[INSERT SPECIFIC RECRUITMENT SITE]
RESEARCH PARTICIPANT INFORMED CONSENT FORM

Protocol Title:	HOPE Consortium Trial to Reduce Pain and Opioid Use in Hemodialysis A National Institutes of Health HEAL Initiative Trial
Principal Investigator:	Insert site-specific PI information
Study Sponsor	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Emergency Contact:	Insert Emergency Contact Insert Phone Number/Pager, etc.

RESEARCH STUDY SUMMARY FOR POTENTIAL PARTICIPANTS

You are being invited to participate in a research study. Your participation is voluntary, which means you can choose whether or not you want to participate. Before deciding to enroll you will need to understand what the study requires and its risks. You should ask the study team any questions you have about participating before agreeing to join the study. If you have any questions about your rights as a research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The focus of this research study is chronic pain experienced by people receiving hemodialysis. The study is testing two interventions to reduce the negative effects of pain on how people feel and participate in life activities. Although reducing the use of pain medication is not the main purpose of the study, it is possible that if you receive the study interventions you may need less medication to treat your pain.

There are two phases in this trial: Phase 1 and Phase 2. During Phase 1, some participants will get Pain Coping Skills Training which teaches people skills for coping with pain, and some participants will continue their usual care. In Phase 2, those participants who are using an opioid pain medication may be offered the opportunity to switch to a pain medication called buprenorphine. Throughout the study, participants will be asked to complete phone surveys about pain and symptoms. Study participation will last for 8 – 10 months. Most study activities can happen during dialysis treatments or at home.

There are no guaranteed benefits of being in the research study. Discussions during the study could be about sensitive topics that may be upsetting. Some people in the study will be treated with buprenorphine but this is not required for study participation. Side effects of buprenorphine include withdrawal symptoms, constipation, dizziness, drowsiness, headache, nausea and dental problems.

Please note that there are other factors to consider before agreeing to participate, such as additional procedures and use of your personal information. If you think you might be interested in participating and want to learn more about the study, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the explanation process.

WHY AM I BEING ASKED TO VOLUNTEER?

You are being invited to participate in this research study because you are receiving hemodialysis for kidney failure and you have ongoing pain. 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 want to discuss the study with your family, friends, or doctors. Please ask the study doctor or other members of the research team if you have any questions. If you decide to participate, you will be asked to sign this form and will be given a copy to keep. If you decide not to participate there will be no penalty or loss of benefits to which you are otherwise entitled.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The goal of this study is to improve pain and reduce the negative impact it has on the lives of people being treated with dialysis. To do this we will test an approach called Pain Coping Skills Training to see how effective this method is at treating pain. This training is done by video or telephone either during dialysis or at home. A second goal is to determine whether a drug called buprenorphine improves pain.

It is important to note that the purpose of this study is not to take away your pain medication. The goal of the study is to see if the interventions reduce the negative impact of pain, which may help people need less pain medication.

HOW LONG WILL I BE IN THE STUDY? HOW MANY OTHER PEOPLE WILL BE IN THE STUDY?

