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_____Medical Record # _____

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What is the purpose of this form?

This form will help you decide if you want to be in the research study. You need to know about the study before you can decide if you want to be in it. 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 the study.

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

If you participate, please keep this form so that you can refer to it during the study. This form will tell you what to expect, what you need to do to participate, and what tests will be done during the study.

Who is funding this study?

This study is being funded by a grant awarded to the University of Virginia by the National Institute of Allergy and Infectious Diseases.

Why is this research being done?

Often when people with asthma get a cold virus, they also get a worsening of their asthma symptoms. Our immune system is the part of our body that works to fight infection.

The purpose of this study is to evaluate how the immune system responds after being exposed to an experimental cold virus called Rhinovirus (RV)-16. There are many different strains of rhinovirus, which is why children and adults can get many colds during a lifetime.

We will be testing whether immune responses are different among people with allergic asthma or allergic rhinitis as compared to people without asthma or allergies. This information may help to explain why viral colds can cause a worsening of asthma.

As part of this study, all participants will receive an investigational cold virus. The virus has not been approved by the Food and Drug Administration (FDA) and has not been proven to be safe. However, the safety testing done on this virus prior to being used in this study has been reviewed by the FDA and the FDA has given us

permission to use the virus for these experimental studies. The virus which will be used for this study is a rhinovirus that was developed from volunteers in previous studies. The donor volunteers were tested for both HIV (AIDS) and hepatitis B infection and found to be negative.

IMPORTANT: Starting on the day you sign this consent form and for the duration of the study, please don't take any newly prescribed or over the counter medications which you have not been using. Please check with us first. We need be sure that these medications won't interfere with the results of the study. This includes nasal sprays, antihistamines, decongestants, dietary supplements, or homeopathic preparations intended for treating colds or allergy. Additionally, you should not take aspirin, steroids, Ibuprofen, Advil, Nuprin, Naproxen or any anti-inflammatory drugs without checking with us first. If you are really feeling bad, please tell us, because it is not common for this cold virus, or the study itself, to make you feel bad. There are things that we can do to make you feel more comfortable.

You are being asked to participate in this study, because you have mild, allergic asthma, or allergic rhinitis (without asthma), or because you are a healthy person (without asthma or allergic rhinitis). We will compare how the virus acts in these different groups of people.

There will be approximately 60 subjects participating in this study: 20 with asthma, 20 with allergic rhinitis, and 20 healthy volunteers.

How long will this study take?

Your participation in this study will require 8 study visits over approximately 21 to 42 days.

Note: ***All the tests and procedures described in this consent are being done solely for research purposes.***

You will not directly benefit from study participation.

What will happen if you are in the study?

Study visits will occur in the Clinical Research Unit (CRU) located on the 1st floor of the Medical Center Barringer Wing at UVA, or the Clinical Research Center located on the 3rd floor of the new Children's Hospital Outpatient clinic building (Battle Building). A member of the study team will tell you where you are to be for each visit. It is possible that screening procedures performed in protocol 12656 or 19512 will not need to be repeated for this study.

- **CoVID-19 test:** Within 3 days of the virus challenge you will be required to have a CoVID-19 test.
- **ACT questionnaire: Asthmatics Only.** You will be asked to fill out a questionnaire during the study. This will ask a few questions about your asthma symptoms and takes less than five minutes to answer.
- **Urine pregnancy test:** If you are a woman who could get pregnant, you will be asked to provide a urine sample in a cup and the study staff will test the urine for pregnancy. If you are pregnant you can no longer be in the study. To remain in this study, a woman who could get pregnant must have a negative urine pregnancy test at enrollment and at other times during the study. You must also agree

to use birth control (for example birth control pills, contraceptive foam, diaphragm, IUD, condoms, or not having sexual intercourse) for 14 days after you receive the cold virus.

- **Nasal Wash:** Salt water will be squirted into each side of your nose and a suction device will be used to re-collect the salt water. This nasal wash will be tested for viruses and chemicals produced by your body that tell the study doctors about the amount of inflammation in your nose.

