DESCRIPTION OF RESEARCH BY INVESTIGATOR

You may be eligible to take part in a research study. This form gives you important information about the study. You will be asked to sign in more than one place in this document.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

Principal Investigator: The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Pedro L. Delgado, MD, Marie Wilson Howells Professor and Chair of the Department of Psychiatry in the UAMS College of Medicine and Director of the UAMS Psychiatric Research Institute (PRI).

Study Sponsor: This study is being funded by UAMS department of Psychiatry internal funds.

SECTION I. THE PURPOSE OF THE STUDY AND HOW LONG IT WILL LAST.

You are being asked to be a participant in this study because you have chronic chronic kidney disease and you have been diagnosed with major depressive disorder (MDD). This study will enroll approximately 50 men and women between 30 and 70 years of age. If you join the study, your participation would last about 14 weeks.

MDD, depressive symptoms, and impaired thinking, reasoning, or remembering (cognitive functioning) are the most common mental health (psychological) problems in patients with chronic kidney disease receiving hemodialysis. MDD can lead to poor quality of life, increased hospitalizations, failure to take medications as directed, dialysis withdrawal, premature death, and other health problems in chronic kidney disease patients. MDD is often under-diagnosed and/or underrated. If we can diagnose MDD early and treat MDD appropriately in patients with chronic kidney disease, these patients may see an improvement in overall quality of life.

This study involves the use of two drugs: Fluoxetine (Prozac™) and sustained release Bupropion (Wellbutrin SR™). These two drugs are different from each other with regard to chemical structures, mechanisms of actions, and other characteristics. The U.S. Food & Drug

Administration (FDA) has approved both drugs for treating MDD. This study will compare the effects, good and/or bad, of Bupropion versus Fluoxetine on chronic kidney disease patients with MDD. The safety of these drugs in humans has been tested in prior research studies; however, some side effects may not yet be known, especially in chronic kidney disease patients on hemodialysis.

SECTION II. DESCRIPTION OF THE STUDY INCLUDING PROCEDURES TO BE USED.

If you decide to take part, you will be asked to sign this consent form.

While you are taking part in this study, you will be asked to complete assessments and study procedures at 10 visits including a screening visit with the researchers or study staff over the period of about 14 weeks. Screening visit is followed by Baseline visit (Week 0) and then visits to complete assessments are scheduled at Weeks 1, 2, 3, 4, 6, 8, 10, and 12. For weeks 5, 7, 9 and 11, you will only be required to come in and pick up your medication for those weeks and return the medication bottle from the previous week. Most visits will occur on the 4th floor of the Psychiatric Research Institute (PRI) at the University of Arkansas for Medical Sciences before or after your regularly scheduled dialysis treatments. Depending on your dialysis site, visits may occur during regularly scheduled dialysis treatments. Extra visits may occur on non-dialysis days, if needed. If your visits need to occur at PRI, we will discuss with you options for traveling to/from PRI and your dialysis site, including providing taxi service, if needed.

Screening:
After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you are eligible to continue in the study. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will have to give us permission to access these tests and/or exams to your medical records. If we are not able to access them, we may need to redo these tests in order to determine your eligibility to participate. You will be told which results we will obtain and which procedures will not have to be repeated.

Screening Procedures – The following procedures will be performed on you by the study team OR the information taken from your medical record in order to evaluate whether you qualify to be in this study.

- *Demographics, medical history, and medications:* We will review your medical history and demographic (date of birth, sex, race, ethnicity) information. You will be asked to report any medications you are taking (including all prescribed medications and any over-the-counter or herbal medications).
- *Physical examination:* You will have a physical exam and an assessment of vital signs (heart rate, blood pressure, temperature, weight and height) and a basic dental evaluation. Most of this examination will occur at PRI on the same floor where you received this form. The dental examination will occur on the first floor of UAMS hospital at

the Dental Hygiene Clinic, attached to PRI (5 minute walk).

