University of Pennsylvania
RESEARCH Subject Informed Consent Form
AND RESEARCH SUBJECT HIPAA AUTHORIZATION

Protocol Title:	**Statin downmodulation of monocyte / macrophage activation for HAND treatment**
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Why am I being asked to volunteer?

You are being invited to participate in a research study because you have HIV infection and are on HIV treatment. HIV infection can cause changes in a type of blood cell ("monocytes") that are thought to lead to brain complications in some people with HIV infection. The research is designed to determine if a type of medication called Atorvastatin can reverse these changes in blood monocytes. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

Some people with HIV infection develop neurological (brain) problems, which eventually can interfere with normal thinking and brain function. One way that HIV affects brain function is by causing inflammation in the blood, causing changes in a type of white blood cell called monocytes. It is believed that when monocytes are affected by HIV in this way, they can eventually enter the brain and cause damage there.

Atorvastatin is a drug that is used commonly to treat high cholesterol and to prevent heart attacks or strokes. In addition to lowering cholesterol, it can also decrease inflammation. The goal of this study is to test whether Atorvastatin will decrease inflammation and reverse the changes in blood monocytes in people with HIV infection.

There is also a substudy involving a PET scan which provides information regarding the amount of inflammation in your body. PET stands for Positron Emission Tomography and is done in combination with a CT. PET/CT Scans take both PET images and CT images at the same time and combines them into a single three-dimensional picture. . The scan uses FDG (Fluorodeoxyglucose) which is a special radioactive type of glucose, the main sugar of the human body, used to show how your body's cells are using glucose. Some cells use glucose in a different way than other cells, and this will provide information regarding the amount of inflammation in your body.

Eligibility to enroll in the study

You are eligible to participate in the study if you:

- have HIV infection and are on HIV medications presently and there have been no changes in the combination of HAART (highly active anti-retroviral therapy; a class of medications that are used to treat HIV) drugs used within 4 weeks of study entry.
- have plasma (a component of blood) viral load ≤200 copies/ml for at least 6 months at screening visit
- do not use recreational drugs, and do not drink more than one drink of alcohol per day
- are not allergic to atorvastatin or have had any prior reaction to atorvastatin (or other drugs in the "statin" group)
- do not have a history of muscle disease or liver disease, or have active hepatitis (liver inflammation) or serious kidney or blood disease.
- are not on any other lipid-lowering agents (ie, cholesterol-lowering agents) or any medications known to interact with atorvastatin, and do not use any over-the-counter, vitamin or herbal supplements that can interact with atorvastatin. It will be important that any new medications or over-the-counter supplements or vitamins are discussed with the study staff to be sure it is safe to take them with atorvastatin.
- If female: are not breast-feeding and, if able to become pregnant, are willing to use a method of contraception during the study period and undergo pregnancy testing on a monthly basis.
- are willing to participate in the study, come to study visits, have samples taken and have neuropsychological testing (these are tests that examine thinking skills) on 4 study visits.

How long will I be in the study? How many other people will be in the study?

You will participate in the study for a total of 38 weeks. During this time you will be on treatment with the Atorvastatin or placebo for a total of 24 weeks. The overall study will last for about 4 years and will include approximately 30 subjects.

What am I being asked to do?

In the first treatment period you will be asked to take the medication Atorvastatin or placebo for 12 weeks. If you are on HAART medications that include protease inhibitors (PI), you will be asked to take Atorvastatin or placebo at 10 mg/day for 2 weeks, then 20 mg/day. If you are on HAART medications that do not include PI or non-nucleoside reverse transcriptase inhibitors (NNRTIs), you will be asked to take Atorvastatin / placebo at 20 mg/day for 2 weeks, then 40

mg/day. If you are on NNRTI HAART medications, you will be asked to take Atorvastatin / placebo at 40 mg/day for 2 weeks, then 80 mg/day. There will then be a period of 6 weeks without study medication ("washout phase"), followed by a second treatment period in which treatment will be switched and you will be asked to take placebo or Atorvastatin for 12 weeks, at the same dose as in the first treatment period.