- **Nasal lining fluid**: We will sample your nasal secretions by applying a small piece of sterile gauze (for 5 minutes) inside your nose before the nasal wash to absorb fluid which can be used to measure the levels of the immune response in your nose.

- **Nasal sample (ASI Rhino-Pro®):** After the nasal wash, a small plastic device will be inserted into your nose. This device is shaped like a toothpick and has a small cup at the end and is used to gently scrape some cells from inside your nose.

- **Nasal Biopsy**. Your nose will be sprayed with a decongestant (oxymetazoline). This will open up your nasal airway and make it easier for us to pass through our instruments. Your nose will then be sprayed with a local anesthetic (lidocaine). We will wait for the decongestant and anesthetic to take effect. After 5-10 minutes we will pass a rhinoscope into one of your nostrils. This is a narrow instrument roughly the size of a pencil which will allow us to see the inside of your nose. Through this instrument we will spray more anesthetic (lidocaine) into 3 different areas of your nose. This anesthetic will also contain a small amount of adrenaline (epinephrine) which is designed to prevent bleeding. After waiting another 5 minutes we will then use an instrument to grab and collect a very small piece of the surface of your nostril from up to 3 areas (roughly $1/10^{th}$ the area of the surface of a penny). We may apply silver nitrate cautery following the procedure. Silver nitrate is an antiseptic chemical, and cauterization is a technique that uses a metal device to burn tissue to stop bleeding. Silver nitrate cautery is generally painless, but after the anesthetic wears off, you may experience tenderness or pain for a few days, and your nose may run for up to a week after the treatment. We will provide Afrin spray as needed following the procedure to help prevent any mild bleeding that may occur following the procedure.

- **Spirometry**: This is a breathing test that is frequently done in allergy and pulmonary clinics to evaluate and monitor asthma. The test tells us how well your lungs are functioning. You will be asked to wear a nose clip, take a deep breath, and then blow out through a mouthpiece in one breath for as long as possible (usually at least 6 seconds).

- **Methacholine Challenge Test**: A methacholine test is used by doctors in pulmonary and allergy clinics to help with the diagnosis of asthma. During this breathing test, you will receive an FDA-approved drug called Provocholine® (methacholine). This drug will be inhaled and may cause mild symptoms of asthma to occur. You will be asked to breathe in different mists of methacholine that are slightly stronger each time. You will have spirometry testing after each dose to see how your lungs function. The test will be stopped if your spirometry test decreases by 20%. If your breathing remains the same the test is stopped after the 5th mist is given. The test will also be stopped if you have any difficulty

breathing. After the test is stopped, you will be given a treatment of albuterol to open up the airways if you need it. Albuterol is often used by people with asthma to open up the breathing tubes to make breathing easier.

- **Expired/Exhaled NO (nitric oxide):** – Nitric Oxide (NO) is a chemical normally made in the lungs which can be used to measure inflammation (part of the immune response) and help determine how well your asthma is controlled at any one time. This test is also used by doctors to monitor asthma in clinics. To measure the amount of NO coming from your lungs, you will take in a single breath and blow out steadily into a special instrument which measures NO. This test will only be done on asthmatic subjects.

- **Lung function breathing tests at home**: You will be given a hand-held monitor to record your lung function twice daily at home. This monitor is approved by the American Thoracic Society. It is like a peak flow meter which many asthmatics use to evaluate their lung function daily, or when they are experiencing symptoms. You will be asked to use this monitor twice daily throughout the study (each test takes about 3 to 5 minutes). We will ask you to write the results on your diary card and we will evaluate the results every time you come in for a visit.

- **Physical exam:** During each study visit, doctors will examine you to check on how well you are breathing. The exam will include looking into your ears, throat, nose, and we will listen to your breathing with a stethoscope placed on different areas of your chest and back.

- **Blood samples: Several different blood tests will be done during the study, but the blood for these tests will usually all be drawn at the same time to minimize the number of needle sticks:**

    - A "blood count test" counts the number of red blood cells, and white blood ("immune") cells. This is called a "complete blood count with differential" (CBC with diff). For this test we will collect about a teaspoon of blood.

