Allergic Reaction Risks

Occasionally, people have allergic reactions to medications which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include: a rash; shortness of breath; wheezing; difficulty breathing; sudden drop in blood pressure; swelling around the mouth, throat, or eye; fast pulse; and sweating. You should get immediate medical help and contact the study doctor if you have any of these or any other side effects during the study.

Anesthesia Risks (General Anesthesia)

Risks of general anesthesia include nausea, vomiting, blood vessel injury, nerve injury, lung injury, heart attack, allergy to drugs, brain damage, and death.

Biopsy - Liver

For patients undergoing liver biopsy, there may be increased risk in certain circumstances. When doctors perform your liver biopsy, they do so by passing a needle into the liver usually through your side. Doctors are usually able to get a large enough piece of liver to examine under the microscope by taking a single biopsy of the liver. However, in some patients, only a small piece is retrieved (not enough to look at under the microscope) and in this case, a second specimen from the liver is taken for clinical diagnosis. However, after the first attempt, if there is enough for clinical purposes, but not for research purposes, a second piece will be taken for research purposes. Thus, by participating in this study, in a small fraction of patients undergoing liver biopsy (less than 5% of all patients), there will be a chance that a second piece of liver will be taken for research purposes. The additional risk of an additional liver sampling is approximately 1 in 1,000 for increased bleeding, and 1 in 2,000 for other complications such as puncture of a lung or colon. These complications are managed by observation and, in some circumstances, surgery.

Biopsy - Skin
Standard Language for Risks from Skin Biopsy

Skin biopsy is generally a non-hazardous procedure; however, possible hazards may include: 1) reaction to anesthetic (numbing medicine), 2) excessive bleeding, 3) bruising, 4) infection and 5) excessive scarring. While the local numbing medicine xylocaine is almost entirely free from allergic properties (such as causing hives), an allergic reaction is possible, and you will not be given xylocaine if you have a history of such a reaction. The xylocaine will be given by a small injection into the skin at the site of the skin biopsy. To speed healing, one or two stitches (also known as sutures) will be placed, which will be removed 5 - 7 days later. During the healing process, you will be asked to keep the biopsy site clean and dry, and to apply antibiotic ointment. Infection rarely occurs and is largely prevented by the use of an aseptic (or sterile) biopsy technique and proper wound care. If infection does occur, you will be instructed to keep the wound clean and to apply warm, wet compresses for 15 minutes, three times a day, until the infection subsides. If the infection persists, antibiotics may be prescribed.

Only 10-15 minutes will be required for the biopsy procedure. After the anesthesia wears off, there will be some soreness at the biopsy site that will last for a few hours. A small scar will develop at the site of the biopsy.

Blood Draw Risks

Standard Language for Risks of Blood Drawing

Venipuncture ? Taking blood from a vein in your arm by needle stick

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.

Blood Transfusion Risks

Standard Language for Risks from Blood Product Transfusions

As part of your medical treatment, you may need to receive transfusions of blood products. These products come from healthy volunteers from the general population who choose to donate blood for the use of patients. Blood donors and blood products are carefully screened and tested to minimize the risk of transmitting any infectious disease or problems, but it is impossible to eliminate all risks. However, not receiving a transfusion when needed can carry a great risk of serious injury or death.

If your treatment schedule and general health allow, you may arrange for friends or family members to donate blood for you, but, since many products must be matched to your own blood type to be used, blood donated by relatives/friends may not be suitable for your use. Therefore, receiving blood products from Duke Hospital Transfusion Service may be best for you. Alternatives to transfusion such as hemoglobin substitutes are not in general use at this time.
Bone Marrow Aspiration and Biopsy

*Standard Language for Risks from Bone Marrow Aspiration and Biopsy*

A bone marrow aspiration and biopsy is a procedure done in the clinic in which an area of the hip (either one hip or both hips) is numbed and a small sample of bone marrow is withdrawn. When the local anesthesia (numbing medication) is given, you may initially feel a burning sensation in your skin and bone surface for several seconds. During the procedure, you may temporarily feel pressure and/or pain of varying degrees. If necessary, you may ask your physician for additional local anesthesia or a medication to ease your stress. You also may experience minimal bleeding, and/or bruising after the procedure is completed and you may experience soreness in the area for a few days afterwards. Rarely, infection can develop.

