Consent to Participate in a Research Study
ADULT
(Insert protocol title here)


Items below in yellow highlight are required for the Revised Common Rule.

This consent form template contains examples of HIPAA language. ALL consent forms for studies that involve the use or disclosure of protected health information must contain the appropriate HIPAA language, examples of which can be found in their entirety under “Consent Form Templates (Consent Form Language for HIPAA Compliance)” on the DUHS IRB web site.

CONCISE SUMMARY

The revised Common Rule requires that consent forms contain a concise presentation of key information. The intention of this section is to provide potential research participants with a better understanding of the project’s scope, including major risks and benefits, so they can make a more fully informed decision about whether to participate.

This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study. The information presented in this section may be discussed in greater detail later in the consent form.

Examples of model summary statements are available on the IRB website. Go to https://irb.duhs.duke.edu/forms/duhs-sample-consent and click on yellow box in middle of page.

You are being asked to take part in this research study because you have (name condition here). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

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

(Insert one of the following if applicable)
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(PI Name) will conduct the study and it is funded by (Sponsor Name). The sponsor of this study, (Sponsor Name), will pay Duke University to perform this research, and these funds may reimburse part of (PI Name’s) salary.

OR if relevant:

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of (PI’s Name) and his/her research team’s salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Dr. ________ will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to…….

Please note: If you are using an investigational drug, drug combination, biologic and/or device, please always indicate what is FDA approved and what is investigational, and define “investigational.” For example, “The word “investigational” means the study drug or device or biologic is still being tested in research studies and is not approved by the U.S. Food and Drug Administration (FDA).” Refrain from using “medicine,” “treatment,” or “therapy” for the investigational drug or device. Instead, use study drug, study procedures, study processes, etc. If you will be using an investigational procedure, such as an investigational surgical procedure or innovative diagnostic procedure, please clearly identify it as investigational.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately ___ people will take part in this study at ___ (if multicenter, add number of hospitals/medical facilities) different hospitals and medical facilities, and approximately ____ people will take part at Duke.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

- Physical exam and medical history
- Vital signs
- Blood tests
- Electrocardiogram (EKG), a tracing of the electrical activity of the heart

Also describe in this section the procedures, study drug, samples, questionnaires, follow-up, etc, (whatever is applicable to your study).
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For randomized studies: You will be randomly assigned (like the flip of a coin) to receive either (arm 1 or arm 2). You have a ( ) in ( ) chance of receiving study drug. For studies with more than 2 arms, use “like drawing numbers from a hat.”

When describing what is involved in the study, consider laying out a timeline. For example, on Day 1, you will have an EKG and two tablespoons of blood will be drawn from your arm by needlestick for blood tests. On Day 2, you will receive the study drug intravenously (into your vein) for two hours (and so forth). You can also create a timeline using visits. For example, on Visit 1, you will receive study drug to take daily until Visit 2.

Please note: If your study will use a placebo, please define placebo. For example, “A placebo is an inactive substance given in the same form as the active drug, Paclitaxel.”

Be sure to disclose:
- The identification of any procedures that are investigational/experimental. (May be omitted if there are none.)
- A statement that notes the possibility that the Food and Drug Administration may inspect the records. (May be omitted for research that is not FDA-regulated.)
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- Procedures for orderly termination of participation by the subject.
- A statement that “If you do not sign this consent form, you will continue to receive care, but not as a part of this study.”
- A statement on whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (may be omitted if not applicable)

HOW LONG WILL I BE IN THIS STUDY?
Describe here how long the study will be (in weeks, days or months). Describe also (if applicable) if you intend to collect follow-up information and how long this will be done. For example, until six months after last study drug dose, for the rest of your life, etc.

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

Clinically relevant results of this research will be communicated with you (describe when and under what conditions). (if applicable)
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WHAT ARE THE RISKS OF THE STUDY?
Please note: The risk section should only contain the risks associated with study procedures. Risks of standard care procedures should not be included in the consent form.

Please note: For minimal risk studies (such as questionnaires/surveys) where loss of confidentiality or psychological stress is the only risk; these need to be listed. For example: There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this can not be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

(Study Drug Name) may cause some, all or none of the side-effects listed below.

