

## 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 \_\_\_\_\_

<b>Principal Investigator:</b>	Ronald Turner, MD University of Virginia School of Medicine P.O. Box 800386 Charlottesville, VA 22908 Telephone: 434-243-9864
<b>Sponsor:</b>	Defense Advanced Research Projects Agency (DARPA) Duke University

### 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 signed copy of this form.

### Who is funding this study?

This study is being funded by the Defense Advanced Research Projects Agency (DARPA) a federal agency. The grant was given to Duke University and UVA is doing a portion of the study under a subcontract from Duke.

Lumos Labs and Empatica are providing access to their tests either at no cost or at a subsidized academic rate. One or more study researchers at Duke have or may in the future, receive research grants and advisory payments or shares from biotechnology, healthcare and sensor manufacturers.

### Why is this research being done?

The purpose of this study is to determine whether researchers can detect evidence that a person will become ill before they actually have symptoms.

A way of studying infections such as the common-cold, is to give research participants rhinovirus. As part of this study, you will receive an experimental cold virus. This virus has not been approved by the Food and Drug Administration (FDA); it 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.

In this study, you will also be asked to wear a monitor (called the **Empatica Sensor**) to document sleep and activity. Brief assessments of psychological and cognitive function and blood and nasal secretion collections

will be done every 8 hours for the 4 days prior to rhinovirus challenge and for four days after. Although you will not directly benefit from study participation, the hope is that data collected such as this, will be used to develop a baseline model of an individual's health which could be used in the future to develop models for predicting how someone may be more inclined to contract an infectious disease or not.

You are being asked to be in this study, because you participated in an earlier study (IRB-HSR#9948) to determine if you had antibodies to the virus (rhinovirus) that will be used to infect volunteers in this study and you were found to be susceptible to the virus.

Up to 50 people will sign consents to be in this study. At the enrollment visit we will determine eligibility to proceed and 30 volunteers will continue in the study. Five of these volunteers will be "alternates" in case other volunteers are not able to continue in the study. A total of 25 volunteers will be infected with the study virus.

### **How long will this study take?**

Your participation in this study will require 21 study visits (including this visit today) over one month. During the main part of the study you will be required to come to the study site up to 3 times a day at 8 hour intervals at approximately the same time each day. The enrollment visit (today) may take up to an hour. Each subsequent visit will last between 30-60 minutes.

### **What will happen if you are in the study?**

**All procedures and assessments described in this consent are being done for research purposes only.**

**All study visits will be done in the research space assigned to the Investigator in the Old Medical School building of the Medical Center (the site where you are reviewing this consent).**

### **SCREENING (will take about 1 hour to complete):**

#### ***Visit 1 (Study day -7, -6, or -5)-PRIOR TO INOCULATION WITH RHINOVIRUS***

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

- Review of your medical history
- Review current medications:
- Vital signs (blood pressure, heart rate, breathing rate, weight)
- Blood will be collected (1 tablespoon) from a needle in your vein to be sure you are not anemic (low blood count)
- Nasal swab-involves putting a moistened cotton swab part way into your nose to collect a sample of any bacteria that might be in your nose.
- Nasal lavage: involves putting about 1 teaspoon of salt water into each side of your nose and then having you blow the liquid into a cup for analysis.

- You will be asked to take some paper AND on-line web-based tests of mental health, stress, morningness (how alert you are in the morning), fatigue, reaction time and vigilance (wakefulness). These tests will be done on your own computer or tablet. These assessments should take about 10 minutes to complete.
- You will be given a physiologic monitor (Empatica Sensor-Figure 1)) to wear continuously for the duration of the main part of the study .This monitor will collect information such as heart rate, temperature, amount of moisture on the skin, and physical motion. You will be asked to wear this monitor for up to 10 days.
- If you are a female able to get pregnant, we will collect a urine specimen for pregnancy testing. This test must be negative in order to continue study participation.



Figure 1-Empatica Sensor monitor

If these tests show you are eligible, you will return to the clinic in 3-4 days to continue with study procedures.

## Study Visits

**Study days -3 through 4 (each visit will last approximately 30 minutes):**

The main part of the study involves visits to the study site approximately every 8 hours (morning, afternoon, night) on 5 days (days -3, -2, -1, 1, and 2) and twice each day (morning, afternoon) on 3 days (days 0, 3 and 4).

At these visits the following procedures will be done:

- You will continue to wear your Empatica Sensor Monitor for the remainder of your study participation.
- Nasal swabs will be done at each morning visit.
- Nasal lavage will be done at the morning and afternoon visits on each day.
- Approximately 1 tablespoon of blood will be collected at each visit.
- You will be asked to complete the paper and web-based assessments of reaction time and vigilance. This will be done on your own computer or tablet and will take about 10 minutes to complete.
- **On the afternoon of the Day 0 visit you will be given the rhinovirus challenge.** This involves placing a small amount (1/10 of a teaspoon) of liquid containing the virus into each side of your nose.
- Just before the rhinovirus challenge and at each visit after that (days 1-4) you will be asked about any common cold symptoms and how severe there are by a study nurse.
- At each morning visit throughout the study you will be asked if you have experienced any unexpected events or taken any medications.

