follow-up care and testing that would help the most.
- Before you leave the study, the study team would ask you to complete the End of Study procedures.

What are my responsibilities as a research subject?If you join this study, you will have some responsibilities.

- Follow the schedule of study visits and procedures.
- Take study medications as directed.
- Prevent pregnancy.
- Tell us about side effects.

- **Who should I call if I have questions or research study problems?**

For Questions About	Please Contact
This study (including complaints and requests for information)	Dr. Chetan Seshadri 206-543-6709
Your rights as a participant in a research study	Director of Institutional Review Office of the Fred Hutchinson Cancer Center: (206) 667-5900 or irodirector@fredhutch.org
A research related symptom or injury	Dr. Chetan Seshadri 206-543-6709
What if I need emergency care?	Emergency (24 hour) phone: (206) 540-9680

Earlier in this consent form, we told you about possible other uses of your extra samples and information outside this study. **Please choose only one of the options below and INITIAL** next to the option you choose. Whatever you choose, the research team will keep track of your decision about how your samples and information can be used. You can change your mind after signing this form.

_____ **Yes, I agree** to allow my extra samples and information to be used for other studies related to TB, vaccines, the immune system, and other diseases. This may include genetic testing and keeping my cells growing over time.

OR

_____ **Yes, I agree to the option above and also agree** to allow my extra samples and information to be used in genome wide studies.

OR

_____ **No, I do not agree** to allow my extra samples to be used in any other studies. This includes **not** allowing genetic testing, growing more of my cells, or genome wide studies.

I also give permission to the people and organizations connected with this research study to review and copy my research records, both during and after the study.

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date/Time

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date/Time

IR File: 10903
Copies to: Participant, Researcher