**Certificate of Confidentiality Language**

*Please use this language if a Certificate of Confidentiality from the federal government has been issued for your study:*

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.

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.
ClinicalTrials.gov language

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.

Communicable Diseases ? Reporting of

Standard Language For Reportable Communicable Diseases

As part of this protocol, you will be tested for [name of infectious organism], which causes [describe what it causes]. You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with [name the organism], you will receive additional counseling about the significance of your care and possible risks to other people. We are required to report all positive results to the North Carolina Division of Public Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for [name of organism], then you should not agree to participate in this study.

(For additional information go to the website of Epidemiology in North Carolina.)

Compensation over $600

Standard Language for Payments to Subjects over $600

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds $600 in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

Conflict of Interest Disclosure

Use this standard language below when the PI has a conflict of interest management plan for corporate relationships such as speaking, consulting, advisory board, etc. This statement can be modified as appropriate to accurately reflect the investigator's conflict of interest (such as equity, stock, or ownership in a company). If another member of key personnel has a conflict of interest management plan, this statement should also be appropriately revised to reflect that conflict of interest:

"Dr. __________ has received personal compensation from the sponsor of this study in the past for his/her work on ____________________ and may receive personal compensation from the sponsor in the future."

Standard language for when the PI is the inventor of the technology being used in the study:
"Dr. ___________ [and other study team members] has/have developed the technology that is being used in the study. If the technology is commercially successful in the future, the developers and Duke University may benefit financially."

**Contraceptive Measures for Females**

Click Here for Required Elements on Reproductive Risks for Informed Consent Forms.

**Contraceptive Measures for Males**

Click Here for Required Elements on Reproductive Risks for Informed Consent Forms.

**Cost ? Expensive Treatment**

*Standard Language Regarding Expensive Treatment*

The expenses charged to you for being in this study could be unusually high. Therefore, we recommend that you discuss these costs with [insert PI?s name here] or your insurance company before agreeing to be in this study.

**CT Scan**

*Standard Language for Risks from CT-Scan*

Computed Tomography (CT) is a way to make x-ray images of the inside of the body. The CT scanner is a doughnut-shaped machine that uses x-rays to create computer pictures that show structures inside your body more clearly than regular x-ray pictures. During the procedure, a technologist will take you into the CT scan room where you will lie down on the patient table (usually on your back) inside of the CT machine. You should get comfortable because it is very important that you not move during certain parts of the test.

CT examinations differ depending on the part of your body being studied. For example, if your abdomen is being studied, a series of pictures will be taken from your lower chest to your lower pelvis. During the study, you will be asked to hold your breath so that the pictures will not be blurred. The machine will make some noise, and the table will move during the scan. Also, you may receive signals from the technologist or from the machine about your breathing. Before or during the study, you may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs. If you have any discomfort during the test or after the injection, be sure to tell the technologist.

**DNA ? Definition**

*Standard Language for Definition of DNA for Consent Forms*

Your genes are made up of DNA. DNA is short for deoxyribonucleic acid. A gene, or DNA,
contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child.

**DNA/Genetic Banking**

DNA/Genetic Banking Information

Genetic research studies may present unique risks to human subjects and their relatives. These involve medical, psychosocial and economic risks, such as the possible loss of confidentiality, of insurability and employability, a change in immigration status, potential limits on education options, and social stigmas. Knowledge of one’s genetic make-up may also affect one’s knowledge of the disease risk status of family members.

In studies involving genetic testing, the protocol should clearly answer the following questions. It is also likely that the consent form will need to include some of this information. The following standard language is also available in a Word document.

Examples of lay language that can be used in the consent form are provided below:

- Will test results be given the subjects, their physicians, and/or placed in medical records?
- Are tests for diagnostic purposes or for research only?
- Will research results be confirmed by a Clinical Laboratory Improvement Amendments (CLIA) approved laboratory?
- If results are provided to subjects, will disease risk be quantified, including the limits on certainty of the testing?
- Will a genetic counselor be involved in informing the subject of the results?
- Will any change in a family relationship be disclosed, such as mistaken paternity?
- Does the subject or family member have the option not to know the results? How will this decision be recorded?
- Could other clinically relevant information be uncovered by the study (i.e., Incidental Findings)? Will disclosure of this added information occur?
- Do any limitations exist on the subject’s right to withdraw from the research, withdraw data, and/or withdraw genetic material?
- Is the subject permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?
- Will genetic material be stored or shared? If shared, will the subject’s identity be known by the new recipient investigator?
- Will the subject be contacted in the future by the investigator or have their medical records reviewed to obtain updated clinical information?
- How can the subject opt-out of any distribution or subsequent use of his/her genetic material?
The following text is provided to assist investigators in developing a more lay-friendly consent form. Please incorporate all applicable sections, and if needed, alter the text to reflect the details specified by your protocol (e.g., if the subject may choose to agree to part of the study but refuse genetic testing or DNA banking, or if you plan to send materials to another investigator with subject identifiers as part of the study).