More likely (insert more common side effect below using bullets)

•

Less Likely (insert less common side effect below using bullets)

•

For Those of Reproductive Potential (insert this risk section if applicable to your study)

•

Female and/or Male Contraception Language: (insert language if applicable to your study)

Please see the Standard Language on the IRB web site:
https://irb.duhs.duke.edu/standard-language/english-standard-language
For any questions regarding the language, please consult Dr. Evan Myers:
evan.myers@duke.edu

Risks of Radiation: (insert this risk statement if applicable to your study)
Please see the following website for specific radiation safety language:
https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/finding.asp

Risks of Drawing Blood: (insert this risk statement if applicable to your study)
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Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

**Drug and Food Interactions:** (insert this risk statement if applicable to your study)
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

**Risks of Washout:** (insert this risk statement if applicable to your study)
During the washout period, your symptoms of _____ may get worse. Please discuss the washout period with the study doctor.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
If you agree to take part in this study, there may be direct medical benefit to you. *(Insert the potential direct medical benefit here. If there is none, alter the initial sentence to indicate that.)* We hope that in the future the information learned from this study will benefit other people with your condition.
*(Note that this is merely sample language; please modify it to fit your protocol.)*

**WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?**
Instead of being in this study, you have the following alternatives:
Please talk to your doctor about these and perhaps other options.

*Please note: If the only alternative is not to participate, please leave this section out of the consent form.*

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
*Please see the following HIPAA language and insert applicable language for your study here.*

*Please edit the following language as appropriate*
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.
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As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to [Sponsor Name] and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include [representatives from the Food and Drug Administration], representatives and affiliates of [Sponsor Name], the Duke University Health System Institutional Review Board, [add others as appropriate], and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

For research involving Duke patients:

As part of this study, you will be asked to have certain tests, x-rays, and/or procedures performed. Some of these tests, x-rays and/or procedures would have been done as part of your regular care. The study doctor will use these test results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the [research data office at Duke] OR [data coordinating center in…] OR representatives and affiliates of [Sponsor Name]. Results of tests and studies done solely for this research study and not as part of your regular care will [also] OR [not] be included in your medical record.

For ALL NIH funded research and any other research with a Certificate of Confidentiality:

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.
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Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

For research involving healthy participants who are not Duke patients:

All of the blood, urine and x-ray studies are being done only because you are in this study. The study results will [not] be provided to you OR sent to your physician.

Expiration date or event for the retention of records (Adult)

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

OR

The study results will be retained in your research record forever. Any research information in your medical record will also be kept indefinitely.

For blinded studies, please include the following statement regarding temporary restriction of access to study records:

Some information collected in research studies is maintained in your medical record. However, for this study that information will be inaccessible until the end of the study, unless your physician(s) decide that it is necessary for your care.

For all funded studies:

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.
If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

For all studies:
While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.
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Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

If applicable:
A representative from the sponsor may be present at certain study visits/procedures.

WHAT ARE THE COSTS TO YOU?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with [the PI]. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

Insert if applicable:
The study sponsor [Sponsor Name] has agreed to pay for services and procedures that are done solely for research purposes. Please talk with the PI/study team about the specific services and procedures (including the device, if applicable) that the sponsor will pay for, and the ones for which you or your insurance will be responsible.

We will monitor your DUHS patient care charges to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

(If sponsor is providing drug/biologic)
(Sponsor) will provide the study drug/biologic free of charge to you. At the end of the study, or if you decide to withdraw from the study before it ends, you may be asked to return all unused study drug. Your study doctor may request that you return for a checkup before you stop your study drug/biologic if he/she thinks that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.
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Please note: If there are potential additional costs to the subject for participating in the study (and they are not being compensated for them), you must clearly state this in this section.
Taking part in this study may cost you and/or your insurance company more than the cost of getting regular medical treatment. (Include cost details here).

Please note: If there are potential additional costs to the subject for participating in the study (and they are not being compensated for them), you must clearly state this in this section.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $( ) for your expenses related to your participation (parking, gas, and time). (Please do not use decimal point. For example, use $25, not $25.00)

Please note: Compensation must be prorated so that if a subject withdraws from the study, the subject will receive compensation for the parts of the study he/she completed.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact (insert PI’s name here) at (insert PI’s number here with area code) during regular business hours and at (insert PI’s 24-hour number here with area code) after hours and on weekends and holidays.

Please note: For Commercial/Industry Sponsored studies, please refer to the Research Related Injury language on the IRB web site.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
Please see the following HIPAA language and insert applicable language for your study here.

One of the following 6 sections must be included in every consent form. Please determine which category applies to your study, and add the appropriate section.

For Studies involving an FDA regulated product (drug, device, or biologic) (Outside DUHS Sponsor)

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been
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collected for study purposes, and any new information about an adverse event related to the study, will
be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of
benefits to which you are entitled, and will not affect your access to health care at Duke. [Describe any
consequence of withdrawal. For example, subjects on a diabetes drug may experience loss of control of
their diabetes unless they are switched to another medication. Subjects on corticosteroids may
experience life-threatening problems unless the subject is slowly taken off the steroids. Subjects on
marrow transplantation trials are likely to die if they withdraw between marrow ablation and marrow
reconstitution. Omit if there are no adverse consequences.] If you do decide to withdraw, we ask that
you contact Dr. [PI] in writing and let [him/her] know that you are withdrawing from the study.
[His/her] mailing address is [address]. You will be asked to [describe any procedures for orderly
termination from the protocol. For example, switching to another diabetes drug, tapering of steroids, or
referral to another health care provider.]

