Informed Consent Cover Page for FDAAA consent posting:

Official Title:	Red Cell Half Life Determination in Patients with and without Sickle Cell Disease
NCT number:	NCT04476277
Document Type:	Informed Consent Form
Document Date:	11/30/2021

PRINCIPAL INVESTIGATOR: John F Tisdale, MD

STUDY TITLE: Red Cell Half Life Determination in Patients with and without Sickle Cell Disease

STUDY SITE: NIH Clinical Center

Cohort: Standard

Consent Version: November 23, 2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: John Tisdale, M.D., Ph. (301)402-6497, Email johntis@nhlbi.nih.gov

Study Coordinator: Christina Luckett, RN, Ph. (301)827-7901, Email christina.luckett@nih.gov

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research at the NIH is your choice.

You are being asked to participate in this research study because you either have Sickle Cell Disease (SCD), had SCD but were cured with a bone marrow transplant, have Sickle Cell Trait (SCT), or are a volunteer without SCD or SCT.

SCD is an inherited blood disorder that results from a single genetic change (mutation) in red blood cells (RBCs). RBCs are the cells that carry oxygen to the body. In people with SCD, the mutated RBCs can become hard, rigid, and contorted into a sickle shape. These abnormal RBCs die early, leaving a shortage of healthy RBCs (sickle cell anemia). RBCs typically survive in the human body for approximately 120 days. However, this duration is shortened to an average of 32 days in patients with SCD. Currently SCD can be cured with a bone marrow transplant. This can result in restoration of the red cell lifetime to greater than 100 days.

Our aim is to study how long RBCs live in the human body in patients with SCD compared to patients with SCD who have been cured by a bone marrow transplant, people with Sickle Cell Trait (SCT) or non-SCD/SCT volunteers. To do this, we will collect a small volume of blood (approximately 5 tablespoons) from your vein. In the laboratory we will mix your blood with a vitamin called Biotin. This vitamin is much smaller than the size of a single red blood cell and sticks to the outside of your RBCs without changing their function, shape, or overall lifetime. This process is known as “biotin labeling of RBCs”. We will then return your “biotin labeled RBCs” to you via vein injection. The collection of your RBCs, the labeling in the laboratory, and the reinfusion of your RBCs back to you will occur on the same day; however in rare

circumstances the reinfusion of your biotin labeled RBCs may occur the following day if we collect your RBCs too late in the day on that first day.

There are three phases of this study: I. Screening, II. Collection and Infusion, and III. Follow-up phases.

You will be asked to provide blood samples at the following times:

I. Screening:

A single sample of venous blood will be required for laboratory tests and other screening procedures.

II. Collection and Infusion:

Day of blood collection

A blood sample will be collected for laboratory tests and other screening procedures prior to blood collection for biotin labeling.

Day of infusion of biotin labeled RBCs

A research blood sample will be taken 20 minutes after the end of the infusion.

III. Follow-up:

Post-infusion day- Month 1

- **SCD participants who have not had a transplant**
  - For the first two weeks (W1 and W2), participants will have samples drawn twice weekly
  - For the next two weeks (W3 and W4), participants will have samples drawn once weekly
- **All other participants**
  - For the - three weeks post infusion (W2, W3, and W4), participants will have samples drawn once a week

Post-infusion day - Month 2 until completion of the study (W24)

- **SCD Participants who have not had a transplant**
  - Will have a sample drawn weekly until biotinylation can no longer be detected in your RBCs, and once again during W24
- **All other participants**
  - No sample will be drawn for W5
  - Starting on W6, participants will have a sample drawn every other week until biotinylation can no longer be detected in your RBCs, and once again during W24

There are a few known risks associated with Biotin, IV placement, blood draws, learning your HIV testing results, and the infusion. Although there is no direct benefit to you, by participating

in this study we will learn about RBC lifespan in patients with SCD and what factors influence this red blood cell survival.

The remaining document will now describe more about the research study. This information should be considered before you make your choice. Members of the study team will talk with you about the information described in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time needed to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

This is a research study. The purpose of this research study is to investigate how long red blood cells (RBCs) live in patients with and without Sickle Cell Disease (SCD).

SCD is an inherited blood disorder that results from a single genetic change (mutation) in RBCs. RBCs are the cells that carry oxygen to the body. In people with SCD, the mutated RBCs can become hard, rigid, and contorted into a sickle shape. These abnormal RBCs die early, leaving a shortage of healthy RBCs (sickle cell anemia). RBCs typically survive in the human body for approximately 120 days. However, this duration is shortened to an average of 32 days in patients with SCD. Currently SCD can be cured with a bone marrow transplant. This can result in restoration of the red cell lifetime to greater than 100 days. We aim to study how long RBCs live in the human body in patients with SCD compared to patients with SCD who have been cured by a bone marrow transplant, people with Sickle Cell Trait (SCT) or non-SCD/SCT volunteers. We hope the knowledge gained from this study will allow us to better understand and enhance curative therapies for patients with SCD.

