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_____

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 Cytokinetics, Inc.

Key Information About This Research Study

Principal Investigator:	Christopher Kramer, MD Box 800158 Charlottesville VA 22908 434-982-1058
Funding Source:	Cytokinetics, Inc. 280 East Grand Avenue south San Francisco, CA 9408

You are being asked to take part in a research study. You do not have to take part in this study as participation is voluntary. 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 is the purpose of this study?

This study aims to learn what might predict heart problems (like sudden death from a fast heart rhythm or heart failure) in people with a genetic condition called hypertrophic cardiomyopathy (HCM). HCM causes the heart muscle to become thick, which can make the heart stiff and harder to work properly. It can also affect the heart's electrical system.

You are being invited to take part in this study because you have been diagnosed with hypertrophic cardiomyopathy and were previously part of a research project called "HCMR -

Novel Predictors of Outcome in Hypertrophic Cardiomyopathy" – IRB-HSR# 21381. The results of that study are still being reviewed, but they might show that people who had a substance called Gadolinium (MRI contrast or dye) collected in their heart muscle may have a higher risk for heart problems, including sudden cardiac death. This is called "late gadolinium enhancement" (LGE). The study team is doing follow-up imaging on participants to better understand how LGE affects people with HCM.

Why would you want to take part in this study?
You will likely 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 of the risks associated with the use of Gadolinium, which are discussed in detail later in this form. Some risks include:

- Potential allergic reaction
- Nephrogenic Systemic Fibrosis

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 agree to take part in this study, you will:

- Sign this informed consent.
- Have a cardiac MRI performed with and without Gadolinium (MRI contrast/dye).
- Have your blood drawn to determine cardiac biomarkers & blood counts and for specimen banking.
- Medication/Medical History Review
- Urine Pregnancy Testing (if applicable)

What is the difference between being in this study and getting usual care?
If you choose not to participate in this study, there will be no changes to your current or future medical care.

What other treatments may I receive if I decide to not take part in this study?
This is not a treatment trial, therefore there are no alternative treatments.

How many people will take part in this study?
Up to 35 people will sign consent to be in this study at UVA. Up to 314 people will be in this study at all places.

How long will this study take?

Your participation in this study will require 1 study visit on-site.

What will happen if you are in the study?

Screening and Study Procedures

Visit 1

Before you come for the study, you will have been asked to have nothing to eat or drink after midnight the night before and that you have not exercised for 24 hours prior to the study visit. This is because food, drink, or exercise may change your blood findings.

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, the following procedures will take place to make sure are eligible and that it is safe for you to participate. All of the following procedures will be completed for research purposes:

- Review of your medical history and medications.
- Brief physical exam and vital signs (blood pressure, heart rate)
- Standard urine test for pregnancy (if necessary). The pregnancy test must be negative in order to continue with study participation.
- A questionnaire to determine if you are claustrophobic (fear of small places) or have metal objects in your body (such as a brain aneurysm clip, a pacemaker, a defibrillator, ear or eye implants or metal from injuries) to determine if MRI is safe.

Once it is determined that it is safe for you to participate, the following will occur for research purposes:

- Blood draw:
  - 5 Tablespoons of blood will be drawn from a vein in your arm. This is for a blood count and measuring blood proteins called biomarkers, as well as specimen banking. More information regarding this topic is found under “Specimen Banking” at the end of the consent.
  - Standard blood test (your kidney function if it hasn’t been tested in the last 30 days) to check for kidney function.

- Cardiac MRI:
  - An intravenous catheter (IV) will be placed in one arm by trained staff. An IV is a small flexible tube inserted in a vein and guided by a needle.
  - If the heart monitoring associated with the Cardiac MRI shows that you do not have a normal heart rhythm (called sinus rhythm), the MRI will be completed for research and you will be rescheduled.
  - You will then be placed in the center of a large donut-shaped magnet on a padded stretcher, on your back, while pictures are being taken. You will need to lie still as much as possible during the study. Earplugs and an earphone will be supplied to reduce any discomfort from the knocking sound of the MRI machine.

You will be asked to hold your breath for short periods of 10-15 seconds while different pictures of your heart are being taken.