    - A blood test to see if your body is responding to the cold virus. This is called an antibody ("neutralization") test. For this test we will take about a teaspoon of blood.

    - A blood test to check on other immune system responses will be done. This test requires 5 to 6 tablespoons of blood. If you agree, this blood sample will be saved, or "banked" for these studies. You will receive more information about this later in this consent form.

  When these tests are done any left-over sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

- **Diary Cards:** We will give you a diary to keep track of your asthma, cold symptoms and breathing. You will write your symptoms and breathing tests on this diary twice daily starting 5 to 7 days before and

for 7 days after you receive the cold virus. We will learn from you about the cold symptoms you are experiencing during the time you have the cold. We will ask you to bring the completed cards with you to each clinic appointment so that we can keep up with your symptoms and not lose any of the information which you will be recording daily. **This diary card is one of the most important parts of the study and you will need to record your information accurately.**

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must come to 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.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.
- **Contact the study team if you have any concerns or worsening symptoms at any point while you are in the study, including after Day 14.**

Additional responsibilities related to the CoVID-19 pandemic. Since the risk of developing CoVID-19 while simulatenously infected with the common cold virus is unknown, it is imperative that you are particularly attentive about minimizing your risk of exposure to CoVID-19. In addition to being tested for CoVID-19 shortly prior to the inoculation, you will be asked at each visit whether you have symptoms suggestive of CoVID-19 and if present you will be required to undergo a repeat CoVID-19 test.

During the course of this study, you will be contagious and can spread the cold virus to close contacts. In addition to any theoretical risk to you should you become infected with CoVID-19 in the course of the study, a similar risk would apply to anyone you inadvertently infected. As such, it is particularly imperative that you comply with the following guidelines to protect those you come in contact with. This will be especially important days 2-3 after the infection (typically Wednesday/Thursday) when you will be at your peak for virus shedding.

You must come unaccompanied to all clinic visits. You will be required to wear a mask during these visits (except for when nasal samples are being collected).

For 1 week after the inoculation, you will be expected to self-quarantine as much as feasible. You will still be permitted to attend classes, places of employment, dining facilities, and other essential activities during this period. However, you should not engage in any non-essential social activities. You will be required to wear your mask (except while eating) and to socially distance whenever you leave your residence. If you do not live alone, as much as possible you should isolate yourselves from household contacts for the 7 days after inoculation."

Study Schedule:

Visit 1a: The Screening/Baseline Visit - (Between 5 and 28 days before you get the cold virus)
(This visit will take about 1.5 hours)

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible and it is safe for you to participate. These include the following:

- Urine Pregnancy Test
- Blood pressure, heart rate, temperature, height and weight
- Spirometry
- Exhaled Nitric Oxide (eNO) asthmatics only
- You will complete the Asthma Control Test (ACT) only if you have asthma – must be ≥20
- Blood draw – 2 teaspoons (10 ml) of blood will be obtained for lab tests
  3 tablespoons (50-ml) of blood will be obtained for research (which can be collected at Visit 2 as long as collection is before inoculation).
- A limited physical examination will be performed including listening to your lungs/breathing.
- Methacholine test. This will not be performed if you needed to use your albuterol rescue inhaler within 8 hrs of the visit.
- Asthmatics will receive an Albuterol Inhaler with a puff counter and instructions on how to use this medication during the study. We want you to use this inhaler instead of your own albuterol inhaler while you are enrolled in this study. We will track how many puffs you use from the albuterol inhaler we will give to you.
- Receive your diary cards and lung function monitor and instructions on how to use and complete this information. You will also fill out a short questionnaire about how well your asthma symptoms have been over the last month. This questionnaire will be completed before you receive any study drug.

If necessary, the procedures can be done during 2 visits rather than 1.