a. **Participation in genetic studies**: The genetic studies described are for research purposes only. Therefore, you will receive no results from this study (except as described below). It is not the purpose of this study to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. The research tests are not being used as diagnostic tests for any disease or illness. Your participation in this study is not a substitute for your regular medical care or check-ups.

b. **Research Results**: Through this research, we may find that you have an abnormal gene or gene product (RNA or protein) which indicates a risk for developing a disease at some time in the future. It is also possible that the research results may indirectly provide unexpected personal information about you or your family (such as ethnic/racial background or an unknown genetic relationship between family members). Please talk with the study doctor if you have any questions or concerns about the genetic testing being done in this research study. *He/she* may also refer you to a genetic counselor for further information.

c. **Incidental Findings**: It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician unless the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with Dr. ______________ at Duke University Health System (DUHS). DUHS staff will not provide this information in a voice mail, email, or otherwise prior to contacting you. Please notify us of any change in your contact information.

If you do not want to be notified of any incidental findings, please initial below.

____ Please do not notify me of any incidental findings obtained from this research.

If you prefer, we can ask you at the time of notification whether or not you want to receive incidental findings information. In this case, please initial below.

____ Please ask me at the time of notification whether or not I want to receive incidental findings information.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact us at ______________.

After providing the information to you, Dr. ______________ may arrange for you to meet with him/her and/or a genetic counselor or refer you to another appropriate health care provider to review the incidental findings information with you or your physician.
Guidance for Incidental Findings: Based on the specifics of the protocol, broader reporting of incidental findings may be appropriate. For example, you may choose to notify the subject of any clinically relevant findings rather than just findings that relate to potentially serious conditions. Incidental Findings should be confirmed (e.g. validated in a CLIA lab) before providing to a subject or his/her physician. Study teams are encouraged to contact the IRB when an incidental finding has been made that appears to be clinically actionable, and in particular, if it relates to a serious or life-threatening condition, to discuss the specific circumstances and how best to proceed.

The possibility of incidental findings should be addressed in all protocols conducting broad testing of the subject’s genetic material, such as genome-wide single nucleotide polymorphism (SNP) testing, DNA sequencing, whole genome sequencing (WGS) and whole exome sequencing (WES). It is not needed when the genetic testing is only of tumors, viruses, or other microbes obtained from subjects. It is also not needed when the genetic testing is limited to a few specified variants described in the protocol.

If Incidental Findings Will Not Be Provided (e.g. protocols with commercial outside Sponsors): It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

Guidance: This language should be used only after confirmation from the Sponsor that they are unwilling/unable to provide even incidental findings of clinical significance (which indicate a risk of treatable serious illness, such as those described in the American College of Medical Genetics and Genomics report for release of incidental findings (see pdf/link on our web site)).

d. Use and ownership of samples: By agreeing to participate in this research, you authorize DUHS and members of its staff to use your tissue, blood or other samples for the purposes described in this consent form. DUHS will maintain these samples indefinitely or until they are exhausted.

[Add if applicable: Your blood or tissue samples may be used to generate cell lines that can be cultured and used for a longer period of time than the original samples. These cell lines will only be used as described in this consent form and will be destroyed once the research has been completed.]

These samples will not be available to you for diagnostic or therapeutic purposes. Therefore, for any future diagnostic testing or treatments, a new sample will be obtained from you. Tissue, blood, or other samples [add all sample types or cell lines as applicable] collected as part of this study may be valuable for scientific, research, or teaching purposes or for the development of a new medical or commercial product. DUHS and/or the developers will assert all rights of ownership in the samples and all rights arising from use of the samples. There is no plan to compensate you for any use of the samples.

e. Secondary uses of specimens: With your permission, your blood and/or tissue samples may be shared anonymously with other investigators for research purposes. The samples may be used for study of disorders unrelated to the one(s) in your family. Such research will be strictly anonymous, in that no identifying information that would link the samples to you is provided to the researcher. An ethics board will review any such research prior to access being given to your samples. This secondary use will in no way compromise the study of the disorder(s) in your family or the use of your samples as part of this study.