For Studies involving an FDA regulated product (drug, device, or biologic) (DUHS Sponsor)

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the
study at any time. If you withdraw from the study, no new data about you will be collected for study
purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse
event occurs, we may need to review your entire medical record.

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consequence of withdrawal. For example, subjects on a diabetes drug may experience loss of control of
their diabetes unless they are switched to another medication. Subjects on corticosteroids may
experience life-threatening problems unless the subject is slowly taken off the steroids. Subjects on
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reconstitution. Omit if there are no adverse consequences.] If you do decide to withdraw, we ask that
you contact Dr. [PI] in writing and let [him/her] know that you are withdrawing from the study.
[His/her] mailing address is [address]. You will be asked to [describe any procedures for orderly
termination from the protocol. For example, switching to another diabetes drug, tapering of steroids, or
referral to another health care provider.]

For Studies not involving FDA regulated products (Outside DUHS sponsor)

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the
study at any time. If you withdraw from the study, no new data about you will be collected for study
purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse
event occurs, we may need to review your entire medical record. All data that have already been
collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you withdraw from the research [Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.] If you do decide to withdraw, we ask that you contact Dr. [PI] in writing and let [him/her] know that you are withdrawing from the study. [His/her] mailing address is [address]. You will be asked to [describe any procedures for orderly termination from the protocol. For example, return electronic diary, or referral to another health care provider.]

For Studies not involving FDA regulated products (DUHS sponsored)

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you withdraw from the research [Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.] If you do decide to withdraw, we ask that you contact Dr. [PI] in writing and let [him/her] know that you are withdrawing from the study. [His/her] mailing address is [address]. You will be asked to [describe any procedures for orderly termination from the protocol. For example, return electronic diary, or referral to another health care provider.]

For Minimal Risk Studies (Risk no greater than the typical daily experience of a healthy person) (Outside DUHS sponsor)

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. [Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.] If you do decide to withdraw, we ask that you contact Dr. [PI] in writing and let [him/her] know that you are withdrawing from the study. [His/her] mailing address is [address]. You will be asked to [describe any procedures for orderly termination from the protocol. For example, return electronic diary, or return equipment or videotapes.]
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For Minimal Risk Studies (Risk no greater than the typical daily experience of a healthy person) (DUHS sponsored)

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. [Describe any consequence of withdrawal. Omit if there are no adverse consequences associated with withdrawal.] If you do decide to withdraw, we ask that you contact Dr. [PI] in writing and let [him/her] know that you are withdrawing from the study. [His/her] mailing address is [address]. You will be asked to [describe any procedures for orderly termination from the protocol. For example, return electronic diary, or return equipment or videotapes.]

Additional information that must be shared with the subject if applicable:

In addition, you must return all unused study drug to Dr. [PI] or [his/her] staff. and/or

Dr. [PI] may ask you to return for a checkup before you stop your study drug if [he/she] thinks that stopping the drug suddenly may harm you. and/or

[He/she] may also ask you to complete the tests that would ordinarily occur when a person completes the study.

For all studies

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at anytime without your consent. Reasons why this might occur include … [describe anticipated circumstances under which participation may be terminated by the investigator without regard to the participant’s consent.] If this occurs, you will be notified and your study doctor will discuss other options with you.
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For withdrawal of samples

If you agree to allow your [tissue/blood/cells] to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact Dr. [PI] in writing and let [him/her] know you are withdrawing your permission for your identifiable [tissue/blood/cells] to be used for future research. [His/her] mailing address is [address]. At that time we will ask you to indicate in writing if you want the unused identifiable [tissue/blood/cells] destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

Required if any identifiable samples or data are collected

Your [samples and/or data] may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

Required language for all studies registered on the web site ClinicalTrials.gov

A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. (PI’s Name) at (PI’s Number with Area Code) during regular business hours and at (PI’s 24-hour Number with Area Code) after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.
STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

______________________________  __________________  _____________
Signature of Subject  Date  Time

______________________________  __________________  _____________
Signature of Person Obtaining Consent  Date  Time

(Optional)

______________________________  __________________  _____________
Signature of Principal Investigator  Date  Time

(If applicable, add or substitute any of the following:)

______________________________  __________________  _____________
Signature of Legal Representative  Date  Time

______________________________
Relationship to Subject