During this study, you will be asked to fill out some online questionnaires and do some online tasks. These include:

- Mental health questionnaire: this is a brief (~1 minute) survey to be sure that you do not have symptoms of depression. Depression would alter your biorhythms and interfere with the study. This survey is administered once at screening for enrollment.
- Stress questionnaire: This questionnaire will assess your acute and chronic stress. It is administered once at the enrollment visit and will take about 1 minute to complete
- Morningness questionnaire: This questionnaire will assess whether you are a “morning” person. It will be administered once at the enrollment visit and will take about 1 minute to complete.
- Fatigue and Mood questionnaires: These questionnaires measure your level of fatigue and mood, and will be administered at enrollment and throughout the study associated with study visits. It will take about 5 minutes to complete
- Reaction time and vigilance will be assessed by a set of online tasks. These will be done at enrollment and throughout the study associated with the study visits. This will take about 10 minutes to complete.

**Final Visit:**

**Study Visit 23, Study Day 21: Less than 30 minutes**

- You will be asked if you have had any unexpected events since the last visit in the study
- You will have a final blood sample taken (2 teaspoons)

**Prior to Challenge**

<b>Study Day</b>	-7 to -5	Day -3			Day -2			Day -1		
<b>Time (visit)</b>	(1)	AM (2)	PM (3)	PM2 (4)	AM (5)	PM (6)	PM2 (7)	AM (8)	PM (9)	PM2 (10)
Consent	X									
Vital Signs	X									
Medical History	X									
Urine pregnancy screen	X									
Nasal Swab	X	X			X			X		
Nasal Lavage	X	X	X		X	X		X	X	
Blood Draw	X	X	X	X	X	X	X	X	X	X
Web-based tests	X	X	X	X	X	X	X	X	X	X
Physiologic monitoring (continuous)	X	X	X	X	X	X	X	X	X	X
Review health related problems	X	X			X			X		
Review Current Medications	X	X			X			X		

**RHINOVIRUS Challenge and ADDITIONAL VISITS POST CHALLENGE**

<b>Study Day</b>	Day 0		Day 1			Day 2			Day 3		Day 4		Day 21-28
	AM (11)	PM (12)	AM (13)	PM (14)	PM2 (15)	AM (16)	PM (17)	PM2 (18)	AM (19)	PM (20)	AM (21)	PM (22)	(23)
Nasal Swab	X		X			X			X		X		
Nasal Lavage	X	X	X	X		X	X		X	X	X	X	
Blood Draw	X	X	X	X	X	X	X	X	X	X	X	X	X
Web-based tests	X	X	X	X	X	X	X	X	X	X	X	X	
Physiologic monitoring (continuous)	X	X	X	X	X	X	X	X	X	X	X	X	
Symptom score		X	X	X	X	X	X	X	X	X	X	X	
Rhinovirus challenge		X											
Review Health Related Problems	X		X			X			X		X		X
Review current Medications	X		X			X			X		X		

**What are your responsibilities in the study?**

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

- You are expected to complete all of the study activities as directed.
- 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.
- 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.
- You must return the study device to the study site.

**Blood Testing**

We will take (or “draw”) up to one tablespoons of blood per day for 10 days. The total amount of blood we will take will be about 15 tablespoons (150 ml).

The blood we take will be tested to measure different things. One the enrollment day the blood will be tested to measure your red blood count to be sure you are not anemic. During the main study the blood will be processed to measure whether certain genes are active. Different genes become active in response to time of day and environmental factors (including infection) and we will trend this over the course of the study. On day 0 and 21 some of the blood will be used to measure the concentration of antibodies to the rhinovirus challenge virus.

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.

### Mandatory Collection of Samples and Health Information for Genetic Research

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

You are being asked to provide samples of your blood to be used for research. Along with specimens, researchers will collect the other health information about you described in this consent. We plan to do genetic research on the DNA in your specimen sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child. We will also be looking at which genes are “turned on” at different time over the study. This will allow evaluation of your biologic timing and how you respond to the virus infection.

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

The study team will obtain blood from you for testing. This will be collected at the time points indicated elsewhere in this consent.

#### **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 the other information collected in the study. 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.

#### **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 with other institutions. Dr. Turner 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?**

The genetic research 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**

**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 is very small. However, we cannot *guarantee* it will be safe. Because everyone has unique DNA, it is also possible, although very unlikely, that someone could identify you through your DNA if they have another sample of your DNA. To further safeguard your privacy, information obtained from this research will not be placed in your medical record.

#### **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.

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

During the study you are having an investigational test done. The purpose of the test is NOT to diagnose any disease or abnormality you may have. Because the test is investigational there is no way for the study leader to understand if the results are “normal” or “abnormal”. However, if any test results are concerning, your study leader will let you know. In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself 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. At that time you can ask for more information about the study results.

### **What are the risks of being in this study?**

#### **Risks associated with the experimental rhinovirus:**

##### **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.

##### **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 very 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.