Between All Visits

- **Completing your diary card twice daily (in the morning when you get up and at bedtime) will be very important.** This information will be the main source of information collected about your symptoms during the study. **Accurately recording your symptoms, scores and lung function test results daily during this study will be very important!**

- **We will also keep in touch with you by e-mail or text to learn how you are doing with your symptoms and diary card recordings. If you do not have easy access to e-mail, we will need a phone/cell number where we can usually reach you by talking to you or texting during the study so that we can stay up to date with your symptoms and lung function test results at home.**

NOTE: During your participation, you will be asked to NOT take any anti-inflammatory medications (NSAIDS or steroids) or cough/cold treatments from 4 weeks prior to each virus challenge until one week after the challenge.

Visit 1b – Screening for CoVID-19, 3 days priot to inoculation (This visit will take about 5 minutes)

- Nasal swab will be obtained for CoVID-19 testing

Visit 2 – Inoculation (Day 0) (This visit will take about 2-3 hours)

- Urine Pregnancy Test for women who could become pregnant.
- **Bring in your diary cards for review**
- You will complete the Asthma Control Test (ACT) questionnaire
- Vital signs including temperature
- Spirometry
- Blood draw – 3 tablespoons (50ml) of blood will be obtained for research ONLY if not collected at Visit 1
- A limited physical examination will be performed including listening to your lungs/breathing.
- Exhaled nitric oxide – asthmatics only
- Nasal Lining Fluid (sterile gauze)
- Nasal wash
- Nasal scraping

Inoculation of subjects with RV-16:
When the virus (cold) is given, you will receive 5 drops of the virus in sprayed in each nostril. Five to ten minutes after the initial dose, another five drops will be sprayed in each nostril. The process of giving someone a cold is called an inoculation and/or a "virus challenge". After you receive the cold virus you will continue to record your symptom scores twice daily and will return to our research area daily for 4 days to monitor and evaluate your symptoms.

If you are not well or have a lot of allergy or cold symptoms, we may reschedule the Inoculation visit.

Visits 3, 4 and 5 (Days 1, 2, and 3) (These visits will take about 30 – 45 minutes)

- **Bring in your diary cards for review**
- Limited Physical exam including taking your temperature
- Nasal Wash
- Nasal Lining Fluid (sterile gauze)
- Nasal scraping.
- Spirometry
- Exhaled nitric oxide – asthmatics only

Visit 6: **(Day 4)**: (This visit will take about 3-4 hours)

- **Bring in your diary cards for review**

- Urine pregnancy test (for women who could become pregnant)
- Limited Physical exam including taking your temperature
- Spirometry
- Exhaled nitric oxide – asthmatics only
- Blood sample for immune response (about 4 tablespoons)
- Nasal Lining Fluid (sterile gauze)
- Nasal scraping
- Nasal wash
- Methacholine Challenge. This will not be performed if you needed to use your albuterol rescue inhaler within 8 hrs of the visit.
- Nasal biopsies

Between Visit 6 and Visit 7:

- You will need to continue to keep your symptom diary
- You will need to continue to record your lung function test results

At Visit 7: (7 days after receiving the cold virus, this visit will take about 1 1/2 hour):

- Bring in your diary cards for review
- Urine pregnancy test (for women who could become pregnant)
- Limited Physical exam including taking your temperature
- Spirometry
- Exhaled nitric oxide – asthmatics only
- Nasal Lining Fluid (sterile gauze)
- Nasal wash
- Nasal scraping

At Visit 8: (14 to 19 days after receiving the cold virus – this visit will take about 30 minutes)

- You will complete the Asthma Control Test (ACT) questionnaire
- Spirometry
- Exhaled NO (nitric oxide)- asthmatics only
- Symptom assessment and temperature check
- Blood sample to check blood cell counts ONLY if they were lower than expected at Day 4 (about 1/3 tablespoon)

If you still have cold symptoms at this visit, or if your blood counts are lower than expected, we will contact you for a Day 21 visit. We may ask you to come back to clinic for a follow-up (unscheduled) study visit.

If you become pregnant during the study, we will contact you at the end of your pregnancy to find out how you and your baby are doing.

Study Visit 9 (Day 21, takes about 5 minutes by phone, and about 15 minutes if done in clinic)

The Day 21 visit will typically be a Phone Contact visit. It will only occur if you have symptoms at Day 14 or if your Day 14 blood draw results showed lower than expected blood cell counts. If contacted by phone, you will be asked if you have had any new or worsening symptoms since Day 14. If you have had new or worsening symptoms since Day 14, the study PI will be contacted to see if you should return for a follow-up (unscheduled) visit.

