Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____ Participant study ID# _____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is funded by the National Institutes of Health (NIH).

Key Information About This Research Study

Principal Investigator:	Eric R. Houpt, Division of Infectious Diseases, Box 801340, University of Virginia, Charlottesville VA 22908, 434-243-9326
Sponsor:	NIH

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team.
You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

This study is trying to find out more about nontuberculous mycobacteria (NTM), how to treat patients with NTM and the importance of NTM in the home environment.
You are being asked to take part in this study because a respiratory specimen submitted by your doctor revealed NTM, making you eligible to participate in this study.

Why would you want to take part in this study?

You will not be helped by being in this study, but the information gained by doing this study may help others in the future.

Why would you NOT want to take part in this study?

You might not want to take part in this study because you may not wish to have environmental samples taken of your home environment and you may not wish to be followed every three months for up to five years.

What will I have to do if I take part in this study?

Full details of all the procedures are found later in this form.
If you take part in this study you will allow

- analysis, and storage of sputum or other respiratory samples collected as part of your clinical care for this illness,
- collection of additional sputum and blood samples,
- review of medical records, including images of x-rays and CT scans,
- environmental sampling of your household,
- study questionnaires,
- phone calls every 3 months for up to five years.

In addition, if you are beginning antibiotics for NTM for the first time or if you have been on antibiotics for NTM for less than 5 years, you can also participate in the pharmacokinetic sub study. This sub study includes having blood drawn on two different days during the study.

What is the difference between being in this study and getting usual care?

All of the procedures done in this study are done in addition to your usual medical treatment for NTM. Your usual medical treatment will not be changed or affected by participation in this study.

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

STUDY PROCEDURES for Research

If you agree to be in the study, you allow the researchers to retrieve samples from the lab that processed your NTM test from a respiratory specimen, obtain results of your NTM test from the Virginia Department of Health and to collect medical information related to your NTM illness from your medical records. If you are not a patient at UVA, you will be asked to sign a release of medical records form so that your health care provider may share information about you with the UVA study team. We will ask you to collect samples from your household environment to test for NTM.

All participants:
If you receive clinical care for your Mycobacterium illness at UVA, a study team member may meet with you to review the study requirements. If your local doctor provides your care, or you

couldn't be seen at UVA while you were in clinic, a study team member will call you to review the study requirements.

- After consenting for the study, we will ask you general questions about yourself and your medical history. We will also ask questions regarding your household environment.
- A Quality of Life questionnaire (QOL-Bronchiectasis) and QOL-B NTM module, plus a Bronchiectasis Health Questionnaire (BHQ) will be administered (either in person, over the phone, or by email) at enrollment and every 6 months thereafter for up to five years. These questionnaires will ask you how you have been feeling and they will also have questions about your NTM symptoms. Environmental household testing at time of study enrollment (within 2 months) and, if your NTM infection recurs, at time of recurrence (within 2 months). UVA will give or send a kit of supplies and instructions to you so that you can collect samples from possible NTM sources in your home environment such as a showerhead, faucets, and soil. If you are unable to collect the samples, a member of the UVA study team can help collect the samples, observing UVA COVID precautions.
- If your respiratory sample is not available from UVA lab or your local lab, we will ask you to try to provide a sputum sample in a cup and return it by mail to UVA. The collection cup and instructions for collection, and how to send the sample back to UVA will be sent to you..
- We will also be collecting your medical records related to your NTM, any sputum culture results and CT scan results from the last 2 years (if applicable) after you have signed this form.

Optional pharmacokinetics:

You may participate in the optional pharmocakinetics study if you agree and if you are selected. Based on short duration of current antibiotic course. This will check how much the antibiotic gets into your blood. It involves three blood collections on the same day two different days during the study.

- During the first month (+30 days) after enrollment:
  Blood draws at these times after you take your prescribed antibiotics
  - 2 hours (+/- 30 min.) 1 tube (1 1/2 teaspoons)
  - 4 hours (+/- 30 min.), 1 tube (1 1/2 teaspoons)
  - 6 hours (+/- 30 min.), 1 tube (1 1/2 teaspoons)

  The total amount of blood will be 1.5 tablespoons.