- *Blood:* 20 ml blood (about four teaspoons) will be collected at screening if no current lab results can be extracted from your medical record.
- *Electrocardiogram (EKG)*: An EKG (a painless test that provides a recording of your heart rhythm) will be performed on you.
- *The Hamilton Depression (HAM-D) Scale*: You will complete a 25-item questionnaire to assess depression.
- *Clinical Interview*: A psychiatrist, a member of the study team, will conduct a structured clinical interview to evaluate your depression.

We will have you sign a release of information so that we can request information from your medical record such as dialysis dose, pre- and post-dialysis body weight and blood pressure. Although this information will not be necessary for enrollment, we will obtain it to confirm dialysis adequacy (kt/V).

The procedures listed above may take approximately 90 minutes.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons and other possible options with you.

Assignment to Study Groups - When it is determined that you are eligible for the study, you will be assigned randomly (by chance-like flipping a coin) to one of 2 study groups: Bupropion SR or Fluoxetine. You have equal probability of being assigned to either group. Both of these drugs are taken by mouth. We may change your dose later on, depending on how you do on the medication. Your study doctor will know which drug you are taking, but you and the study raters will not know.

Study Procedures: As a participant, you will undergo the following procedures:

Treatment Phase – Baseline visit (Week 0):

After randomization, you will have the following procedures completed and/or the information will be obtained from your medical record:

- Assessment of any changes in prior/current medical conditions, symptoms, and complaints, including any changes in other medications you may be taking.
- Assessment of vital signs: heart rate, temperature, pre- and post-dialysis body weight, and pre- and post-dialysis blood pressure.
- Blood: 20 ml blood (about four teaspoons) will be collected at the middle of the week (either Wednesday or Thursday depending on your dialysis regimen) pre-dialysis to be tested for several biomarkers related to the breakdown of a substance called tryptophan and inflammatory markers. Whenever possible, blood will be drawn from your pre-dialysis intravenous line rather than doing a separate needle stick.
- *Pregnancy test:* For **female** patients capable of becoming pregnant, a pregnancy test in

blood will be done before you receive study treatment. If you are pregnant you will not be allowed to continue in the study.

- Interview and questionnaires: we will do several interview and questionnaire tools with you, typically at the middle of the week (either Wednesday or Thursday). You will be asked to participate in interviews, fill out questionnaires, and complete computer tasks that are designed to measure your mood, depression symptoms, treatment response, fatigue, cognitive ability, medication side effects, and medication adherence.

We will measure your pain sensitivity by gently placing a pressure indicator on the skin of both legs for approximately 5 seconds until you report any sensation of discomfort or mild pain. We will also measure your pain sensitivity with a thermal (warm and cold) sensor in your right hand with approximately 5 series of questions about your temperature perception (some will ask for pain recognition and other for how much pain you can take) for approximately 45 seconds each. You will then receive study medication bottles with instructions on when to start the study medication as well as timing and dose.

This visit will take approximately 2 hours.

Treatment Phase – Week 1 - 12 [Week 12 will be the final study visit.]:

During weeks 1,2,3,4,6,8,10, and 12 you will have the following procedures completed at the middle of the week (typically either Wednesday or Thursday) and/or the information will be taken from your medical record.

- Assessment of any changes in prior/current medical conditions, symptoms, and complaints including changes in other medications you may be taking.
- Assessment of vital signs: heart rate, temperature, pre- and post-dialysis body weight, and pre- and post-dialysis blood pressure.
- Blood: On weeks 1, 4 and 12, 20 ml blood (about 4 teaspoons) will be collected pre-dialysis to be tested for tryptophan (TRP) and TRP metabolites, and inflammatory markers. Blood levels of study medication metabolites will also be measured.
- EKG (week 4)
- Mood and cognitive assessments: We will ask you to participate in interviews, fill out questionnaires, and complete computer tasks that are designed to measure your mood, depression symptoms, treatment response, fatigue, cognitive ability, medication side effects, and medication adherence.
- Measure of pain sensitivity.