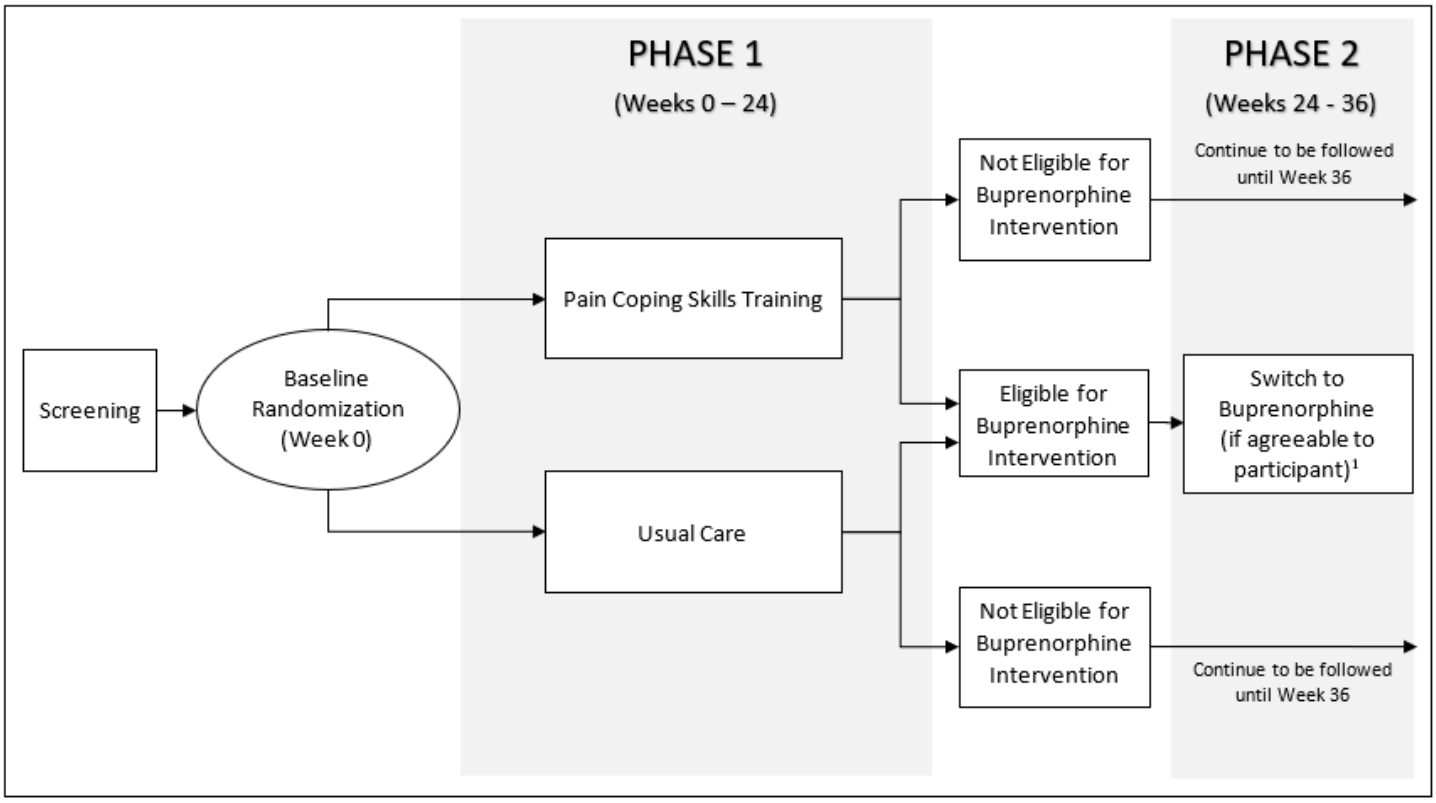
Your participation in the study will last 8 to 10 months. The study will enroll 640 participants throughout the United States. The study is expected to be completed within four years.

WHAT AM I BEING ASKED TO DO?

The first step is to make sure that you are eligible for the study meaning that it is safe and appropriate for you to participate. If you are eligible, you will be asked to complete two study phases. For Phase 1 you will be assigned to one of 2 groups: Pain Coping Skills Training or Usual Care. These Phase 1 groups are described in detail below. After 24 weeks (about 6 months), you will be evaluated for eligibility for Phase 2 of the study. You will be eligible for Phase 2 if you are using opioid medication for your pain. If you are able to become pregnant you will be asked to complete a blood pregnancy test and will be required to have a negative result before participating in Phase 2. You might also need to have a blood test to check your liver function if this is not already available in your medical records. If you are eligible for Phase 2, you will meet with a study doctor and be encouraged (but not required) to change from your current pain medication to buprenorphine which you will take for 12 weeks. Before switching to buprenorphine, you will be asked to complete a saliva drug test. This test is to monitor for drugs or medications that should be avoided while taking buprenorphine. Specific

information about buprenorphine is provided below. All participants, regardless of Phase 2 eligibility, will be followed in the study for 36 weeks (about 9 months).