Blood will be taken prior to beginning Atorvastatin / placebo, periodically while on treatment and during the washout phase for the duration of the study. The blood samples will be used to test whether the monocytes have changed, or whether there are changes in blood proteins that are made by monocytes when they are activated.

You will also be asked to undergo neuropsychological testing at 4 visits during the treatment period.

SPINAL TAP SUBSTUDY

If you agree, you can participate in the spinal tap substudy (until a total of 16 participants are reached).

If you decide to participate you will have a spinal tap to measure the levels of inflammation in the spinal fluid

A spinal tap is the removal of a small amount of fluid from your spine. This is done by numbing a small patch of skin on your back and inserting a needle in between some bones in your lower back. About 2 to 3 teaspoons of spinal fluid will be collected for routine safety tests. About 2 teaspoons of spinal fluid will be collected to evaluate the effects of atorvastatin in thie spinal fluid.

Please put your initials and date next to your choice.

_____ YES, I agree to participate in the spinal tap substudy

_____ NO, I do not agree to participate in the spinal tap substudy.

PET SCAN SUBSTUDY

If you agree, you can participate in the PET substudy (until a total of 10 participants are reached). You will have a total of 4 scans over the 30 week study period.

Preparation for the PET/CT Scans:
Before each PET/CT scan, you should not eat for 6 hours before your appointment time. You should drink plenty of water, at least two to three 8oz. glasses. Your blood glucose level will be checked by finger stick to make sure it is within the allowable range. If it is not, it may need to be checked more than once. If your blood glucose remains outside of the allowable range you will not receive the FDG-PET/CT scan because the results will be less accurate due to the sugar within your body.

During the Exam:
On the day of your FDG-PET/CT scan, a technician will inject a small amount of FDG into your vein through the i.v. catheter described above. You will be asked to drink plenty of water (at least two to three 8oz. glasses) and to empty your bladder frequently before and again after the PET/CT scan. This helps your body get rid of the FDG.

About 120 minutes after the injection, you will be asked to lie on the special table of the PET/CT scanner and the PET/CT scan will begin. The PET/CT scanner is a large machine with a hole in the middle, like a donut. The partially enclosed scanning table is in the middle of the hole. The table will slide into the machine. The size of the opening is 27 to 30 inches. If you feel any anxiety about being in enclosed spaces, let your study doctor know. The technologist will also keep an eye on you through an observation window during the scan and there will be an intercom to let you talk to each other if you need any clarification on various instructions. You will be asked to remain still during the scan, about 30-60 minutes. It is normal for you to hear buzzing or clicking sounds during the scan.

Please put your initials and date next to your choice.

_____ YES, I agree to participate in the PET substudy

_____ NO, I do not agree to participate in the PET substudy.

Tests when starting the study (2 weeks before beginning treatment)

- A medical history and physical examination. The history will include a review of all of your previous health problems, and your recent and current medications.
- Blood tests: If you have not had a blood count and blood chemistry within the past month, these tests will be done. Blood chemistry will include tests to monitor for liver or muscle problems at the start of the study (ALT/AST and CPK). We will also test for inflammation (high sensitivity C-reactive protein, or "hs-CRP"). Approximately 25 mL of blood (1-1/2 tablespoon) will be taken for these tests. An additional 10 mL blood (less than one tablespoon) will be collected and stored for later testing of plasma proteins.
- Blood will be drawn for HIV viral load testing and CD4 count if it has not been done within the past 3 months.
- Women will have a pregnancy test on a urine sample
- If you do not have evidence of any serious liver, muscle, kidney or other problems, and the blood test shows hs-CRP ≥ 2 mg/L, you will be asked to enroll in the treatment study.