To study how long RBCs live, we will collect a small volume of blood (approximately 70 mL; this is equivalent to approximately 5 tablespoons) from your vein. In the laboratory, we will mix your blood with a vitamin called Biotin which sticks to the outside of your RBCs. This process is known as “biotin labeling of RBCs”. We will then return your “biotin labeled RBCs” to you via vein injection. We can then measure the amount of biotin labeled RBCs remaining over the lifespan of those RBCs by drawing a small amount of blood (approximately 10 mL; this is equivalent to 2 teaspoons) until we can no longer detect any biotin labeled RBCs.

We are asking you to join this research study because you either have SCD, had SCD but were cured with a bone marrow transplant, have Sickle Cell Trait (SCT), or are a volunteer without SCD or SCT.

Although biotin is a vitamin we consume regularly in our diets, the use of biotin in this manner to label RBCs is considered investigational.

WHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to donate blood and will receive a transfusion of your own blood so we can measure how long your RBCs live. This procedure will take no more than 10 total hours for completion.

here are three phases required in participating on this protocol:

I. Screening
II. Collection and Infusion
III. Follow-up

Screening: After the consent is reviewed and signed, a medical history is collected and a physical exam is performed. We will collect approximately 50 mL of blood (approximately 3-4 tablespoons) for blood tests that will tell us about your blood counts, liver and kidney functions. We may also test your blood for certain diseases: hepatitis B and C viruses, HIV, syphilis, and others that can be transmitted by blood. You will be asked to provide a urine sample to see if there are any abnormal cells, protein, or sugar. Pregnancy testing will be performed for all female subjects of childbearing age. You will be seen in the Department of Transfusion Medicine, where we will look at your arms to determine whether your veins are suitable for placing needles for the collection. All patients who have received a transplant on a Gene Therapy protocol may require additional confirmatory HIV testing during screening which will be performed under this protocol.

Collection and Infusion: If eligible, we will collect about 100 mL of blood (about 7 tablespoons) from your vein. In the laboratory we will mix your blood with a vitamin called Biotin. This vitamin is much smaller than the size of a single red blood cell and sticks to the outside of your RBCs without changing their function, shape, or overall lifetime. This process is known as "biotin labeling of RBCs". We will then return your "biotin labeled RBCs" to you via vein injection. The collection of your RBCs, the labeling in the laboratory, and the reinfusion of your RBCs back to you will occur on the same day; however in rare circumstances the reinfusion of your biotin labeled RBCs may occur the following day if we collect your RBCs too late in the day on that first day. Some of the blood will be taken for lab tests and screening (approximately 20 mL, about 1.5 tablespoons), while the rest of the blood will be used for biotin labeling (approximately 80 mL, about 5.5 tablespoons). A single blood sample will be taken 20 minutes *after* infusion (approximately 5 mL of whole blood, about 1 teaspoon) to measure the biotin labeling of RBCs.

Follow-up: We will calculate how long your RBCs live by measuring the amount of biotin that remains on your RBCs at frequent intervals until we can no longer detect any biotin labeled RBCs. Our bodies are naturally producing millions of RBCs every day, therefore over time your body naturally removes old blood cells. Just as the body removes old RBCs, it will remove the biotin that was attached to it. We will therefore be able to measure less and less biotin on your RBCs over time until all of it has been removed.

To do this, you will provide a small sample of blood (approximately 10 mL; this is equivalent to 2 teaspoons) according to the following schedule below until the completion of the study. For some patients, this may be as short as a week, for others it may be up to 16 weeks.

Number of blood samples

Post-infusion day- Month 1

SCD participants who have not had a transplant:

- A total of 5 samples will be drawn.
- Participants will have samples drawn once on W1 and twice on W2, (total of both weeks will be approximately 30 mL (about 2 tablespoons).
- For W3 and W4, participants will have samples drawn once weekly (total of both weeks will be approximately 20 mL (about 1.5 tablespoons).

All other participants:

- A total of 3 samples will be drawn.
- No sample will be drawn on W1.
- For W2, W3, and W4 participants will have samples drawn once weekly (total of three weeks will be approximately 30 mL (about 2 tablespoons).

Post-infusion day - Month 2 until completion of the study (W24)

SCD Participants who have not had a transplant:

- Will have samples drawn weekly until the percentage of biotinylated RBCs has decreased (up until week 8), and once again at W24 (weekly draw will be approximately 10 mL, (about 2 teaspoons); a total of approximately 50 mL (about 3-4 tablespoons).