- Approximately six months after starting treatment:
  Blood draws at these times after you take your prescribed antibiotics
  - 2 hours (+/- 30 min.), 1 tube (1 1/2 teaspoons)
  - 4 hours (+/- 30 min.), 1 tube (1 1/2 teaspoons)
  - 6 hours (+/- 30 min.) 1 tube (1 1/2 teaspoons)

  The total amount of blood will be 1.5 tablespoons.

_____**yes/no/NA**(not applicable) to indicate your choice about participating in the optional pharmacokinetic (PK) sub-study.

Clinical care for your mycobacterial illness provided by your local doctor or UVA generally includes visits every few months for medical care and collection of sputum samples as part of standard of care for NTM. These visits are not part of the research, but medical information and lab and diagnostic results obtained from these visits will be used for this study.

FOLLOW UP:

Every three months for up to five years, a study team member will contact you to follow up on how you are doing. These contact will take about 30 minutes.

- You will be given the symptom questionnaire's every 6 months for up to 5 years so we can see if there are any changes in your symptoms.
- We will review your medical records, which will include, any sputum culture results and CT scan results that have occurred since your last visit/contact.
- We may need to collect a NTM respiratory sample. If a recent NTM culture is not available from the UVA lab or local lab, we will ask you to provide a sputum sample in a cup and return it by mail to UVA. The collection cup and instructions will be mailed to you with return instruction and supplies.

Study Schedule

	Visit 1 (Screening/Baseline)	**Visit 2**	**Visit 3**	**Visit 4 (Follow-up)**	**As needed**
Study Week	0	Month 1 (within 30 days)	Month 6 of treatment (within 30 days)	Every 3 months for 5 years	
Informed Consent	X				
Review study eligibility	X				
Medical records review, including lab and diagnostic results	X			X	
Symptom Questionnaires	X		X	X*** (every 6 months)	
Obtain sputum sample	X*				X*
Environmental sampling of household	X within 2 months				X** within 2 months

Blood draw (for PK study participants only)		X	X		
Call or check-in at clinical care visit				X	

**Sputum sample may be collected if sample obtained for clinical care is unavailable from local lab*

*** Additional environmental samples may be collected if there is recurrence*

****Every 6 months after the enrollment visit*

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You must participate in each study visit.
- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.

How long will this study take?

For all participants, this study will require about 20 study visits over five years. The initial visit will last about 1.5 hour. This visit will consist of review and signing this consent form, NTM medication review (if applicable), medical questions, study specific questions, and a Symptom Questionnaire. Each Follow Up visit will last about 40 minutes by phone or in clinic, if you receive clinical care at UVA. If your sputum or respiratory sample is not available from the lab, you will be provided a cup and shipping supplies to send a sample to UVA at no cost to you. Collection of samples from your household environment will take about 1 hour. This will occur once during the first two months of your study participation. If you have recurrence of your NTM infection, we will ask you to repeat the household samples.

For prior and newly diagnosed patients starting antibiotics for NTM, there will be two more visits to draw blood to measure the amount of antibiotics in your blood. The first visit will be about one month after you are enrolled in the study and the second visit will be at six months after starting treatment. The study visits require drawing a total of 1.5 tablespoon of blood on each visit day, once at two hours, four hours and then at six hours after taking the antibiotics for NTM. A total of 3 tablespoons of blood will be taken over the entire study.

If you want to know about the results before the study is done:

Your doctor may obtain sputum from you periodically for routine clinical care, however If the study needs to obtain any additional sputum from you for Mycobacterium culture, we will notify your doctor of those Mycobacterium culture results.