Figure 1. Study Design



[1]Participants who do not switch to buprenorphine will continue to be followed until Week 36.

Screening Visit (today):

The purpose of today's visit is to explain the study procedures and to see if you are eligible to join. As part of your screening you will be asked to:

- Complete the informed consent process with a member of the research team. This will include going through the informed consent form and having your questions answered. If you choose not to participate in the study and do not sign this form, no further research procedures will take place;
- Answer questions about your medical history including information about your kidney disease, pain experience, and mental health;

If you are eligible for the study you will be asked to schedule your baseline activities and complete a W-9 tax form for your compensation.

Baseline Survey (within 4 weeks of screening):

At the baseline visit, which may take place in person or by telephone, a member of the research team will ask you additional questions about your medical history and the medicines you are taking. You will also complete a set of surveys by telephone. The phone surveys are described further later in this form.

Group Assignment (Randomization):

You will be randomly assigned by a computer to one of two groups: Pain Coping Skills Training or Usual Care. You will have an equal chance of being assigned to either of these groups like flipping a coin. Neither you nor your study doctor gets to choose which group you are assigned to. Before you decide to participate, you should think about whether you would be okay being assigned to either group.

Phase 1 Intervention Groups (Weeks 0 – 24):

Pain Coping Skills Training Group: If you are assigned to this group, you will work with a trained personal coach to help you learn skills to manage pain, the impact pain has on your life, and the emotional distress pain can cause. The Pain Coping Skills Training includes the following:

Weeks 1-12: Weekly, 45-50-minute telehealth sessions focused on developing coping skills. Telehealth means real-time video similar to Facetime or Skype. The skills taught in these sessions are designed to reduce the negative effects pain has on how you feel and function and also might help you to reduce use of pain medications.

Telehealth sessions will require the use of a smartphone, tablet, or computer. If you do not have access to one of these, a device will be given to you at your dialysis clinic for use during the study. The devices (either your own or one provided by the study) will use a secure system that reduces risks to your privacy. The telehealth sessions with your coach can take place during your dialysis sessions if that is your preference. If so, you will be given a headset and audio device so other people in the dialysis unit cannot hear what your coach is saying and cannot easily hear what you are saying.

Weeks 13-24: Daily, 5-minute telephone booster sessions delivered through a system called Interactive Voice Response (IVR). Each day you will receive a scheduled, automated, pre-recorded phone call (without a live person on the phone) during which you will be asked to answer brief questions about your pain. Based on your responses to these questions, once each week you will be provided with personalized feedback from your coach in the form of a message that you can access through the IVR system. You will also be able to listen to pre-recorded, short messages that review different coping skills that you learned during the first 12 weeks of the study.

Interactive Voice Response (IVR) calls will require the use of a smartphone, cell phone, or landline so that you may use the keypad to enter data and listen to pre-recorded messages. The IVR platform is compliant with the Health Insurance Portability and Accountability Act (HIPAA) to protect your privacy. Your coach will show you how to use the IVR system and will be able to answer any questions you may have.

Usual Care Group: If you are assigned to this group, you will be provided with information about pain, pain medications, and ways to manage pain. You will continue to work with your usual doctors to manage your pain.

For both the Pain Coping Skills Training and Usual Care groups, information describing the trial and your assigned study group will be provided to the doctor(s) who normally help you manage your pain.

Phase 2 Intervention: Buprenorphine (Weeks 24 – 36):

Phase 2 of the study will begin at Week 24 of your participation and will last for 12 weeks. Participants from both groups who, at the end of Phase 1, are taking opioid pain medications above a specific dose will be encouraged (but not required) to change from their current pain medication to buprenorphine. Buprenorphine is a unique type of opioid medication that has similar effects on pain as other opioid medications but has a lower risk of slowing or stopping your breathing. If you are not taking opioid medications at all or above the specific dose, you will not be offered buprenorphine and you will continue to be followed in the trial until Week 36.