Guidance - Secondary uses require separate consent/authorization. Add opt-in/opt-out to the consent form for this secondary use unless protocol under review is a database/repository designed to store samples for unspecified, future research studies.
f. **Availability/withdrawal of samples**: You will not have access to the sample once it is obtained. Samples may be stored indefinitely. If you decide to withdraw your permission to use your samples in this research project, please contact the study doctor, __________, in writing and let [him/her] know you are withdrawing your permission for your samples to be stored and used for this or future research. [His/her] mailing address is (list address). At that time, we will ask you to indicate in writing if you want your unused samples destroyed or if your samples (with all identifying information removed that would link the sample to you) could be used in research. Data collected using your sample before your withdrawal will continue to be used as part of the study.

**Guidance**: This language should be used in addition to, not in lieu of, the standard Right to Withdraw information in the consent form that describes how a subject may withdraw from the study itself.

g. **Right to New Information**: We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

**Guidance**: *This is typically found in the Right to Withdraw section of the consent form. It is an additional consent form element under the Common Rule and FDA regulations, required when appropriate. The Duke IRB’s has determined is it is appropriate for all studies.*

h. **Potential Risks and the Genetic Information Non-Discrimination Act (GINA)**: There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research [will/will not] be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at DUHS, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:
- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

**Guidance**:
*Use for studies that involve genetic testing of the subject?s DNA. While the protections of the Act apply in the US whether this language is included or not, the subject needs to know when they are not protected under the Act (see last paragraph).*

i. **Genome Wide Association Studies (GWAS)**: Genome-wide association studies (GWAS) look at the genetic differences between individuals that may be found in the human genome (the complete set of all human genes) to find out if there is a relationship between certain traits (such as blood pressure, or weight) and the presence or absence of a disease or condition.
As part of this study, we will be collecting genetic data about you and these data will be sent to the National Institutes of Health (NIH) GWAS repository (a repository is a place where data are stored for use in future research). The data will not be labeled with any information that can be used to identify you. GWAS data may be shared with other researchers around the world. Researchers will have to get approval from an ethics board to use this information for research prior to getting access to this data.

Guidance for GWAS: *Use of this language is appropriate whenever the study is being funded by a grant that requires such language, or you are applying for funding from an agency that requires such language and are seeking a declaration of concordance.*


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**Databases and Repositories of Genetic Information for Future Research:**

Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information; this risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have.

Your samples and genetic information may be used for research for many years in the future. We will protect your privacy and confidential information by labeling your samples and genetic information only with a code number. Researchers outside of Duke University will not be given a link between the code number and your name or any other identifying information. While we hope this will prevent any potential loss of privacy or confidentiality, we cannot make any guarantees.

**Guidance:** *Use this language for protocols depositing genetic information or samples/cell lines to be used for genetic testing in databases widely available to researchers for a long period of time (for example, national databases) for future research. When applicable, indicate if other health information will be stored with the genetic information and/or samples, such as the disease or condition the subject has and/or demographic information, such as age, gender, and ethnicity.*

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**Drug and Food Interactions**

**Standard Language for Drug and Food Interactions**

**Drug and Food Interactions:**

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.

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**ECG (Electrocardiogram) Risks**

**Standard Language for ECG (Electrocardiogram) Risks**
Possible side effects of the ECG are skin irritation, itching and redness from the ECG electrode pads.

**Endoscopy**

*Standard Language for Risks from Associated with Endoscopy*

Risks associated with endoscopy include aspiration (choking and/or gagging), sore throat, bleeding, and infection. Major complications occur in a small number of people who have endoscopy. The endoscope could puncture or pierce the intestines (less than 1 in 1,000 chances). This could require additional treatment or surgery.