1st treatment period

Tests when starting treatment with Atorvastatin / placebo

- Blood will be collected and used to examine the monocytes, and some will be stored for testing plasma proteins. In addition, blood will be drawn for HIV viral load testing. All together this will include approximately 100 ml (6-1/2 tablespoon) of blood.
- In addition, neuropsychological testing will be done to detect any HIV-associated neurocognitive disorders.
- If enrolled in the Spinal tap sub-study, a spinal tap will be carried out to collect cerebrospinal fluid (CSF) to test for the presence of inflammation.
- If enrolled in the PET substudy a PET SCAN will be done. The PET Scan can be done 1 or 2 days before the enrollment visit.

Tests 2 weeks after starting Atorvastatin / placebo

- Blood will be drawn for blood count and blood chemistry test, including tests to monitor for liver and muscle problems (ALT/AST and CPK). Additionally, some blood will be drawn for testing plasma proteins. All together this will include approximately 30 mL (2 tablespoons) of blood.
- Women will have a pregnancy test on a urine sample
- If the blood tests show no indication of problems, the dose of Atorvastatin will be increased (from 10 mg/day to 20 mg/day if you are on HAART that includes PI; from 20 mg/day to 40 mg/day if you are on HAART medications that do not include PI or NNRTI); from 40 mg/day to 80 mg/day if you are on HAART that include NNRTIs.

Tests 6 weeks after starting Atorvastatin / placebo

- Blood will be drawn for blood count and blood chemistry test, including tests to monitor for liver and muscle problems (ALT/AST and CPK). In addition, some blood will be collected to examine the monocytes and some will be stored for testing the plasma proteins. All together this will include approximately 90 mL (6 tablespoons) of blood.
- Women will have a pregnancy test on a urine sample

Tests 12 weeks after starting Atorvastatin / placebo

- Blood will be drawn for blood count and blood chemistry test, including tests to monitor for liver and muscle problems (ALT/AST and CPK). Blood will also be taken for monitoring HIV viral load, CD4 counts and lipid levels. In addition, blood will be taken for examining the monocytes and some will be stored for testing plasma proteins. Overall, approximately 120 mL (8 tablespoons) of blood will be taken.
- Women will have a pregnancy test on a urine sample
- In addition, neuropsychological testing will be done to detect any HIV-associated neurocognitive disorders.
- If enrolled in the spinal tap sub-study, a spinal tap will be carried out to collect CSF to test for the presence of inflammation.
- If enrolled in the PET substudy, a PET scan will be done. The PET scan can be done 1-2 days before the week 12 visit if necessary.

Tests during the washout phase (week 12 through week 18)

- Blood will be drawn at week 16, for blood chemistry tests, including tests to monitor for liver and muscle problems (ALT/AST and CPK). In addition, some blood will be stored for testing plasma proteins. All together this will include approximately 20 mL (1-1/2 tablespoons) of blood.
- Women will have a pregnancy test on a urine sample

2nd treatment period

Tests 18 weeks after entering the study (when starting the 2nd treatment phase with placebo / Atorvastatin)

- Blood will be drawn to test for hs-CRP, lipid levels, CD4 counts and viral load. Blood will also be collected and used to examine the monocytes, and some will be stored for testing plasma proteins. Approximately 110 mL of blood (7-1/2 tablespoons) will be taken at this visit.
- In addition, neuropsychological testing will be done to detect any HIV-associated neurocognitive disorders.
- If enrolled in the PET substudy, a PET scan will be done. The PET scan can be done 1-2 days before the week 18 visit if necessary.

Tests 20 weeks after entering the study (2 weeks after starting the 2nd treatment phase with placebo / Atorvastatin)

- Blood will be drawn to do blood chemistry tests to monitor for liver and muscle problems (ALT/AST and CPK). Blood will also be drawn for testing lipid levels and some will be stored for testing plasma proteins. All together this will include approximately 30 mL (2 tablespoons) of blood.
- Women will have a pregnancy test on a urine sample

Tests 24 weeks after entering the study (6 weeks after starting the 2nd treatment phase with placebo / Atorvastatin)

- Blood will be drawn to do blood chemistry tests to monitor for liver and muscle problems (ALT/AST and CPK). In addition blood will also be collected and used to examine the monocytes, and some will be stored for testing plasma proteins. About 100 mL of blood (6-1/2 tablespoons) will be taken at this visit
- Women will have a pregnancy test on a urine sample