To determine if you can switch to buprenorphine, we will review your most recent liver function tests. If you have had these tests performed as part of your usual care within the 12 weeks before Phase 2, we will be able to use those results. If you have not had liver function tests performed within the 12 weeks before Phase 2 these tests will need to be done in order to determine eligibility. If you are able to become pregnant you will be asked to complete a blood pregnancy test and will be required to have a negative result before being offered buprenorphine. Because the blood for both the liver function and pregnancy test can be obtained at dialysis through the dialysis tubing, these measurements will not require a needle stick. Each of these tests requires 5 - 10 ml (1 - 2 teaspoons of blood), which means that if you require both tests, the amount of blood required will be 10 - 20 ml (2 - 4 teaspoons).

If you are eligible for buprenorphine you will be asked to switch from your current opioid medication to buprenorphine. You will meet with the study doctor and will be provided with individualized dosage recommendations and instructions. You will be asked to sign a new informed consent form before starting buprenorphine and will have time to get your questions answered before you sign the form. Before your visit with the study doctor you will be asked to complete a saliva drug test to monitor for drugs or medications that should be avoided while taking buprenorphine. You will not be required to start buprenorphine or change your medication if that is your preference. Regardless of whether or not you start buprenorphine, you will continue to be followed in the trial until Week 36.

HOW WILL INFORMATION BE COLLECTED?

Check-Ins with the Research Team (Every 4 weeks):

You will be contacted by research coordinators either in-person or by telephone every 4 weeks throughout your study participation regardless of your assigned group. During these check-ins you will be asked questions about recent hospitalizations, falls, medical events, changes to your medications, and any new or different ways you are treating or managing your pain. During these check-ins you will also schedule your upcoming telephone surveys.

Telephone Surveys (Weeks 0, 12, 24 & 36):

Your name and phone number will be provided to interviewers working with the study at the University of New Mexico and the University of Pittsburgh. Your research team will schedule a time, based on your availability, for the interviewers to contact you to complete survey calls. During these calls, you will be asked a variety of questions about how you are feeling physically, emotionally, and mentally, as well as your opioid pain medication use. These telephone calls are expected to take up to 45 minutes.

Communication with your Doctor(s) (Weeks 0 & 24 - 36)

If you take opioid pain medication, the research team will contact your nephrologist and the doctor who prescribes the medicine to inform them of your participation in this research study. If you switch your usual opioid pain medication to buprenorphine as part of the study, the study team will let your doctor(s) know this and will work with them to plan for use of buprenorphine or your current opioid pain medication after the study ends.

WHAT ARE THE POSSIBLE RISKS?

There are risks associated with this study that you should be aware of:

Emotional Distress: During the study you will be asked to answer questions about sensitive topics that may be upsetting. The research team will help you get additional care, if needed.

Buprenorphine: Buprenorphine is an FDA-approved medication for the treatment of Opioid Use Disorder (OUD) and for the treatment of pain. Common side effects of buprenorphine are opioid withdrawal, constipation, dizziness, drowsiness, headache, dry mouth, mouth numbness, insomnia, abdominal pain, nausea, numbness and tingling. Dental problems such as tooth decay, cavities, oral infections, and loss of teeth have recently been reported as possible side effects of buprenorphine. These may happen even if you have no history of dental issues. The FDA has said that the benefits of buprenorphine still outweigh the risks.

You can do the following to decrease the risk of dental problems:

- After the medication film has dissolved, you should take a large sip of water and rinse your mouth.

- Wait at least one hour after taking buprenorphine before brushing your teeth.
- Visit your dentist soon after switching to buprenorphine and attend regular dental check-ups while taking buprenorphine so that your dentist can monitor your dental health.