If you want to know about the results before the study is done:

During the study you are having a tests done for determining the level of antibiotic in your blood and environmental sampling of your household. PK (level of antibiotic in your blood) samples will be analyzed in batches. It is not standard clinical practice to obtain these results or modify therapy based on these results, so we will release these results only to your physician if specifically requested. Environmental samples that identify Mycobacteria will be reported back to you, if you wish to have these results. However, the final results of the environmental testing will not be known until all the information from everyone is combined and reviewed, so these environmental testing results will not be reported until the end of the study. It is important to recognize that NTM live throughout the natural environment, so it would not be surprising if NTM are detected in any household environment, and therefore there is currently no evidence that recommends one attempt to remove any NTM from one's environment.

Collection of Samples and Health Information for Genetic Research and/or Specimen Banking

What Sort of Research Will Be Done On Your Sample(s)?

You are being asked to provide samples of your blood, sputum and household environment to be used for research. Environmental samples from your home may include samples from showerheads, sink faucets and drains, garden hose, water heater, indoor potted plant, outdoor soil, refrigerator icemaker, hot tub, humidifiers and/or ponds. Along with specimens, researchers may need to collect some health information about you. Combining information from the specimen with information from your health records may be useful for this research. For this research, the following types of information could be included: medical history, medications and treatments, clinical information including diagnoses, lab and diagnostic test results (such as CT scan reports and images) and environmental testing results.

We plan to do genetic research on the DNA from your sputum or respiratory and environmental samples and their Mycobacterium. DNA is the material that makes up the genes in the cells of all living things.

In addition, as part of your participation in this study, specimens collected for research will be added to a research specimen bank. The purpose of a specimen bank is to process, and store samples until researchers need them for future research. The long-term goals of the samples collected in this bank will be mainly used for research on Mycobacterium. It is not possible to list every research project that will include the samples because we cannot predict all of the research questions that will be important over the coming years. As we learn more, new research questions and new types of research may be done.

What will you have to do to give samples for research?

<u>For all participants:</u>

Environmental samples from your household will be collected for research once during the first two months you are in the study and may be repeated if your NTM recurs.

You may be asked to provide a sputum sample, at the beginning of the study, if the study team is not able to obtain the sputum sample last completed at your local physician's office.

If you have a recurrence of your NTM, you may be asked to provide a sputum sample, if the study team is not able to obtain the sputum sample last completed at your local lab.

For study participants beginning antibiotics for NTM:
In addition to the collection of environmental samples, blood will be collected at Month 1 and Month 6.

After the tests for your medical care are completed, there may be samples left over. Normally, these leftover samples would be thrown away. We are asking you to allow us to collect this leftover material for genetic research and/or specimen banking.

How Will Your Sample(s) Be Labeled?
Your sample(s) will not be labeled with your name or other information that would identify you directly. Instead, it will have a unique code that allows for it to be linked to some of your health information. This link means that your specimen can be identified but only indirectly. We can find out if we need to know which sample is yours in the event you wish the sample to be removed at a later date.
This research specimen bank is located at the University of Virginia under the leadership of Dr. Eric Houpt. There is no set limit to the number of people who will provide samples to this bank.

Which researchers can use your samples and what information about you can they have?
Your sample may be shared with researchers at the University of Virginia and at other institutions or with the sponsor.

Dr. Houpt will not give your name to other researchers who want to use your sample, but will only give them information like your age and what disease/condition you have. Those who would see the information would include researchers and the others listed under "Who will see your private information?" section of this consent document.

Some of the people who receive your information may not have to follow the privacy laws and may share or release your information because they do not have to follow the privacy laws.

What Are the Benefits To Donating Your Sample(s) For Genetic Research and/or Specimen Banking?
The genetic research and/or specimen banking that is done with your sample is not meant to help you. But, doctors hope that in the future it will help people who have other diseases or conditions.

What Are The Risks of Donating Your Sample(s) For This Study?

Risks to Privacy from Genetic Research and/or Specimen Banking:

The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else without your permission is very small. However, we cannot *guarantee* it will be safe. To further safeguard your privacy, information obtained from future research will not be placed in your medical record.

There are certain risks of having health information given to other people by mistake. In the unlikely event that this happens, it could cause discrimination or mental harm to you or your family members if others were to see this information. The results could be that you may not be able to get or keep certain kinds of insurance. It could also hurt family relationships.