Tests 30 weeks after entering the study (12 weeks after starting the 2nd treatment phase with placebo / Atorvastatin)

- Blood will be drawn to do the same tests that were done in the week 12 visit. Approximately 120 mL of blood (8 tablespoons) will be taken at this visit.
- Women will have a pregnancy test on a urine sample
- In addition, neuropsychological testing will be done to detect any HIV-associated neurocognitive disorders.
- If enrolled in the PET substudy, a PET scan will be done. The PET scan can be done 1-2 days before the week 30 visit if necessary.

Tests at end of 2nd washout phase (week 36 of the study)

- Blood will be collected and used to examine the monocytes, and some will be stored for testing plasma proteins. All together this will include approximately 70 mL (approximately 5 tablespoons) of blood.

Explanation of tests

Monocyte testing White blood cells will be analyzed in the laboratory by a method that determines if treatment has changed the types of proteins on the surface of the cells, and stored for later analysis of whether treatment has changed the types of proteins the monocytes makes based on RNA levels.

Plasma protein testing Monocytes release certain proteins into the liquid part of the blood (plasma). After the study is complete, we will test the stored plasma samples to determine if treatment has changed the amount of these proteins the monocytes released into the blood.

Neuropsychological testing This is a standard test that determines the ability and speed of a person's thinking, memory and motor coordination. This test takes about a half hour, and is one by answering questions or working with a pegboard, with our study personnel.

What are the possible risks or discomforts?

We will minimize the chance of any risk occurring by carefully questioning you for anything that might increase your chance of having a side effect from Atorvastatin, and by blood tests prior to beginning treatment and during treatment. The following risks may occur as the result of your participation in this research:

Atorvastatin

The main side effects of Atorvastatin treatment are possible liver problems or muscle problems. The liver problems include changes in the liver blood tests, and will be monitored, and it would be very important to immediately report any change such as yellowing of the skin or eyes or dark urine. The muscle problems ("myopathy") include muscle pain or damage to the muscles. A blood test for muscle injury will be monitored, and it would be very important to immediately report any new muscle pain or weakness or dark urine. In very rare cases these side effects may be severe.

Atorvastatin may cause fetal harm in pregnant women and may have serious adverse reactions in nursing infants. Therefore individuals (especially women), participating in the study must use a form of contraception to avoid pregnancy and must not be breastfeeding.

Some other side effects associated with taking Atorvastatin include allergic reactions or rash; fever or fatigue; abdominal pain.

Blood drawing

Bruising, bleeding, fainting and infections may result from obtaining blood.

Risks for the Spinal Tap Substudy:

Lumbar Puncture

The most common risk of a lumbar puncture is that it can cause a temporary headache. Lying down for a few hours after the test can make a headache less likely to occur. Other problems

are rare and include infection or bleeding. Very rarely, some people can have an allergic reaction to Lidocaine used for numbing.

Risks for the PET Scan Substudy:

Blood draw / Injection site risks: Local pain, bruising, bleeding, blood clot formation, and in rare instances, an infection might occur at the site of the needle stick where the blood draw and injection occur.

Radio-tracer Risks: This research study involves exposure to radiation from the PET/CT scan. Therefore, you will receive a radiation dose. This radiation dose is not necessary for medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive in this study, radiation is known to increase the risk of developing cancer after many years. At the doses of radiation you will receive in this study, it is very likely that you will see no effects at all.

Allergy Risk: There is a risk of allergic or other adverse type reaction to the radiotracers but this is extremely rare. FDG is a natural sugar which has a radio-label attached. There have not been any reactions reported to FDG in the past decade, but if you were to develop an allergic reaction, we would treat it immediately with anti-allergy medicines (Benadryl, Zantac, prednisone depending on severity of the reaction).