Opioid Withdrawal: If you are currently using opioid pain medications, and you reduce your opioid pain medicine or switch to buprenorphine, you may experience withdrawal symptoms such as nausea, vomiting, diarrhea, new or increased pain, severe itching, depression, agitation, sweating, headache and/or shaking due to reducing opioid doses, switching from one opioid medication to another, or transitioning to non-opioid medications. Study staff will talk to you about withdrawal symptoms, take precautions to prevent withdrawal, and manage symptoms if they occur. You may have some of these symptoms or you may have none at all.

Reproductive risks: You will not be offered buprenorphine if you are pregnant, breastfeeding, or planning to become pregnant. If you are able to become pregnant, you will have a pregnancy test to determine your eligibility for the buprenorphine portion of this study. If you become pregnant while you're in this study, tell us right away.

If you are able to become pregnant and you are taking buprenorphine, you will need to take steps to prevent pregnancy by using a medically accepted method of birth control or abstaining from sexual intercourse with persons of the opposite sex. Accepted methods include intrauterine devices (IUD), hormonal implants or injections, birth control pills, patches, or ring, a diaphragm with spermicide, or latex condoms.

Unforeseeable Risks: This research study may involve risks that are currently unforeseeable.

WHAT IF NEW INFORMATION BECOMES AVAILABLE ABOUT THE STUDY?

During 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. A Data and Safety Monitoring Committee, which is an independent group of experts, will review the safety of this study while the study is being carried out.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

There are no guaranteed benefits for being in the research study.

Your participation in this research study may contribute to the development of treatments for chronic pain management in patients receiving maintenance hemodialysis and may benefit the future health of the community at large.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?

If you decide not to participate in this study, your care will not be impacted. You will continue to get care from your usual dialysis team and other medical providers.

WILL I BE PAID FOR BEING IN THIS STUDY?

As compensation for the time required for this research, you will receive up to $550 for successfully completing all study activities. A breakdown of the compensation plan is detailed in the table that follows. Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. It is important to know that if you earn more than $600 in one year from being in research studies, including this one, at INSERT SPECIFIC SITE NAME that money will be reported to the IRS for tax purposes. Researchers will use your data to make discoveries. If this study leads to new tests, medicines or products, they could make a profit. You will not get any of these profits. As the sponsor of this study, NIDDK will not financially benefit from any discoveries that may result from this study.

Table 1. Study Compensation

Study Time Point	Study Week	Compensation
Check-in 1/Baseline	0	$25
Telephone Survey 1	0	$50
Check-in 2	4	$25
Check-in 3	8	$25
Check-in 4	12	$25
Telephone Survey 2	12	$50
Check-in 5	16	$25
Check-in 6	20	$25
Check-in 7	24	$25
Telephone Survey 3	24	$100
Check-in 8	28	$25
Check-in 9	32	$25
Check-in 10	36	$25
Telephone Survey 4	36	$100
	TOTAL	**$550**

WILL I HAVE TO PAY FOR ANYTHING?

There will be no cost to you for being in this research study. You and/or your health insurance may be billed for the costs of medical care during this study for expenses that would have occurred if you were not in the study.

WHAT HAPPENS IF I AM INJURED FROM BEING IN THE STUDY?

Medical care will be provided if needed to treat injuries directly resulting from taking part in this research. This care will be billed to your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for costs if they are not covered by your insurance.

There are no plans for the [insert specific clinical center] to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

For participants who take buprenorphine as part of the trial, $500.00 will be provided to cover costs of the recommended dental evaluation. The study will not cover the costs for any additional dental work that is required.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed on the first page of this form.

CAN I LEAVE THE STUDY BEFORE IT ENDS?

If you decide to participate, you are free to leave the study at any time. Leaving the study will not change your future care. If you are taking buprenorphine as part of the study and decide to leave the study before it ends, the research team will work with you and your doctors to set up a plan for either continuing or stopping the buprenorphine.

Your participation in the study may be stopped early by your research team or the Study sponsor (NIDDK) because:

- The Principal Investigator (research doctor) feels it is needed 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.
- The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study before it has been completed.