In-person Day 21 visit: When you have your blood drawn on Day 4, we will measure your white blood cells (neutrophil and lymphocyte counts), and if either or both of these values drop below what we expect, you will have a repeat blood draw on Day 14 (1/3 tablespoon). If either value remains low on Day 14, you will be asked to have your Day 21 visit in the clinic to have your blood drawn again. If there are any concerns following the Day 21 visit, we will ask you to follow-up with your regular healthcare provider, as RV-16 should only cause these cell counts to drop temporarily.

Follow-up (Unscheduled) Study Visits (will take about 30 minutes):

Contact the study site if you have worsening symptoms after Day 7, or if you have concerns between Days 4 and 14, or after Day 14. You may be asked to come for a follow-up (unscheduled) study visit if you experience worsening symptoms or there are concerns after Day 7.

If you are asked to come for a follow-up/unscheduled visit, you will:

- have a physical exam including temperature
- be asked about new and/or worsening symptoms and conditions
- be asked about medications you have taken since the last study contact
- perform spirometry testing
- be asked to bring your diary cards so we can review them

You will not receive any additional study payments for follow-up/unscheduled visits.

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

During the study, your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. This is expected to take at least 5 years. At that time you can ask for more information about the study results.

STUDY SCHEDULE

	Visit 1a	Visit 1b	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9
	5 to 28 Days prior to Inoculation	3 days prior to inoculation	Day 0 Cold virus Inoculation	Day +1	Day +2	Day +3	Day +4	Post-Inoculation Day 7	Post-Inoculation Day 14-19	Day 21*
Sign consent	X									
Nasal swab for Covid-19		X								
Urine Pregnancy Test	X		X				X	X		
Nasal Wash			X	X	X	X	X	X		
Nasal lining fluid (NLF)			X	X	X	X	X	X		
Nasal scrapings			X	X	X	X	X	X		
Spirometry	X		X	X	X	X	X	X	X	
Exhaled Nitric Oxide (eNO)	X		X	X	X	X	X	X	X	
Blood Draw	X		**X				X	X		
Complete Diary Cards	Daily starting on day -5)		Daily	Daily	Daily	Daily	Daily	Daily		
ACT questionnaire	X								X	
Methacholine Challenge Test	X						X			
Nasal Biopsy							X			
Rhinovirus -16 Inoculation			X							
Limited Physical Exam	X		X	X	X	X	X	X	Symptom assessment	
Vital Signs	X		X	Temp only	Temp only	Temp only		Temp only		
Assess symptoms	X		X	X	X	X	X	X	X	X

*The Day 21 visit will be done by phone except in cases where blood cell counts are low on Day 14. In these instances, an in-person visit will be scheduled.
** Blood draw – 3 tablespoons (50mls) of blood will be obtained for research ONLY if not collected at Visit 1

What are the risks of being in this study?

Risk of the experimental cold virus (Human Rhinovirus-16) (RV-16):

Likely

- If you become ill from the rhinovirus, you can expect to develop a common cold-like illness and other symptoms such as sore throat, headache, general muscle aches, runny nose, nasal congestion, sneezing, and fatigue. The illness may persist for several days.
- Numbers of blood cells called neutrophils and lymphocytes may drop temporarily after you have been infected with RV-16. This does not generally cause any symptoms.

Less Likely

- Rhinovirus infections may infrequently be associated with ear infections or sinus infections. Ear infections cause ear pain (earache) and sinusitis may cause sinus pressure or pain. These complications have been uncommon in volunteers experimentally infected with rhinovirus. If these infections develop, they can be treated with antibiotics.
- Rhinovirus infections are associated with asthma attacks in people who have asthma. You should not participate in this study if you have asthma that requires medications or if you have a history of severe bronchitis or coughing when you have a cold or if you have ever had wheezing when you had a cold.