**Gadolinium Based Contrast Material**

*For Studies Involving Gadolinium-Based Contrast Material*

For Adults:

A rare but potentially serious drug reaction called nephrogenic systemic fibrosis (NSF) has been observed in patients who received a gadolinium-based contrast agent (GBCA) during MRI examinations. Patients with severe kidney disease are at increased risk of developing NSF. NSF may cause skin thickening, joint pain and/or swelling. In rare cases NSF can lead to lung and heart problems and cause death. To minimize the likelihood that you will be affected, you will have a blood test to measure your kidney function. If your blood test is abnormal, you will not be permitted to receive a GBCA.

Additionally, it has been shown that patients who receive multiple doses of GBCAs may have gadolinium remain in some tissues. Some individuals who received GBCAs have reported general symptoms such as skin burning, confusion, bone pain, and others, which has been termed “Gadolinium Deposition Disease” by some. However, it is not clear that there is a link between GBCAs and these symptoms, and no authoritative group has determined that this is a disease.

For Children:

A rare but potentially serious drug reaction called nephrogenic systemic fibrosis (NSF) has been observed in patients who received a gadolinium-based contrast agent (GBCA) during MRI examinations. Patients with severe kidney disease are at increased risk of developing NSF. NSF may cause skin thickening, joint pain and/or swelling. In rare cases NSF can lead to lung and heart problems and cause death. To minimize the likelihood that your child will be affected, your child will be evaluated by the Pediatric Radiologist to ensure that your child meets Duke Pediatric Radiology standards to receive gadolinium. If your child does not meet those standards, gadolinium will not be used.

Additionally, it has been shown that patients who receive multiple doses of GBCAs may have gadolinium remain in some tissues. Some individuals who received GBCAs have reported
general symptoms such as skin burning, confusion, bone pain, and others, which has been
termed “Gadolinium Deposition Disease” by some. However, it is not clear that there is a link
between GBCAs and these symptoms, and no recognized group of experts or society has
determined that this is a disease. This has also not been reported in any children.

**HIV Testing**

*Standard Language for HIV Testing*

As part of this protocol, you will be tested for HIV (human immunodeficiency virus, which is
the virus that causes the acquired immunodeficiency syndrome [AIDS]). You will be notified of
the results of the testing, and counseled as to the meaning of the results, whether they are
positive or negative. If the test indicates that you are infected with HIV, you will receive
additional counseling about the significance of your care and possible risks to other people.
We are required to report all positive results to the North Carolina Division of Public Health.
The test results will be kept confidential to the extent permissible under the law. If you do not
want to be tested for HIV, then you should not agree to participate in this study.

**Identifiers  From X-Rays or Other Images Sent Outside Duke ? DICOM language**

DICOM Standard Language:  *Please add this language to the consent form when x-rays or
other images containing identifiers are to be sent outside of Duke. Please insert under the
section titled “Will My Information Be Kept Confidential?” in the consent form:*

Study records that identify you will be kept confidential as required by law. Federal Privacy
Regulations provide safeguards for privacy, security, and authorized access. Except when
required by law or as outlined in this consent, you will not be identified by name, social
security number, address, telephone number, or any other direct personal identifier in study
records disclosed outside of Duke University Health System (DUHS). For records disclosed
outside of DUHS, you will be assigned a unique code number. The key to the code will be
kept in a locked file in Dr. [PI]’s office.

As part of this study, you will have [image tests]. For the tests to be useful, limited identifiers
like test dates [include other identifiers as necessary, e.g., date of birth, initials] are
necessary. By signing this consent form, you authorize Dr. [PI] to send these specific
identifiers in the images to [Sponsor Name] and their designated affiliates.

**Injury Language (Research Related)**

*Standard Language for Studies NOT Commercial/Industry Sponsored:*
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 Dr. (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.

Standard Language for Commercial/Industry Sponsored Studies:
Following are three optional formats for the Research Related Injury section of the Informed Consent for use in Commercial/Industry Sponsored studies. This language is provided for general reference; the optional format selected must coincide with the terms and conditions of the Contract between Duke and the Sponsor. Before submitting the Informed Consent to the IRB, contact the Agreement Manager in ORC to discuss the correct option to be used and any special contractual conditions that may apply to this section of the Consent.

Option 1: When the Sponsor Provides for Payment for Research-Related Injury (not conditioned on first billing third party payers)

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. The study sponsor, Company X, will reimburse you or the provider of services for the medical care you receive for your injuries provided all aspects of the study protocol have been followed correctly.

For questions about the study or research-related injury, contact Dr. (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.