WHAT PERSONAL HEALTH INFORMATION ABOUT ME MAY BE COLLECTED, USED OR SHARED WITH OTHERS?

The following information may be collected from you, your medical records, or your dialysis unit records:

- Name, address, telephone number, date of birth
- Email address

- Social Security number (to pay you)
- Medical history
- Prescription information gathered from your doctor, medical records, and/or pharmacy records
- Current medications or therapies
- Information from visits, questionnaires, and blood or saliva tests
- Recordings of Pain Coping Skills Training sessions, IVR voice messages, and answers to the daily IVR system call questions (if you are assigned to the PCST group)
- Safety information such as adverse events

WHY IS MY PERSONAL HEALTH 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.

WHO CAN SEE OR USE MY PERSONAL HEALTH INFORMATION?

The following individuals may use or share your information for this research study:

- The study doctor and the study team at _____
- The University of Pennsylvania Institutional Review Boards (the committees that oversee research on human research participants)
- The Scientific and Data Research Center (SDRC) at the University of Pennsylvania
- The researchers at the University of New Mexico and the University of Pittsburgh who are conducting the telephone interviews
- The Pain Coping Skills Training (PCST) coaches and quality monitors, if you are assigned to the PCST Group
- The contractor, Tech4Research, that maintains the IVR system used to deliver the brief telephone PCST booster sessions, if you are assigned to the PCST group
- The centralized pharmacy if you change from your current pain medication to buprenorphine
- The clinical laboratory at Hennepin Healthcare if you change from your current pain medication to buprenorphine
- The Data and Safety Monitoring Board (DSMB) for this study

- Representatives of government agencies, including the National Institutes of Health (NIH), the National Institute of Digestive, Diabetes and Kidney Diseases (NIDDK) which is the government agency sponsoring this study), the Office of Human Research Protections, and others who watch over the safety, effectiveness, and conduct of the research.
- Other approved personnel at [insert specific recruitment site], at your dialysis unit, or the HOPE Trial research team who may need to access your information to do their duties (for example: to provide treatment, to make sure the research was done correctly, for accounting or billing matters, etc.).

If anyone new is added to this list, they will need to follow [insert specific recruitment site]'s rules developed to protect your privacy.

ELECTRONIC MEDICAL RECORDS AND RESEARCH RESULTS

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 and is different from the Data Management System that the research team uses to track information collected about you for the research study.

If you have ever received care within the [INSERT LOCAL HEALTH SYSTEM HERE] (outpatient or inpatient) and are participating in a [INSERT HEALTH SYSTEM OR SITE] research study, information related to your participation in the research (i.e. laboratory tests or clinical procedures) may be placed in your existing EMR maintained by [INSERT LOCAL HEALTH SYSTEM HERE] in addition to the Data Management System used by the research team.

If you have never received care within [INSERT LOCAL HEALTH SYSTEM HERE] and decide to enroll in this research study, an EMR may be created for you for the purpose of maintaining any information produced from your study participation. 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). Information related to your participation in the study (i.e. laboratory tests or clinical procedures) may be placed in this EMR.

Once placed in your EMR, your information may be accessible to appropriate [INSERT LOCAL HEALTH SYSTEM HERE] workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by [INSERT LOCAL HEALTH SYSTEM HERE] to be appropriate to have access to your EMR (e.g., health insurance company, disability provider, etc.).

HOW WILL MY PERSONAL HEALTH INFORMATION BE PROTECTED?

When your information is released outside of insert site name you are not identified by name, social security number, address, or any other direct personal identifier. You are identified by a unique ID number that is assigned to you for this study. The link between your name and code number is kept in a secure file and is not shared with anyone outside insert site name. The exception to this is that your contact information will be provided to the University of New Mexico, the University of Pittsburgh, and the University of Pennsylvania. If you are in the Pain Coping Skills Training group, your contact information and responses to daily IVR questions will be held in the IVR system and accessible to the coaches and IVR system vendor, Tech4Research, for the purpose of carrying out the study.