Risk of Incidental Findings: Unanticipated clinically insignificant or potentially significant abnormalities may be detected from the proposed imaging or non-imaging test procedures proposed in this study. Such abnormalities will be communicated to you and to your health-care providers in a timely fashion. As for any abnormalities that are detected upon clinical diagnostic procedures, there is the risk of future potentially unnecessary additional diagnostic testing or therapeutic intervention, which can be associated with various complications.

Reproductive Risks: Because this research involves exposure to radiation which can damage an unborn baby, you should not become pregnant or father a baby while on this study. Some doctors tell PET scan patients that they should not have close contact with pregnant women, babies and young children for a few hours after their scan. It is important you understand that you need to use birth control while on this study whether you are a woman or a man. Ask your study doctor about what kind of birth control methods to use and how long to use them. If you are a woman who can become pregnant, you must agree to a pregnancy test (blood or urine) before each PET/CT scan. A negative pregnancy test will be mandated before a woman of child-bearing potential can participate in this study.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study. Your participation will help us learn whether Atorvastatin is a treatment that might be useful to help prevent or treat

neurological (brain) complications of HIV infection. Participation in the PET substudy will benefit research and enable the investigators to better understand the relationship between HIV and atherosclerosis. We hope to better understand how treatment of HIV and how improved assessment of cardiovascular risk in these patients will lead to improved outcomes.

What other choices do I have if I do not participate?

You do not have to participate in this research.

Will I be paid for being in this study?

The study involves one screening visit plus 10 study visits, for a total of 11 visits. You will be paid $50 for the screening visit and up to $50 for each regular study visit. The compensation for the 8 study visits when you are required to return pill bottles (wk 2, 6, 12, 16, 20, 24, 30 and 36) will be $40 and an additional $10 if the pill bottles are returned at that visit. If you attend all study visits and return all the pill bottles at the required visits, the maximum compensation you can receive is $550. If you are required by the study staff to come in for any additional unscheduled visits (usually to check a lab value), you will be compensated $25 for every visit.

If you are enrolled in the Lumbar puncture (LP) sub-study you will also be paid $200 for each LP. If you are enrolled in the LP sub-study, the maximum compensation you can receive from participating in this study is $400.

If you are enrolled in the PET-Scan substudy, you will be paid $50 for each scan; the maximum compensation for this study is $200.

For the study and PET-scan visits, you will be paid cash at the time of your study visit. The compensation for the LP will be provided as a check through the University's accounts payable system and may take 4-6 weeks to process. The check will be sent to your home address.

Please note that if you receive more than $600 in payment in one year for participation in research studies at the University of Pennsylvania, you must provide an Individual Tax Identification Number or Social Security Number for tax purposes.

Will I have to pay for anything?

You and/or your health insurance will not be billed for any of the research procedures performed in this study.

What happens if I am injured from being in the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania, and the name of the medicine you are on. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care.

In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

In the event of any physical injury resulting from research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise offered from the University of Pennsylvania. If you have an illness or injury during this research trial that is not directly related to your participation in this study, you and/or your insurance will be responsible for the cost of the medical care of that illness or injury.

When is the Study over? Can I leave the Study before it ends?
This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or the National Institutes of Health without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the National Institutes of Health has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

CONFIDENTIALITY AND HIPAA
The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What information about me may be collected, used or shared with others?

- Name, address, telephone number, date of birth
- Medical record number
- Social security number
- Personal medical history
- Results from all tests obtained as part of this research study
- Any results of tests obtained due to complications of the research procedures

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right

How will my personal information be protected?
Your research records and specimens will be identified by a code to separate them from your personal information or your identity. The researchers involved with this study will make every reasonable effort to protect the confidentiality of your information. Your information will be kept

in locked cabinets or in secured computers and your specimens will be protected in a secure facility.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, for example: for research oversight and monitoring.

Who, outside of the School of Medicine, might receive my information?

- The National Institute of Health
- The Office of Human Research Protections (OHRP)
- The study data and safety monitoring board

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health

System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR (Electronic Medical Record) maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

In addition, 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.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent/HIPAA Authorization form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date