Either Bupropion SR or Fluoxetine will be given in bottle to take at home at weekly intervals during the study. During weeks 5, 7, 9, and 11 you will only come in to pick up your medication for the week and to return the pill bottle from the previous week.
For Week 12 (End of Study Visit) either the medication will be stopped or you will be given instructions to taper off the study medication over 1-2 weeks. If you decide that it would be beneficial for you to continue the medication once you are no longer a research participant, you can sign a release of information for one of the study physicians to inform your primary care provider about the medication and dose you had been taking. You can then follow up with your

own physician to be prescribed the medication once your participation has ended.

These visits will take approximately 30-60 minutes.

Could your participation end early? There are several reasons why the researchers may end your participation in the study at any time (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped prematurely.
- The investigator can end your participation at any time for any reason.

The researchers will discuss your options for medical care when your participation in this study ends. You always have the option of withdrawing your consent at any time during the study and not have any further study procedures.

What happens after treatment? 12 weeks of treatment with either antidepressant typically leads to improvement in depressed mood state. However, not all people respond to medications the same way. Two weeks after you finish the study, we will call you to see how you are doing and how well you are tolerating the stoppage of study medications. If you experience any distress related to stoppage of medication, please contact Dr. Delgado at the phone numbers given below.

SECTION III. DESCRIPTION OF ANY PROCEDURES THAT MAY RESULT IN DISCOMFORT OR INCONVENIENCE.

There are procedures that may result in discomfort or inconvenience during your participation in this study. These include:

1. You may be bored during the study visits.
2. You may find that filling out forms and doing computerized tasks tedious, redundant, stressful, or boring.
3. It may be inconvenient for you to attend the study visits.
4. You will briefly experience pain in the form of pressure, cold or heat from the pain sensitivity measures.

SECTION IV. EXPECTED RISKS OF STUDY.

The investigators have designed this study to learn how effective Bupropion SR is versus Fluoxetine for MDD in chronic kidney disease patients. There is a risk that the effectiveness and/or safety of Bupropion SR and/or Fluoxetine may not be as good as it is for patients with

MDD who do not have chronic kidney disease. Bupropion SR or Fluoxetine may not help treat your MDD and continuing to be depressed may make your condition or disease worse.

Collecting the blood samples. You will have approximately 20mL (about 4 teaspoons) of blood drawn during screening, baseline (week 0), week 1, week 4, and week 12. This is a small quantity of blood and should have minimal if any effect on your total blood volume. Blood drawing may result in pain and bruising at the site and/or feeling faint, especially if we need to do an extra needle stick rather than draw the blood from the IV line during dialysis.

Risks from the specific research procedures. There are risks to taking part in this research study. One risk is that you may experience side effects related to Bupropion SR or Fluoxetine while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are life threatening or fatal (could cause death). The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

The following sections describe the risks related to each drug and procedure that is part of this research study. These are these most commonly reported side effects; there may be additional side effects that we do not know. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Risks and side effects related to **Bupropion SR** include those that are:

Likely (10 or more subjects out of 100)	
Not Serious	**Potentially Serious**
• Dizziness • Agitation • Blurred vision • Tremor • Sweating • Headache/migraine • Inability to get adequate sleep • Increased heart beat • Dry mouth • Constipation • Decreased appetite • Nausea, vomiting • Weight gain	• None
Less Likely (Between 2-9 subjects out of 100)	

Not Serious	Serious
• High blood pressure (Hypertension) • Low blood pressure (Hypotension) • Skin rash and itching • Impotence • Urinary frequency • Arthritis • Slowness in movement (bradykinesia) • Upper respiratory complaints • Fatigue • Anxiety • Decreased sexual desire (libido)	• Abnormal heart rhythm
Rare (Less than 1 subject out of 100)	
Not Serious	**Serious**
• Urinary retention	• Suicidal ideation • Suicide • Faint (syncope) • Seizures. At doses similar to the initial dose used in this study, the chance of a seizure is approximately 1 in about 1,000 patients. At doses higher than the initial dose, the chance of a seizure can increase at least 4 out of every 1,000 patients.