Rare but serious

- The virus that will be used for the study is a rhinovirus that was isolated from a volunteer in a previous study. The donor volunteer was tested for HIV (AIDS), hepatitis C, and hepatitis B infection and found to be negative. After isolation, the virus was cultured two times in the laboratory and has been tested for the presence of other germs associated with infections in humans. Although none were found there is a remote chance that an unknown pathogen could be present and cause infection. The safety testing done on this virus has been reviewed by the FDA and the FDA has given us permission to use the virus for these experimental studies.

Risk of Worsening Asthma Symptoms:
If you have asthma, your symptoms may get worse, stay the same, or get better. If you feel that your asthma is getting worse, use the albuterol inhaler given to you. If your asthma does not get better after using the inhaler, call the study doctor at the phone number listed on this form. **If your symptoms are severe, go immediately to the emergency room for medical attention, or call 911,** depending on the severity of your symptoms. Thus far, no asthmatics who have participated in experimental infections with rhinovirus as planned for this study have been treated in the emergency room or needed hospitalization.

Risks of Spirometry

- Likely: Mild light-headedness and coughing
- Less likely: shortness of breath, mild respiratory fatigue, fainting, and/or chest tightness, chest soreness. If any of these things should happen to you, you will receive medical treatment.

Risks of Methacholine Challenge Test:

- Likely: You may have mild symptoms of asthma.
- Less likely: Moderate to severe asthma symptoms which include- coughing, chest tightness, shortness of breath, wheezing. If this occurs, you will be treated immediately.
- Rarely: Narrowing of your breathing tubes causing difficulty breathing. If this occurs, you will be treated immediately.

Risks of Albuterol Inhaler:

- Likely: Mild throat irritation, cough, mild increased pulse rate and tremor (shakiness of hands),
- Less likely: headache, dizziness, insomnia, sweating, nausea, vomiting, dry mouth
- Rare: allergic reaction, chest pain.

Risk of Nasal Swab:

- Likley: Discomfort during the procedure

Risk of Nasal Washes:

- The study staff will squirt some water up your nose to help get nasal mucus samples from you. This procedure is associated with minimal discomfort.

Risks of Nasal Scrapings using the small plastic ASI Rhino-Pro®:

- Likely: Discomfort during the procedure and sometimes sneezing.
- Less likely: Minor problems nose bleeds

Risks of Nasal Biopsy:

- Likely: Discomfort and some pain during the procedure
- Less likely: nose bleeds
- Rare: Feeling lightheaded or faint during the procedure, which can cause your blood pressure to be low for a short period of time Rare: infection, heart palpitations
- Risks of the decongestant, lidocaine, and epinephrine are very rare and include a small possibility of palpitations.

Risks of Silver Nitrate Cautery:

- Likely: nose tenderness/pain
- Likely: runny nose
- Rare: infection

Risk of obtaining nasal lining fluid:

- The soft sterile gauze may cause some mild discomfort and sneezing.

Reproductive Risks:

Risks for Women:

Pregnancy and Contraception

It is not known whether the cold virus we give you may harm an unborn or nursing baby. Therefore, you cannot be in this study if you are pregnant or nursing a baby. A pregnancy urine test will be done before each virus challenge.

You and your partner must use an approved form of birth control during this study. Examples of birth control you may use are

- Norplant
- IUD (intrauterine device)
- Depo-Provera
- Birth Control Pills
- Birth Control Patch
- Sterilization

The birth control methods listed below are less effective. They may be used if combined with other birth control methods

- Condoms
- Jellies or foam
- Withdrawal
- Sponge
- Diaphragm
- Rhythm
- Cervical cap

Ask your doctor for more details about the proper birth control method for you. If you become pregnant during your participation in this study, you must tell your doctor right away. Your doctor will discuss your treatment and the effect on the pregnancy.

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 virus,
- 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 how to find counseling. You may want help in understanding what the results mean for you.