- During the MRI, we will give you a contrast agent called gadolinium through your IV and take more pictures to see the blood flow in your heart muscle. Gadolinium is an FDA approved contrast agent for MRI examinations. Gadolinium is routinely used for heart MRI studies. However, it is not specifically approved by the FDA for heart examinations and is considered experimental for this study. The gadolinium contrast agent allows us to visualize any scar in the heart muscle.
- You will be in the MRI machine for approximately 60 minutes.
- **We will perform the cardiac MRI (for research purposes only) if one has not already been ordered for you by your doctor as part of your care.**

Study Schedule

Study Procedures	**Screening/Baseline**
Signed Consent Form	x
Assessment of Eligibility	x
Review of Medical History	x
Review of Current Medications	x
Physical Exam (Vital Signs)	x
Blood Draw for labs/Specimen Banking	x
Urine Pregnancy Test (if applicable)	x
MRI Screening Questionnaire	x
Cardiac MRI	x

What are your responsibilities in the study?

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

- You must attend the 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.

Blood Testing

We will take (or "draw") up to 5 tablespoons of blood in total for this study visit.
A portion of the blood we take will be tested to measure your blood counts. This will show how many red blood cells and white blood cells you have in your blood.

The remaining portion will be sent to an off-site facility (Brigham and Women's Hospital Core Lab) for specimen banking and cardiac biomarkers. These markers include enzymes, hormones, and proteins. Cardiac biomarkers show up in your blood after your heart has been under severe stress and becomes injured because it isn't getting enough oxygen. This can happen for various reasons.

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. At that time, you can ask for more information about the study results.

Collection of Samples and Health Information for Mandatory Specimen Banking

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 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: medications, diagnoses, medical history, and symptoms you may be experiencing.

In addition, if you agree, 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 heart disease. 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?
Your doctor or trained study team member will obtain blood from you for testing. This will be collected during your study visit.

How Will Your Sample(s) Be Stored and Labeled for Specimen Banking?
Brigham and Women's Hospital Core Lab located at 850 Boylston St, Chestnut Hill, MA 02467 will be responsible for storing your sample and for protecting your privacy.

This research specimen bank is located with Brigham and Women's Hospital Core Lab located in Boston, Massachusetts. There is no set limit to the number of people who will provide samples to this bank.

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.

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. Dr. Christopher Kramer 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 Specimen Banking?
The 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 For 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. One of the risks to you is the release of information from your health records. 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. 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.

Will You Find Out the Results of the Research on Your Sample(s) for Specimen Banking?
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.

What If You Change Your Mind About Donating Your Sample(s) for or Specimen Banking?
If you decide now that your sample(s) can be kept for 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. Unless you withdraw from the study, permission for researchers to use your blood 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 Specimen Banking?

You will not be paid to donate your sample(s) for 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.

What are the risks of being in this study?

A risk of allowing us to collect information about you 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.

Risks of having an MRI:
MRI scanning is a painless procedure that only requires that you lie quietly on a padded table that gently glides you into a large magnet. While the scanner is performing your scan, you will hear some humming and thumping sounds. These are normal and should not worry you. Because of the magnetic field and radio frequencies people with any type of metal in their body should NOT have an MRI. This may include things like pacemakers, aneurysm clips, or shrapnel. It is important that you inform the technologist if you have any of these metallic appliances. Please inform the technologist if you are pregnant or think that you may be pregnant. There is a low risk of experiencing symptoms of anxiety or claustrophobia while lying in the scanner. Should you experience these symptoms or otherwise become uncomfortable you can

voluntarily stop your participation in this study. There will be NO consequences to your clinical care or your participation in the study should you choose to stop your participation.

Risk of using gadolinium:

You will receive or are scheduled to receive a contrast called Gadolinium for your MRI/MRA. This substance will help the tissues show up better.

The following risks are associated with gadolinium contrast:

- Allergic reaction. Some people experience temporary itching after receiving MRI contrast. Less than one person in 300,000 will experience a severe allergic reaction which requires treatment. Severe allergic reactions may include difficulty breathing or wheezing, tightness in the throat, swelling of lips, tongue, or throat, and fast heartbeat.
- Contrast infiltration. Contrast that is injected outside the vein into other tissues can cause local pain and swelling at the injection site. Treatment generally consists of hot or cold packs and elevation of the affected arm. Infiltrations most often get better over time.
- Temporary metallic taste in the mouth, tingling in the arm, nausea, or headache occurs in less than 1 in 100 people.
- The FDA has received information about an extremely rare disease called Nephrogenic Systemic Fibrosis (NSF), which is a rare disease that is linked to the use of Gadolinium in people with severe kidney disease.

NSF causes hardening and thickening (fibrosis) of the skin, connective tissues like muscles, tendons, ligaments, and blood vessels throughout the body. In addition, those who develop NSF may have scarring of their body organs. The signs of NSF also include:

- burning, itching, swelling, hardening, and tightening of skin;
- red or dark patches on the skin;
- yellow spots on the whites of the eyes;
- stiffness in joints with trouble moving or straightening the arms, hands, legs or feet;
- pain deep in the hip bones or ribs;
- Muscle weakness.