Risks and side effects that have been observed with **Fluoxetine** include those which are:

Likely (10 or more subjects out of 100)	
Not Serious	**Potentially Serious**
• Decreased appetite • Anxiety • Nervousness • Inability to obtain adequate sleep (insomnia)	• None
Less Likely (Between 2-9 subjects out of 100)	
Not Serious	**Serious**
• Impaired thinking	• Alteration in blood glucose • Abnormal bleeding • Weight loss
Rare (Less than 2 subjects out of 100)	

Not Serious	Serious
•	• Suicidal ideation • Suicide • Serotonin syndrome symptoms (mental status changes [agitation], increased heartbeat, change in blood pressure, dizziness, tremor, seizures, and/or nausea, vomiting, diarrhea) • Allergic reactions (including difficulty breathing (bronchospasm), swelling under the skin (angioedema), involuntary muscle contraction of the vocal cords resulting in difficulty breathing (laryngospasm), hives (urticaria) and skin rash

Risks associated with abruptly stopping the study medication: To our knowledge, abruptly stopping the bupropion will not result in side effects due to the abrupt discontinuation. Fluoxetine at doses up to 20 mg/day may result in mild dizziness or vertigo when the medication is abruptly stopped. If you are maintained on fluoxetine at a higher dose than 20 mg/day, you will be instructed to taper off the medication over a 1-2 week period to help prevent side effects.

When you complete the 12-week study, you may experience withdrawal from the study medication. These drugs are standard treatments for depression and may be obtained from your regular doctor as part of routine care.

Risks and side effects related to the **Blood Collection** include those that are:

Likely and not serious (more than 20 out of 100)
- Pain
- Bruising (black and blue marks)
- Bleeding from the puncture site
- Discomfort

Rare but Serious (less than 5 out of 100)
- Infection
- Formation of a blood clot or swelling of the vein and surrounding tissue

Risks and side effects related to the **Electrocardiogram or EKG**: There are no known risks associated with this test. However, removal of small adhesive patches may cause minor irritation to skin.

There are no known risks associated with any of the following assessment tools – Mini International Psychiatric Interview (MINI), Hamilton Depression (HAM-D) Scale, Profile of Mood States (POMS), Brief Fatigue Inventory (BFI), Modified Mini Mental Status (3MS) Examination, cognitive tasks, Antidepressant Treatment Response Questionnaire (ATRQ), Clinical Global

Impressions - Severity and Improvement (CGI-S, CGI-I), Systematic Assessment For Treatment Emergent Events (SAFTEE), Medication Accountability Record.

For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Risks related to withdrawing from the study. If you decide to withdraw from this study early, please discuss your decision with the principal investigator, Dr. Pedro Delgado. The researchers may ask you to complete study withdrawal procedures at a final study visit. This visit includes the procedures listed for the Week 12 visit described earlier in this document. Depending on the study medication and dose you are on, you may be asked to taper off the medication.

Risks to privacy.
There is a risk that other people may become aware that you are participating in this study. To avoid this risk, we will protect your privacy by assigning you a subject ID code. Identifiable health information gathered from you (such as your name, date of birth, blood samples, test results, etc.) will be linked to your subject ID code rather than your name.

Reproductive Risks.
Concerns for sexually active women. All pregnancies have a background risk of birth defects, loss, or other adverse outcome regardless of drug exposure. Information about risk of the study drugs (Bupropion SR and Fluoxetine) in pregnancy is incomplete. Therefore, you should not become pregnant while taking part in this study. It is important that you talk to your study doctor about avoiding pregnancy during this study. If you think you might have become pregnant while you are in this study, you must tell one of the study doctors right away so that management of the pregnancy and the possibility of stopping the study can be discussed.