All other participants:

- There will be a sample drawn every other week, starting on W6 until the percentage of biotinylated RBCs has decreased (until approximately weeks 14-16), and once again at W24 (every other week draw will be approximately 10 mL (about 2 teaspoons); for a total up to 70 mL (about 4.5 tablespoons).

When you come to the NIH to give these blood samples, we will ask you if there have been any major changes to your health (for examples, a crisis or need for transfusion if you have SCD). We need to be aware of any changes as these could influence how long your RBCs live. Otherwise we do not expect any unwanted side effects from the biotin itself.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for up to 6 months. You will no longer need to come in for regular blood draws once we can no longer detect your biotin labeled RBCs, but will require all participants to come in for a final blood draw at 6 months.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 40 people participate in this study at the NIH.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

From biotin: The use of biotin labeling of RBCs has been studied in adults and babies with and without SCD and is very well tolerated with minimal to no side effects.

Biotin is a water-soluble B-vitamin (also called vitamin B7) that we receive in our diets every day. It is an essential vitamin that helps metabolize fats and carbohydrates and is involved in various metabolic processes in our bodies. The recommended daily allowance of biotin is 0.03 mg. Although no safety events related to biotin have been reported, very high levels of biotin (650 times the recommended intake) can interfere with certain laboratory test results. The amount of biotin used in this study is well below the recommended daily allowance, and there is no need to modify your diet based on this study.

In previous studies that have looked at biotin labeling of RBCs in adult and babies, rarely participants have developed an antibody to biotin (<5%). This antibody has not caused any problems in these participants including no breakdown of their red blood cells. None had changes in their complete blood counts (CBC) or any clinical signs or symptoms. One participant experienced accelerated removal of biotin labeled RBCs when this participant participated in a second biotin labeled study 5 years later. It is therefore possible that if an antibody to biotin develops, you would be excluded from future studies investigating biotin labeling of RBCs.

From IV placement and Blood Draws: Insertion of a needle into a vein for drawing blood and for injection of RBCs may cause mild pain, and there is a small risk of bleeding with bruising at the site. Side effects commonly seen in a normal blood donation (however the volume of blood taken in this study is less than blood donation) includes sweating, light headedness, vomiting, low blood pressure, rapid pulse, and fainting. Although all material used to draw blood are sterile, very rarely infection may occur at the site of the blood draw. Blood samples will be drawn by experienced study personnel using standard measures to minimize each of these risks.

If you are a healthy volunteer, it is recommended that you do not donate blood during this study and for 8 weeks after you complete this study.

From the Infusion: The injection of the treated RBCs is similar to a blood transfusion and could cause some bruising, irritation, or infection. Study infusions will be done by experienced study personnel using standard measures to minimize each of these risks. Infusion of blood may cause fever, chills, nausea, hives, rash, itching, swelling of the face or neck, difficulty breathing, and low blood pressure.

From HIV testing: As part of this study, we will test you for infection with the human immunodeficiency virus (HIV), the virus that causes AIDS. If you are infected with HIV you will not be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report HIV infection, and the importance of informing your partners at possible risk because of your HIV infection.

What are the risks related to pregnancy?

If you are capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to the fetus or unborn child, or risks that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to a fetus. You must tell the study doctor if your birth control method fails while you are in the study. If you think or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. If you plan to become pregnant in the

future, please discuss with the research team how long you need to wait before becoming pregnant after completing the course of this study drug or procedures on this study.

If you are a sexually active person with a partner capable of becoming pregnant, it is important that your partner not become pregnant during your participation in this study. There may be unknown risks to a fetus or risks we did not anticipate. You and your partner must agree to use birth control if you want to take part in this study. If you think your partner has become pregnant during your participation in this study, please contact the research team member identified at the top of this document as soon as possible. If you and your partner plan for your partner to become pregnant after your participation in this study, please discuss this with the study team.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from being in this study.

Your participation will help us develop a better understanding of the shortened red blood cell lifespan in patients with SCD and what factors influence this red blood cell survival. We know that patients with SCD can be cured with a bone marrow transplant, in part because the donor red blood cells survive longer than sickle RBCs. There is no direct benefit to you to participate in this study.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study because information from this study will allow us to better understand this phenomenon and help us improve our curative therapies including bone marrow transplantation and gene therapy methods.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could choose not to take part in this study. If you do not take part in this study, you can still receive your regular medical care by your doctor.