**Risks associated with nasal wash:**

- 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 associated with the nasal swab:**

- The study staff will use a standard cotton swab and collect mucus from each side of your nose. This procedure is associated with minimal discomfort

**Risks of continuous physiologic monitoring using the Empatica Sensor:**

- During this study you will wear a monitor (similar to FitBit) that will continuously monitor your activity, heart rate, skin conductance and body temperature and stream this information to a secure server through your smartphone.

**Risks of the Empatica Sensor:**

The silver in the EDA Electrode may cause contact dermatitis for those who have silver allergies or sensitive skin.

Materials that have potential to contact the skin include:

- Band: polyurethane
- Case: glass fiber reinforced polycarbonate
- Lenses: acrylic and silicon
- Electrodes: silver (Ag) plated
- Charging terminals: gold (Au) plated (recessed)

There is a minor risk of a harmless but noticeable skin pigmentation from the Ag electrode material being transferred to the dermis (this would appear as one or two electrode shaped grey circles on the skin and fade as the skin cycles could be anywhere from a day or two to a week. This is potential with any sensor in which the skin contacts an Ag / AgCl electrode but the risk is reduced in the E4 which employs an alternating current circuit architecture which prevents electrode polarization and subsequent transfer of pigment. Incidence is rare.



**Empatica and Data privacy:**

The Empatica API does not store or transfer any personally identifiable information (this includes location, IP address, email address information). Data collected from you by this device will be linked to your study identifier for use by the research team for the purposes of this study.

**Risks of Paper and Web-based Questionnaires:**

It is possible that you may experience fatigue during the testing, but not any more so than from routine computer use. If you become tired during the test, you may stop at any point. You may also experience some anxiety as a result of the testing. If you do, you can take breaks between tests, or stop at any time. There is a small chance of a breach of confidentiality, but there are measures in place to prevent any violation of privacy or identity. The data that is stored as part of the study includes email addresses and dates of birth and any other information you provide in the questionnaire.

All data, including your test results, is stored on a secure server. Your information will only be tracked by anonymous ID numbers generated when you create an account for the web-based questionnaires, but your email address will be used and retained. If you do not use your real email address for this study, your IP address and your GPS location may still be collected. There is a small risk of breach of confidentiality but the server site has agreed by contract to maintain confidentiality and to use any information collected only for the purposes of this study. If the results of the study are published or presented, your identity will remain as confidential as possible.

The paper and online tests/questionnaires are research tests and not intended for the clinical diagnosis of any physical or psychiatric disorder. Hence, you will not receive any diagnostic feedback. Please inform the study team if you have concerns about any of your responses or any aspect of your mental health.

**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 on at enrollment.

You and your partner must use an approved form of birth control during the course of your participation in 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
- Diaphragm

- Jellies or foam
- Withdrawal
- Sponge
- 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,
- ✓ 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 or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

**A caution about giving too much blood:**

Because of the amount of blood being taken, you should not give blood for other reasons for eight weeks after participating in this study. For example, avoid giving blood at a blood bank or in another research study.

**Other unexpected risks:**

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

**Will You Find Out the Results of the Research on Your Sample(s) for Genetic Research?**

Neither you, your health care provider, nor anyone in your family, will receive the results of any research done on your sample(s). The results will not be put in your health records. Therefore, results from any research done on your sample(s) will not affect your medical care. This helps protect you and other members of your family from harm that might be caused by this information.

**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 a patient at UVa your usual care will not be affected if you decide not to participate 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.

## **Will you be paid for being in this study?**

You will be paid up to \$ 940 for finishing this study by a University check. Your check will be mailed to you around the time of the final study visit. The income may be reported to the IRS as income.

If you do not finish the study, you will be paid \$ 40 for each study visit (21 visits) you complete starting with the visits on day -3 through the visits on day 4 (no one is being paid for the enrollment visit or the final visit). If you complete all activities related to the study as directed and on time you will receive a bonus payment of \$100. If you participate in the study as an alternate from days -3 through day 0 (11 visits), you will receive \$40 for each visit you complete plus a bonus of \$ 50 if you complete all activities related to the study as directed and on time.

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 and nasal 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.

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

- vital signs
- medical history
- urine pregnancy screen (females)
- nasal lavage
- nasal swabs
- rhinovirus

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.

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 study, 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 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) You do not follow the study staff instructions
- c) The study sponsor closes the study for safety, administrative or other reasons

If you decide to stop being in the study, we will ask you to return all study related material to the study site.

### **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

### **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
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)

- People who evaluate study results, which can include researchers at other sites conducting the same study and government agencies that sponsor the study such as DARPA.

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.

### **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. 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.

### **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:**

Ronald Turner, MD  
Pediatrics, School of Medicine  
P.O. Box 800386  
Charlottesville, VA 22908 Telephone: (434)243-9864

### **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 22908 Telephone: 434-924-9634

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 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	PARTICIPANT	DATE
(SIGNATURE)	(PRINT)	

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

**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 **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

**Please indicate with check box the identified individual(s):**

Subject

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