Risk to others:
Do not share your albuterol inhaler with anyone. It is prescribed only for you. If someone else uses it, our counts of the puffs of albuterol would be wrong and the medicine could be harmful to someone else. Keep it out of reach of children and people not able to read or understand the label.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. So call the study leader if you have any symptoms or problems. As with any cold, there is a theoretical chance of your giving the virus to someone else and this would not be expected to be any worse than giving someone any other cold. We strongly encourage those who participate in this study to wash their hands carefully after blowing their nose or touching their face until the study is complete.

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?
The only choice is not to be in this study.
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?
You will be paid $1050.00 by check for completing this study. You will receive additional compensation if you travel from a distance (see note below for details). You will receive a single payment for the study visits and travel (as applicable) after your participation in the study ends. You will fill out a payment form at your last study visit. Below is a list of the amount you will receive for each study visit:

Visit 1a and one week run-in at home:	$110.00
Visit 1b nasal swab for Covid-19	$10.00
Visit 2 Day 0:	$110.00
Visit 3 Day 1:	$60.00
Visit 4 Day 2:	$60.00
Visit 5 Day 3:	$60.00
Visit 6 Day 4:	$300.00
Visit 7 Day 7 (post inoculation):	$80.00
Visit 8 Day 14 (post inoculation):	$20.00
Travel stipends for those from outside the area	$240.00
Total Possible for completing the entire study:	$1050.00

If you do not finish the study for any reason, you will be paid according to the number of visits you have completed.

Note: Participants from the Richmond area (VCU and J. Sargent Reynolds), Staunton/Harrisonburg area (JMU and Mary Baldwin), the Lexington area (Washington and Lee), or the Lynchburg area (Liberty University), will also be paid $30.00 per trip for travel to UVA for visit 1 through 8**.** If you travel from one of the areas listed above and complete the entire study, you will get $240 for travel.

You should get your payment 2-4 weeks after finishing the study. The income may be reported to the IRS as income.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

By agreeing to be in this study, you are donating your blood, bodily fluids, and blood cells 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?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance:

- Pregnancy test
- Lung function test
- All blood tests
- Methacholine challenge
- Nasal Procedures

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

Your travel and parking costs will also be reimbursed. See the "Will you be paid for being in this study?" section of this form for more information.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The National Institutes of Health, including the Division of Allergy, Immunology, and Transplantation do not have programs to pay you if you are injured. 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) Your study physician is concerned about your health
b) The side effects of the study procedures are too dangerous for you
c) New information shows the treatment will not work or is not safe for you
d) You do not follow the instructions or protocol planned for this study in order for the results to be valid.

How will your personal information be shared?

The UVa researchers are asking for your permission to collect, 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.

Your medical and research records will be confidential to the extent permitted by law. Efforts will be made to keep your personal information private. However, we cannot guarantee complete confidentiality.

You will be identified by a code, and personal information from your records will not be released without your written permission. You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers. Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.

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

- Personal information such as name, address, date of birth, social security number
- 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 (if required for this study, this may include mental health care records, substance abuse records, and/or HIV/AIDS records)
- Information needed to bill others for your care

Who will see your private information?

- The researchers to make sure they can conduct the study appropriately, observe the effects of the study and understand its results
- People or committees that oversee the study to make sure it is conducted correctly

- People who pay for the study (National Institute of Allergy and Infectious Disease), including its contractors who will assist in monitoring the study including Pharmaceutical Product Development, LLC (PPD).
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include the sponsors that make the rhinovirus and government agencies that provide oversight such as the Food and Drug Administration (FDA).

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.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. We ask them to protect your privacy. However, 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.

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 tell us to stop sharing your information by sending a letter to the researchers listed on this form. 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. UVa researchers will do everything possible to protect your privacy.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your records will be able to find out that you are in this study. This is done so your regular doctors will know what drugs or treatment you are getting in the study. If you have other health problems during the study, they will be able to treat you properly.

Please contact the researchers listed below 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: Larry Borish MD
Professor of Medicine and Microbiology
University of Virginia Health System MR4 Bldg Rm 5041
409 Lane Rd, Charlottesville, VA 22903 Telephone: (434) 243-6570

What if you have a concern about a study?

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

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 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.

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 understand the information given to you about the study and in this form. If you sign the form it means that you agree to join the study.

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 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

Consent from 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