Taking part in this trial is voluntary. You have the right to stop being a part of this study (this is called withdrawal) at any time, even if you have already signed this consent form and without giving a reason. You will not lose any benefits to which you are entitled; you can continue regular medical care and can go back to your regular doctor and treatment. If you decide you want to stop being a part of this study, you must first tell the study doctor right away.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

The research team will not provide you with any research results unless they are meaningful. Additional research may be needed before these results are meaningful.

By agreeing to participate in this study, you do not waive any right that you may have regarding access to and disclosure of your medical records. For further information on those rights, please contact Dr. Tisdale

The investigators will give you information about the overall results of this study after completion of the study. Published research results will only describe groups of people who took part in the study. Information that points out a single person will not appear in research journals or other reports. You will never personally be identified in any of the publications.

EARLY WITHDRAWAL FROM THE STUDY

You can withdraw from this study at any time. This decision will not affect your legal rights or the quality of health care that you will/may receive at NIH. At any time, the study doctor may tell you to stop taking part in the study. This may happen if you have a health-related event during the course of the study that affects how long your RBCs live or how many RBCs are produced, you do not follow the instructions given by the study doctor, or if the study doctor believes it is in your best interest.

WILL YOUR SPECIMENS OR DATA BE SAVED FOR USE IN OTHER RESEARCH STUDIES?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding SCD, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

WILL YOUR SPECIMENS OR DATA BE SHARED FOR USE IN OTHER RESEARCH STUDIES?

We may share your deidentified biospecimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. These researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

How Long Will Your Specimens and Data be Stored by the NIH?

Your specimens and data may be stored by the NIH possibly indefinitely or until they become irrelevant and are destroyed with the IRB approval. A small amount of your blood sample may be used for research purposes to develop better laboratory techniques for SCD. In addition, we will store certain information in your medical record. We may be interested in using your samples to pursue other research into SCD or similar disorders. We may send your samples elsewhere for analysis. If we do so, we will not reveal your identity, but there will be a code to link your samples with your name and other personal information. The code will be stored in a password protected database under the control of Dr. Tisdale.

Risks of Storage and Sharing of Specimens and Data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information.

New methods may be created in the future that could make it possible to re-identify your specimens and data.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

We will pay you for participating in this research study. The amount will be dependent on the tests performed. We calculate your compensation based on the inconvenience we will cause you for the hours you spend participating on this study, for the procedures and other forms of participation in the study up to a total of $1,600.00 (for at least 12 visits).

Procedure	Inconvenience units ($10 for each inconvenience unit)
Outpatient Visit (first hour)	$20 (2 units)
Outpatient Visit (additional hours, up to 4 hours)	$10 (1 unit)
Screening History & Physical	$25 (2.5 units)**
Research blood sampling (per blood draw)	$40 (4 unit)
IV Placement	$10 (1 unit)
Drug Infusion/Administration by IV	$50 (5 units)
Completion Bonus	$500 (50 units)
Travel Voucher (per visit)	$40 (4 units)
Total Potential Compensation	**up to $1600.00***

**Dependent on the subject's red cell lifetime, the number of blood draws needed to be collected until study completion, although rare, may exceed the projected 16 week collection timeline. Therefore total compensation may exceed $1,600.00.*

***Unless you were screened under another NIH protocol.*

If you are unable to finish the study, you will receive *payment* for the parts you completed.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Review Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

Will you receive reimbursement or direct payment by NIH as part of your participation?

This study offers vouchers for travel (per visit) but does not offer reimbursement for, or payment of, lodging or meals.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

Participation in this study will not cost you.

CONFLICT OF INTEREST (COI)

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

The people working on the study will do whatever they can to keep your information private and not share it with other people unnecessarily. The National Institute of Health (NIH) and its representatives may need to look at and/or make copies of your information and health records. If this happens, the people who review your records will be very careful to protect your identity. In rare cases, people who look at your records may be required by law to share information about you with others.

Federal privacy regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records. NIH may give your health data, without identifiers, to other researchers or use it for other approved research projects not listed in this form. The NIH, Dr. Tisdale, and study staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this information.

Will your medical information be kept private?

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. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor National Heart Lung and Blood Institute or their agent(s)

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the

insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

If we share your specimens or data with other researchers, in most circumstances we will remove your identifiers before sharing your specimens or data. You should be aware that there is a slight possibility that someone could figure out the information is about you.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, John Tisdale, M.D., Ph.: (301)402-6497, Email: johntis@nhlbi.nih.gov. Another researcher you may call is Christina Luckett, RN, Ph. (301)827-7901. You may also call the NIH Clinical Center Patient Representative at (301)496-2626, or the NIH Office of IRB Operations at (301)402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process with a non-English speaking subject and this English consent form has been approved by the IRB for use as the basis of translation.

Witness:

Signature of Witness*	Print Name of Witness	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.