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate of Confidentiality DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Your individual research test results will not be included in your medical records.

The HOPE Trial Scientific and Data Research Center (SDRC) at the University of Pennsylvania stores study information from all participating research centers. All information will be sent to the SDRC by a secure internet connection. The study information is stored in secure electronic files at the

University of Pennsylvania. Only authorized members of the research study have permission to see these data.

A description of this clinical trial is available on http://www.ClinicalTrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website may include a summary of the results of the study. You can search this website at any time.

HOW LONG MAY THE [INSERT INSTITUTION] USE OR DISCLOSE MY PERSONAL HEALTH INFORMATION?

Your permission for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, personal health information collected in this study may not be re-used or re-disclosed for a purpose other than this study unless:

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

COLLECTION OF IDENTIFIABLE BIOSAMPLES

As a part of your participation in this study, you may be asked to provide saliva or blood samples. These samples will be used to make sure that it is safe for you to participate in Phase 2 of the research study. If you are asked to provide blood or saliva samples as part of this study, those samples will not be stored for future use and will not be used for any other reason. Whole genome sequencing, which involves analyzing your entire genetic code, will not be conducted on your samples. Your samples will not be used for commercial profit.

WILL I RECEIVE THE RESULTS OF RESEARCH TESTING?

Yes, you will receive results from tests performed as a part of the research study. If you are required to have a blood pregnancy test the results will be placed in your medical record and will be provided to you. If you are required to complete a saliva drug test the results might be entered into your medical record and will be communicated to you by a member of the research team.

FUTURE USE OF DATA AND BIOSAMPLES

Data without personal identifiers may be shared with investigators that are part of HOPE during and after the study.

At the end of the study, all data (without any personal identifiers) will be sent from the SDRC to the NIDDK Central Repository and the NIH HEAL Repository where it will stay. The purpose of sending data to these repositories is to make data available for use in research on pain, hemodialysis, and

other health-related research, after the current study is completed. Sending data to the repositories may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases. Researchers who plan to use your data for future scientific study will be required to request and receive all the necessary approvals or waivers from the NIDDK and from the NIH HEAL program before using your data. Data will only be released to scientists who are qualified and prepared to conduct a research study.

If you are asked to provide a blood sample or saliva sample as a part of this research study, your sample(s) will not be stored or shared for future research purposes.

CAN I CHANGE MY MIND ABOUT GIVING PERMISSION FOR USE OF MY INFORMATION?

You can change your mind and withdraw consent to continue participation in this study up until the end of the study. When study researchers receive instructions from you to withdraw consent to continue participation in the study, they will not collect any more data on you for the purpose of the study. Data collected up until the time that you withdraw may be retained and used in order for the study to be scientifically valid. Data sent to the NIDDK Repository or the NIH HEAL Repository will be given a unique code number and identifiable information will be removed. Data that have been stripped of personal identifiers cannot be retrieved. After the HOPE Trial ends, you will not be able to withdraw your data because the Repository will not know which data comes from you. The data will stay in the Repository indefinitely.

WHAT IF I DECIDE NOT TO GIVE PERMISSION TO USE AND GIVE OUT MY HEALTH INFORMATION?

If you do not give permission to use and give out your health information 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. By signing this document, you are permitting the INSERT SPECIFIC SITE to use and disclose personal health information collected about you for research purposes as listed above.

WHO CAN I CALL WITH QUESTIONS, COMPLAINTS OR IF I AM CONCERNED ABOUT MY RIGHTS AS A RESEARCH PARTICIPANT?

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 participant, 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 at the University of Pennsylvania with any question, concerns or complaints by calling (215) 898-2614.

SIGNING THE CONSENT FORM

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

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

_____	_____	_____
Name of Participant (Please Print)	Signature of Participant	Date
_____	_____	_____
Name of Person Obtaining Consent (Please Print)	Signature of Person Obtaining Consent	Date