Option 2: When the sponsor conditions its obligation to pay for Research-Related Injury on a primary effort to obtain payment from a third party payer

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.

If you are a Medicare, Medicaid or Tricare patient or you have no health insurance, and you are injured as a result of your participation in this research study, the study sponsor, Company X, will reimburse you or the provider of services for the medical care you receive for your injuries provided all aspects of the study protocol have been followed correctly. Medicare, Medicaid or Tricare will not be billed for these injuries.

If you have commercial (private) insurance, and you are injured as a result of your participation in this research study, your insurance provider will be billed for medical care you receive for these injuries. For any such costs that are not covered by your insurance provider, other than deductibles and co-pays, the study sponsor, Company X, will reimburse you or the provider of services for the medical care you receive for your injuries provided all aspects of the study protocol have been followed correctly.

For questions about the study or research-related injury, contact Dr. (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)
Option 3: When the sponsor makes no provision for payment for research-related injury (our standard paragraphs with addition of ?the study sponsor, Company X?)

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., your Duke physicians or the study sponsor, Company X, 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 Dr. (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.

Legally Authorized Representation (LAR) Language? If Subject Regains Decision-Making Ability (For the LAR Consent Form)

If Subject Regains Decision-Making Ability  (For the LAR Consent Form)

If, during the course of the study, the subject regains the ability to make decisions he/she will be asked to read this consent form and decide whether to continue participation.

Legally Authorized Representation (LAR) Language - When There Is No Direct Benefit to Participant (For the LAR Consent Form)

The Use of the Legally Authorized Representative (LAR) in the Setting of Non-Therapeutic Research

As determined by University Counsel, the statement below must be added to a consent form that will be signed by a legally authorized representative on behalf of an adult research participant, but only in the setting of non-therapeutic research, where there is no prospect of direct therapeutic benefit to the study participant:

"I am the representative of the subject and am acting on behalf of the subject. I am not aware of any factor that might create a conflicting interest for me in this role (for example, something that might bring me personal benefit). I consent to the subject's participation in this study."

Mouse Antibody

Standard Language for Risks from Mouse Antibody

This drug is a protein made from mouse cells. There is the possibility that persons who participate in this research will develop antibodies to mouse proteins. If antibodies are formed, they may reduce the effectiveness of medicines developed from mouse proteins, though this is unlikely to occur. The antibodies may also interfere with certain laboratory tests. Medicines that contain mouse proteins are used to treat diseases such as rheumatoid arthritis, Crohn's...
disease, and cancer. This means that there is a very small possibility that you may not be able to receive other medicines in the future that contain mouse proteins or that the effectiveness of the medicines may be diminished. You should tell your doctors in the future that you have received a drug that contains mouse proteins.

MRI

Standard Language for Risks from MRI

Magnetic resonance imaging (MRI) uses a magnet and radio waves to make diagnostic medical images of the body. There have been no ill effects reported from exposure to the magnetism or radio waves used in this test. However, it is possible that harmful effects could be recognized in the future. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body, including medical implants, devices such as pacemakers and internal defibrillators, or certain dyes found in tattoos. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner.

If there is any question about potentially hazardous metal within your body, you will not undergo the MRI. This may exclude you from participation in this research study. The MRI involves entering a large room in which a magnet is present. You will be placed on a narrow bed and then slid into a small tunnel approximately 6 feet in length and 25 inches in diameter. You will be asked to lie still for about one hour on this bed. You will hear a loud machine-like noise. You may be asked to have a harmless monitoring device applied during the MRI. During the MRI, you can have voice contact and physical contact with someone in attendance if you desire. Let the study doctor know if you have a fear of enclosed spaces.

Peripheral Neuropathy

Standard Language for Risks from Peripheral Neuropathy

Peripheral neuropathy is damage to the peripheral nerves which are a large communications network that carries information from the brain and spinal cord to every other part of the body. This can cause weakness, numbness, abnormal sensations such as prickling, tickling, burning, or tingling and pain in the arms, hands, legs, and/or feet.

Radiation Risk

Please refer to the Radiation Safety Committee Website:

https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/

There you can find pre-computed "canned" statements for popular studies, or you can try out the on-line "Radiation Risk Computer". The "computer" is useful for creating customized statements when multiple diagnostic procedures are involved.
Redisclosure Language

*Redisclosure Standard Language*

**For sponsor generated studies:**

The sponsor may share data: This information may be further disclosed by the sponsor of this study, [Sponsor Name]. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations.