Risks to babies who are being breastfed. Like many other drugs, both Bupropion SR and Fluoxetine may be present in breast milk. The effects of these drugs on breastfed babies are not known. If you are planning to breastfed your baby, please consult with the Principal Investigator Dr. Pedro Delgado.

Risks if you also participate in other research studies.
Being in more than one research study at the same time may increase the risk to you, especially when enrolled in multiple drug treatment studies. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

Risk from not knowing which medication you are taking.
In case of an emergency, a physician outside of the study may need to know which medication (Bupropion or Fluoxetine) you are taking. Dr. Pedro Delgado can also be contacted at his office (501-526-8140) or cell (501-313-6724) at any time to provide this information.

SECTION V. EXPECTED BENEFITS OF STUDY.

You may benefit directly from your study participation. Your MDD may improve as a result of treatment with one of the study drugs. Your mental and physical health will also be closely monitored during the study. Treatment of depression with antidepressants can improve symptoms of depression, including depressed mood, loss of energy and interest, impaired concentration, guilt feelings, impaired sleep or appetite, and others. When these symptoms improve, people can often become more functional in their lives and have the motivation and energy needed to face difficult situations more effectively. There is no guarantee that you will benefit from participation or that the effects of the treatment will outweigh the risks of study participation.

We hope the information learned from this study will benefit other people with similar conditions in the future.

SECTION VI. ALTERNATIVE THERAPY OR DIAGNOSTIC TEST.

There are other options available to you.

You do not have to be in this study to get help for your MDD. If you choose not to participate in this study, you may consider other treatment such as psychotherapy for MDD. Also, both Bupropion SR and fluoxetine are FDA approved drugs and are available for the treatment of MDD off study. You may also seek other FDA approved drugs for treatment of MDD.

You should discuss your alternatives to participating in this research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider.

SECTION VII. USE OF RESEARCH RESULTS.

If results of this study are reported in medical journals or meetings, you will not be identified by name or by any other means without your specific consent. As described above, all research information acquired from you (including blood samples) will be linked to a study code instead of your name. Your medical records will be maintained according to this medical center's requirements.

If suicidal intent or other major clinical findings are observed during clinical or research assessments, the study physician will be notified immediately. If you are suicidal, 911 will be called and an ambulance will take you to an emergency department where you will be further evaluated. You may be hospitalized against your will.

By participating in this study, you also consent that representatives of the Institutional Review Board, other UAMS institutional oversight offices, the Office of Human Research Protection, and/or National Institutes of Health may review your complete research records, including information that identifies you. All such record reviews will be conducted on the premises of the University of Arkansas for Medical Sciences. Your consent to such reviews includes knowing

that any medical record information related to disorders such as drug abuse, HIV infection, alcoholism and/or sickle cell anemia would thereby be disclosed to the representative.

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. By law, we must release information to the appropriate authorities if at any time during the study there is a concern that child abuse or elder abuse has possibly occurred or if you disclose a desire to harm yourself or others.

More information concerning confidentiality is described in the "Authorization to Use and Disclose Protected Health Information as part of a Research Study" located later in this form.

SECTION VIII. SPECIAL CIRCUMSTANCES.

You will receive a small reimbursement for your time in this study. You will be compensated with a check for $25.00 for every study visit that includes completing assessments up to a total of $250.00 upon completing all 10 study visits involving assessments. If you do not finish all the assessment visits, you will receive checks of $25 each only for the visits you have completed. For your information, if you earn more than $600.00 during your participation in this study combined with any other UAMS funded research study during the calendar year (that is, between January 1 and December 31), the amount will be reported to the Internal Revenue Service.

The study will provide you the study drugs, either Bupropion SR or Fluoxetine, free of charge during this study. In addition, all tests, examinations, and medical care required solely for purposes of this study will be provided at no cost to you. There will be no additional costs to you for your participation. You/your insurance company will continue to be responsible for the costs of your standard of care treatment for chronic kidney disease.