In most of the cases reported to the FDA, symptoms of NSF started between 2 days to 18 months after a person received the Gadolinium-based contrast agent. NSF may get worse and may lead to death. There is no known treatment for NSF.

If you have any of the symptoms listed above after receiving Gadolinium-based contrast for a study MRI/MRA, please contact the study team immediately. The study team will review your symptoms and perhaps recommend a skin biopsy, which is the only way to determine if you actually have NSF.

The FDA has received information indicating that gadolinium may deposit in the brain and other organs of some people who have had four or more gadolinium contrast-enhanced MRI scans and it may remain for a long time. Although no signs or symptoms of negative health effects or changes to organs have been seen with these deposits to date, it is not known if these deposits may lead to negative health effects in the future.

Before you receive gadolinium/additional gadolinium for research:

- You will be screened by UVA Department of Radiology staff prior to getting gadolinium. If radiology screening shows that it might be unsafe for you to receive this contrast, then you will not be able to receive the contrast.

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, 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.

Risks of taking blood from an IV catheter:

Risk of Repeated Sticks

Sometimes the catheter stops working. In order to get the blood we need, we may have to stick you again with another needle.

Risks for women:

Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you are pregnant. You must use an effective method of birth control during the study. If you have questions about birth control, please ask the study leader. If you are pregnant now, please tell us right away.

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.

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 are not required to participate in this study. This is not a treatment study, therefore there are no treatment alternatives.

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 $75.00 for finishing this study by check/direct deposit.

You should get your payment about 2-3 weeks after the study visit. The income may be reported to the IRS as income.

By agreeing to be in this study, you are donating your blood for research and giving up any property rights you may have to these specimens or the results of the research. 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:

- Informed Consent
- Medication/Medical History Review
- Labs and Pregnancy Testing (if applicable)
- Cardiac MRI with and without gadolinium

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 your insurance company for an estimate of what these costs might be or if pre-approval is required.

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?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). 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.

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.

If you decide to stop being in the study, we will ask you to write a letter to the PI or study team indicating your intention of withdrawal. You will also need to complete the "Leaving the study early" form at the end of this informed consent.

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.
- Blood samples if you agree to provide them for specimen banking 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 funding source 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).
- 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 samples from you may be given to other researchers outside of the University of Virginia after all identifiers such as name, address, phone number 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 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. They will not be sent with information that could identify you such as name, address or phone number.

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.

Please contact the Principal Investigator listed BELOW to:

- Obtain more information about the study and ask any questions regarding study procedures or study treatments/interventions.

- 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: Christopher Kramer, MD
Address: University of Virginia Box 800158 Charlottesville VA 22908
Phone: 434-982-1058

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 UVA Study Tracking 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.

You do not have to agree to use email or text message to be in this study.
PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to be contacted by email or text.
If you agree to texting or emailing, the study team will collect your phone and /or email address that you would like them to use. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

No_____ I DO NOT agree to be contacted by email or text.

Would you like to be contacted about future studies?

The researchers in this study would like to know if you wish to be contacted regarding participation in additional studies that may be appropriate for you. By agreeing to be contacted, you will allow a qualified member of the study team to contact you in the future to ask if you want to participate in additional studies. You have no obligation to participate in any study.

Declining will have no influence on your present or future status as a patient in this clinic. You will receive the same care as any other patient seen in this clinic. There will be no penalty or loss of benefits to which you are otherwise entitled. Your clinic records will indicate that you do not want to be asked about future research by or through anyone but your treating physician.

Participation in research may involve some loss of privacy. However, your records will be handled as confidentially as possible. Access will be limited to the study team organizing the study. No information will be used for research without additional permission. Your contact information will not be shared with anyone outside of UVA without your permission.

You do not have to agree to be contacted about future research to be in THIS study.
PLEASE INDICATE YOUR CHOICE BELOW if you are willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.

____ No, I do not want to be contacted about future research studies.

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

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

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 **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 (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Leaving the Study Early

Whenever possible, obtain signatures from subjects if they decide to leave the study early. However, verbal withdrawal is acceptable for subjects to leave the study early and must be recorded in the subject's chart and/or study record. Written notice must be obtained to have private information discontinued from use including genetic research and specimen banking withdrawal.

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.

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by:

- Obtaining information from my medical records.

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

Consent From Adult-To be completed by the participant if 18 years of age or older.

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

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