**For PI funded studies:**

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

Risk Management Language-Duke Regional Hospital

*Risk Management Standard Language for Duke Regional Hospital*

For questions regarding your rights as a subject in research you may call the Duke Regional Hospital Risk Management Office at (919) 470-8531.

RNA ? Definition

*Definitions of RNA and Protein for Consent Forms*

RNA is made from DNA. RNA is short for ribonucleic acid. RNA is a genetic material that has a major role in making proteins. Proteins are the building blocks of your body, cells, and organs.

Sample Retention

*Standard Language for Retention of Samples*

Your sample(s) will be kept and stored at _______ by_______. Maintaining confidentiality is important to ______ (sponsor). All samples will be kept and stored in a secure place. Your sample will be identified by a unique barcode, which means that your name will not be on the sample. However, this barcode can be linked to your unique study identification number, age, gender, ethnic background. Besides protecting your confidentiality this barcode system will allow the sponsor to destroy your sample in case you change your mind. Your sample will be kept for ____ years. After that time, the sample will be destroyed by methods in accordance with laboratory or institution procedures.

Statement of Consent

“*The purpose of this study, procedures to be followed, risks and benefits have been explained to me.* (Or for studies involving children over age 6 ? to my child and 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. (Or for studies involving children? I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw my child at any time. [For studies involving children over age 6? We have discussed the study with my child, who agrees to be in the study.]) I have been told that I will be given a signed and dated copy of this consent form."

**Sedation**

*Standard Language for Risks from Sedation*

The risks of sedation include an allergic reaction, aspiration (fluid going into the lungs), and over-sedation. In addition, the IV used may cause a bruise. Occasionally, an infection develops at the IV site.

**Students and Employees in Research**

*Standard Language for Studies Involving Students and Employees*

(Insert after withdrawal language) Nonparticipation or withdrawal from this study will not affect your job status if you are a Duke employee and will not affect your grades if you are a Duke student.

**Tumor Biopsy Risks**

*Standard Language for Tumor Biopsy Risks*

Risks of a tumor biopsy are localized bleeding at the needle injection site or from the surgical incision, pain, inflammation, swelling, and infection. The bleeding may cause discomfort and bruising. In rare circumstances (less than 1%), this bleeding may be severe enough to require further care. If you have a history of excessive bleeding, or if you are receiving medication that might increase your risk of bleeding (such as aspirin or blood thinners), you must notify the physician before the procedure. Infection of the surgical site may require treatment with antibiotics.

*If applicable*: Tumors that are biopsied from the lungs may result in an additional risk of pneumothorax (collapsed lung). Biopsies in or near other vital organs may result in bleeding that can be life-threatening or may cause damage to the organs and affect their function. (If liver biopsies may be done? add IRB standard liver biopsy risk information).

Depending on the site, the biopsy procedure may use local anesthetics (numbing medicine), sedatives, or general anesthesia to reduce the discomfort or pain. All medicines have the possible risk of allergic reaction. Please advise your study doctor if you have ever had an allergic reaction to latex, lidocaine, or any other anesthetic. (See standard language if applicable for sedation and general anesthesia)
Any complications arising from the biopsy may be treated with observation, additional medications, or in some cases, additional surgery. The study doctor will discuss the specific risks of the biopsy with you at the time of the procedure.

*(If image or radiological guidance may be used for the biopsy, those risks, including risks of contrast agent and/or radiation risks, would also be needed. Radiation Safety approval is needed for research-related radiation risks.)*

**Use this language if your study is using the GUID (Global Unique Identifier) Software Tool ([https://nda.nih.gov/s/guid/nda-guid.html](https://nda.nih.gov/s/guid/nda-guid.html)):**

**How will my information be de-identified?**

For this study, a unique identification number (Global Unique Identification, or GUID) will be created for you. This number will be used to connect (link) your research information from this study to other research studies that you may participate in that also use the GUID system. To receive this number, you and a study staff member will go to a secure internet website on a computer at the research clinic and enter information about you: your first, middle and last names at birth, any suffixes (Jr., III, etc.), your date of birth, name of the city where you were born, and your country of birth. Once the GUID is created, your personal information is deleted.