In the event you are hurt by being in this research, treatment will be available. This treatment may include:

First aid,
Emergency treatment and/or
Follow-up care

This treatment may be billed to you, or your insurance company, in the normal manner. Normally, no other form of compensation is available.

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later, you feel you have been hurt by this research or you wish to report a problem that may be related to this study please contact Pedro L. Delgado, MD during and after normal work hours at 501-526-8140 (office) or 501-313-6724 (cell).

You have not waived your legal rights by signing this consent form. If you have any questions about your rights as a research subject or concerning a research related injury, you can call the UAMS Institutional Review Board representative at phone number (501) 686-5667. The

Institutional Review Board of the University of Arkansas for Medical Sciences reviews research projects independently based upon the principle that human participants will be adequately protected.

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.

RESEARCH SUBJECTS' RIGHTS

The purpose and voluntary nature of this study, as well as the potential benefits and risks that are involved have been explained to me. I have been able to ask questions and express concerns, which have been satisfactorily responded to by the study team. I have been told that I will be given a copy of this consent form.

_____	_____	_____
Printed Name of Subject	Signature of Subject	Date
_____	_____	_____
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

Authorization to Use and Disclose
Protected Health Information as part of a Research Study

This section describes the use of your health information. If you agree to allow the researcher to use your private information, you will be asked to sign at the end of this section.

Research policies require that private information about you be protected. This is especially true for your health information.

However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: your medical history and blood work, information that we get from your medical record, information you give us during your participation in the study, results of blood tests, demographic information like your age, gender, race/ethnicity, etc.

We will get this information by asking you, asking your doctor, by reviewing your medical records and charts.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The research study staff and the staff at dialysis centers from where study subjects will be recruited
- The committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason
- The members of the local research team
- The Institutional Review Board and the Compliance Office of the UAMS, and other groups that oversee how research studies are carried out
- The Research offices at the UAMS and the University Health System
- The Food and Drug Administration (FDA)

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Code numbers will be used on any study-related records or materials (such as blood samples) that are sent outside of the UAMS for review or testing.

Blood samples will be sent to the University of Texas Health Sciences Center at San Antonio for analyses; these samples with be coded using your subject ID code. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to **Pedro L. Delgado, M.D.; Department of Psychiatry, University of Arkansas for Medical Sciences; 4301 W. Markham, #554; Little Rock, AR 72205.** If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. During the course of the study, you may be denied access temporarily to certain medical information about you that is study related. However, the Principal Investigator and staff will not automatically deny a request, but will consider whether it is appropriate under the circumstances to allow access. If access is denied during the study, once the study is completed, you will be able to request access to the information again. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
If you sign this form, you are giving us permission to create, collect, use and share your health information as described in this form. You do <u>not</u> have to sign this form. However, if you decide not to sign this form, you cannot be in the research study. You need to sign this form and the research consent form if you want to be in the research study. You agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

If you sign this form but decide later that you no longer want us to collect or share your health information, you must send a letter to the person and the address listed by "Principal Investigator" on the first page of this form. The letter needs to be signed by you, should list the "Study Title" listed on this form, and should state that you have changed your mind and that you are revoking your "HIPAA Research Authorization". You will need to leave the research study if we cannot collect and share any more health information. However, in order to maintain the reliability of the research, we may still use and share your information that was collected before the Principal Investigator received your letter withdrawing the permissions granted under this authorization.

If you decide not to sign this form or change your mind later, this will not affect your current or future medical care at the University of Arkansas for Medical Sciences.

SIGNATURE, DATE, AND IDENTITY OF PERSON SIGNING

The health information about _____ can be collected and used by the researchers and staff for the research study described in this form and the research consent form.

Signature:_____ Date:_____

Print name:_____

The researcher will give you a signed copy of this form.