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and
- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV, we will tell you the results and help you understand what the results mean for you.

Will You Find Out the Results of the Research on Your Sample(s) for Genetic Research and/or Specimen Banking?

Neither you, your health care provider**,** nor anyone in your family, will receive the results of any research done on your blood sample(s). The results will not be put in your health records. Therefore, results from any research done on your blood sample(s) will not affect your medical care. Results of environmental testing will be provided to you, if you wish, at the end of the study. Results from sputum testing, if collected, will be provided to your physician.

What If You Change Your Mind About Donating Your Sample(s) for Genetic Research and/or Specimen Banking?

If you decide now that your sample(s) can be kept for genetic research and/or specimen banking, and later change your mind, you can simply withdraw the sample(s) at that time. To withdraw you will need to write to the Principal Investigator listed on the first page of this form. We will then destroy any of your tissue that has not already been used. However, if your sample has been used in genetic research, the information that we have learned will remain in the study, even if you withdraw. Unless you withdraw from the study, permission for

researchers to use your tissue and to use and share your private health information for this study will never end.

Will You Be Paid For Donating Your Sample(s) for Genetic Research and /or Specimen Banking?

You will not be paid to donate your sample(s) for genetic research and /or specimen banking.

Will Donating Your Sample(s) Cost You Any Money?

There is no cost to you to have your samples collected or used for genetic research and/or specimen banking.

Specimen Banking

To participate in this research you must agree for specimens to be collected for banking for future studies. No matter what you decide to do, your decision will not affect your medical care.

Could you be helped by being in this study?

You will not benefit from being in this study. However, the information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study since this study does not involve treatment for your illness. The usual treatment would include antibiotics or treatments prescribed by your doctor.

If you are an employee of UVA your job will not be affected if you decide not to participate in this study. If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

If you participate in the blood draw part of the study, you will be paid a $50 gift card on each day blood is drawn, for a total of $100. If you are <u>not</u> in the PK sub-study, you will not be paid for your participants.

You should get your gift card payment on the days blood is drawn.
By agreeing to be in this study, you are donating your blood, bodily fluids, tissue samples and environmental samples for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

All of the procedures in this study will be provided at no cost to you or your health insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this observational study when having your blood drawn, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader or the sponsor of this study can take you out of the study. Some of the reasons for doing so may include:

a) You do not follow your doctor's instructions
b) The study leader or sponsor closes the study for safety, administrative or other reasons

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include HIV/AIDS records.
- Tissue, bodily fluids or blood or environmental samples for genetic testing of the mycobacterium for this study

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly

- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors or collaborators , researchers at other sites conducting the same study, and government agencies that provide oversight If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Information about you and/or samples from you will be given to Virginia Tech without identifiers such as name, address, phone #. Other collaborators and researchers outside of the University of Virginia will only receive information about you or your samples after all identifiers have been removed.

Some of the people outside of UVA who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.
Information collected as part of this study may be shared with the research community as required by NIH (the sponsor) with any identifying information about you removed before sharing.

Information and samples obtained from you during this study may be used in future research. Your information and samples may be shared with other researchers inside or outside of the University of Virginia.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA will not use it in the following cases.

- You have agreed in writing to allow UVA to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.
- Reports to authorities if you have an infectious disease that health care providers are required to report by law.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the Principal Investigator to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Eric Houpt, MD
Division of Infectious Diseases, Box 801340,
University of Virginia, Charlottesville VA 22908 Telephone: (434) 243-9552

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483, Charlottesville, Virginia 22903 Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Would you like the study team to communicate with you by email or text message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

___ By initialing here, I opt out of email and/or text message communication.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **Subject** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **Subject** freely gave their informed consent to participate in this trial.

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early the study leader will keep the data collected about you up until the time you leave the study to help determine the results of the study.

____ I am withdrawing my consent for this study. No additional information may be collected about me including from phone calls/interviews and follow up information from my medical records.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE