General Instructions for creating your consent form:

* Hover over text to get detailed instructions.
* Avoid jargon use write your consent on a 6th grade level. For examples of wording substitutes please see <http://www.utrgv.edu/irb> > UTRGV IRB Templates > For Researchers > Other
* Do not use the terms “treatment”, “therapy”, or “device”. Instead use terms such as “investigational treatment/therapy/device” or “research treatment/therapy/device.” This avoids therapeutic misconception.
* Do not use the term “patient” instead use the term “subject” or “participant”

IMPORTANT NOTES

Do not, under any circumstances, submit a consent form with instructional text still included. This will delay approval of your application.

**The instructions in this form were created using hyperlinks. You must remove all hyperlinks before submitting your consent for review. To do this press CTRL + A to select the entire document and the press CTRL+ SHIFT+F9.**



Informed Consent Form and HIPAA Authorization

**Study Title:** [Insert title here](#Title" \o "Insert a brief descriptive title here)

**Consent Name:** [Insert consent name here](#ConsentName" \o "OPTIONAL.  Indicate consent identifier if there is more than one consent for your study (e.g., control consent))

|  |  |  |
| --- | --- | --- |
| **Principal Investigator:** | Investigator Name | Telephone: (xxx) xxx-xxxx |
| **Emergency Contact:[[1]](#endnote-1)** | Name | Telephone: (xxx) xxx-xxxx |
| Omit emergency contact if minimal risk | [Emergency contact should be a phone number accessible 24 hours (i.e. pager, cell) and answered by someone knowledgeable about the study] |

# [Key points you should know](#KeyPoints)

* [We are inviting you to be in a research study we are conducting. Your participation is voluntary. This means it is up to you and only you to decide if you want to be in the study. Even if you decide to join the study, you are free to leave at any time if you change your mind.](#Invite" \o "Do not remover or edit.)

* [Research is different than regular medical care, which has already been tested to make sure it works and is safe.](#ResearchvsTreatment" \o "Delete this entire statement if no research treatment will be delivered as part of the study.)
* Take your time and ask to have any words or information that you do not understand explained to you.
* We are doing this study because we want to learn
	+ *Provide a list or a few brief sentences here, explaining the purpose of the study*
* Why are you being asked to be in this study? *Delete this section if this is not relevant*
	+ You are being asked to be in this study because you have *[insert relevant characteristic, disease, or disorder here]*
* What will you do if you agree to be in the study?
	+ *Provide a list here, explaining step-by step what the participant will do, make sure to include duration of their participation.*
	+ *You may include/alter the following if relevant to your study. Delete anything that is not relevant. Make sure to indicate if any of the procedures being used are experimental.*
	+ *[It is not mandated that standard care procedures be listed. If they are listed, the consent must explain which would be part of usual medical care (would occur even if the subject did not participate in the study), (2) which are standard procedures that will take place during the research and (3) which are the procedures/interventions being tested as part of the study (the research procedures).]*
		- Interviews: A team member will take your medical history, along with a listing of any medications you are taking. Throughout the study you will be asked to report if you think that anything bad has happened as a result of the study.
		- Physical Examination: Exams will be conducted before and during the study including measurements of weight, height, blood pressure, heart rate and respiratory rate, etc. Note: Try to be brief and consolidate similar things. Examples, vital signs can be included with physical exam, interviews can include a wide range of research procedures.
		- Blood Draw: Brief description, including amount of blood to be drawn
		- Urine Collection: Brief description
		- Procedure/Test: Brief description
		- Pregnancy Test: If you are pregnant or nursing, you will not be allowed to participate in this study. If you are eleven years old or older or have already started having periods, you will be asked to take a pregnancy test before starting this study. The results will be shared with you and not with your parent(s). We strongly encourage you to share the results with your parents. If you are found to be pregnant, you will not be able to continue participation in the study. About [XXXX] teaspoons of blood (or urine if urine test) will be needed.
		- Birth Control: For female subjects: You will need to take safety measures to prevent pregnancy (such as not having sexual intercourse, or using a medically accepted form of contraception) for a minimum of XXXX (time period before, during and after the study). If you have questions about how to avoid pregnancy, talk to your doctor or the researcher and they will provide you with information on contraceptive choices. You should contact Dr. XXXXX at once if you become pregnant during this research study.
		- For Male Subjects: You should not father a baby for a minimum of XXXX after administration of XXXX. You need to take safety measures to prevent pregnancy (such as using contraception or not having sexual intercourse) for a minimum of XXXX after administration of XXXX. If you have questions about how to prevent pregnancy, talk to your doctor or the researcher and they will provide you with information on contraceptive choices.
		- Study Drug/Intervention: You will need to take study drug by mouth twice a day for XXXX weeks.
		- *If you are doing a study with multiple visits you may want to include a brief paragraph describing the timeline or you may want to include a table like the one below. Keep the table simple so it can be easily understood by study participants.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit** | **Purpose** | **Main Procedures** | **Duration** |
| Visit 1 | Screening visit  | Blood tests, MRI scan | 2 hours |
| Visit 2, Day 0 | Start study drug | Distribute study drug  | 30 minutes |
| Visit 3, Day 28 | Routine Visit | Lab tests, distribute study drug | 1 hour |
| Visit 4, Day 56 | End of Study | Return unused drug and Quality-of-Life Survey | 1 hour |

* + - *If you are videotaping or audiotaping procedures include one of the following:*
		- Participation in this study requires [videotaping/audiotape] of [all procedures/list of procedures], by signing this consent form you are giving us permission to make and use these recordings.
		- *OR*
		- We would like to *[videotape/audiotape] [list of procedures], please indicate whether you will allow us to do so by initialing one of the following:*
			* \_\_\_\_\_(initials) Yes, I give permission for [videotaping/audiotaping]
			* \_\_\_\_\_(initials) *No, I do not give permission for [videotaping/audiotaping]*
* Can you be harmed by being in this study?
	+ Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to the study doctor.

[NOTE: PICK **ONE OF THE FORMATS** BELOW TO DESCRIBE THE RISKS ASSOCIATED WITH YOUR STUDY – THE ONE YOU BELIEVE PROVIDES THE RELEVANT INFORMATION IN AN UNDERSTANDABLE FORMAT. DELETE IRRELEVANT SECTIONS BELOW OR ADD ADDITIONAL RISKS REVELANT TO YOUR STUDY. *IN THE FUTURE YOU MAY FIND EXAMPLES OF POSSIBLE RISKS THAT YOU CAN INCLUDE IN THIS SECTON ON OUR WEBSITE: XXX. FOR NOW, THEY ARE LISTED BELOW FOR INCLUSION ON THIS FORM AS APPLICABLE TO YOUR STUDY.*]

**FORMAT 1 – BULLET POINTS**:

* **Risks associated with collection of blood:** Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.
* **Risks associated with collection of urine, saliva and cheek cell samples:** The physical risks of these procedures are all minimal. A cheek swab could include irritation of the cheek where the sample was taken.
* **Risks associated with collection of leftover tissue:** Only tissue that is leftover and that would normally be thrown away will be used for the research. There are no additional risks from the collection of these samples.
* **Risks to your personal privacy and confidentiality:** Research that uses health information and that involves genetic testing can affect your privacy. [NOTE: MODIFY THE FOLLOWING STATEMENTS IF NEEDED] Your participation in this research will be held strictly confidential and only a code number will be used to identify your stored samples and data. However, because there will be a link between the code and your identity, confidentiality cannot be guaranteed.
* **Risks associated with DEXA scan:** As a participant in this study, you will be exposed to radiation that you would not be exposed to if you were not a part of the study. Each DXA scan typically delivers 0.1 mrem of effective dose, or 1/10th the radiation dose you would receive from the natural background of the Earth in one day. The increased risk of disease from one DXA scan is negligible and may be non-existent; however, the effects of radiation add up over your lifetime with multiple scans.
* **Risks associated with genetic testing:** Since future research studies will involve genetic analyses, potential risks include stigmatization of individuals or groups of individuals. It could also affect your insurability. [NOTE: MODIFY OR DELETE THE FOLLOWING SENTENCE IF THIS IS NOT TRUE.] The protections in place (described above) minimize those risks. Only coded samples and data will be stored and used for future research. There is also a Federal law, called the Genetic Information Nondiscrimination Act (GINA), which generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

This law may protect you in the following ways:

* + Health insurance companies and group health plans may not request your genetic information that we get from this research.
	+ Health insurance companies and group health 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 that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
* There may be other risks that are not known at this time. Tell the study investigator or study staff right away if you have any problems.
	+ *Provide a list of reasonable, foreseeable risks to the participant (or to the embryo or fetus should the participant become pregnant) and the likelihood they would occur. Use simple terms to explain probability. If there are no risks outside of what a person would face during the course of a normal psychological or medical exam, you can simply state that (e.g., “Being in this study is not more dangerous than doing the types of things you would do during a regular visit with a doctor/counselor”).*

***FORMAT 2: risks with likelihood***

**Likely/Common Risks (more than 35%)**

Life Threatening

* Describe the risks

Serious

* Describe the risks

Mild

* Describe the risks

**Less Likely/Less Common (10% - 35%)**

Life Threatening

* Describe the risks

Serious

* Describe the risks

Mild

* Describe the risks

**Rare (less than 10%)**

Life Threatening

* Describe the risks

Serious

* Describe the risks

Mild

* Describe the risks

***FORMAT 3 – TABLE OF RISKS****: Describe the condition/disease/indication in which these risks were experience if different from the condition/disease/indication of this study.*

|  |  |  |
| --- | --- | --- |
| **Mild** | **Serious** | **Life-Threatening** |
| **Frequency of Risks** | **Likely/Common more than 35%** |  Risk 1 Risk 2 |  Risk 1 Risk 2 |  Risk 1 Risk 2 |
| **Less Likely/Less Common****10-35%** |  Risk 1 Risk 2 |  Risk 1 Risk 2 |  Risk 1 Risk 2 |
| **Rare****Less than 10%** |  Risk 1 Risk 2 |  Risk 1 Risk 2 |  Risk 1 Risk 2 |

* + *If applicable add or modify The* treatments and procedures you undergo as part of this research may have risks for you (and/or a fetus or embryo should you become pregnant or father a child) that we do not know about.
	+ If we learn something new and important while doing this study that would likely affect whether you would want to be in the study, we will contact you to let you know what we have learned.
* What are the costs of being in the study? DELETE THIS SECTION IF IT DOES NOT APPLY TO YOUR STUDY
	+ While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.
	+ There will be no additional costs to you by taking part in this study (or if there are costs, explain them).
	+ [Study sponsor] or UTRGV (pick whichever is appropriate) is providing financial support and material for this study. The following research procedures, study drugs and study visits will be paid by XXX:
		- *Edit as applicable*
		- Cost of travel, parking and meals;
		- Cost of study drug, etc.
		- MRI of the knee
		- Blood tests for X, Y and Z
		- Etc.
	+ *Include the following only if subject or insurance will be billed*
	+ We can help you understand your financial responsibilities. (*Edit as applicable. Everything below depends on the nature of the study and whether or not billing insurance/ financial assistance is available.)*
	+ If your insurance does not pay for all the costs, you will be responsible for the remaining costs, including any co-payments and deductibles as required by your insurance.
	+ If you do not have insurance, you will be responsible for the costs of taking part in this study.
* Will you get anything for being in this study?
	+ *List any benefits to the participant or to others that can be reasonable expected from the study. This could include monetary compensation, extra credit, or treatment free of charge.*
	+ *You can use sample text below or edit/delete as needed.*
	+ We are hoping this study will help us improve treatment for XX.
	+ You will not receive any payments for taking part in this study.
	+ *OR*
	+ *If there will be payments and/or reimbursement, the consent form should specify how much will be paid for reimbursement of expenses (not taxable) and the form (cash, check, gift card) and the timing of payment. Also, if a child is the subject*, specify how much is going to the parent and how much is going to the subject.
	+ Parents/participants will be reimbursed $XXXX for travel, meals and parking. Receipts must be provided for all expenses.
	+ *OR*
	+ *(for flat rate reimbursement use the following)* Parents and participants will be reimbursed a per diem of $XXXX to offset the costs of meals and incidentals (this must be in accordance with the www.gsa.gov guidance).
	+ Parents will be paid $XXXX for their time and effort.
	+ Children/participants will be paid $XXXX for their time and effort**.**
	+ If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.
	+ *(Include only if applicable)* If your travel to UTRGV (e.g. flight, hotel) is arranged and paid for by the study team, the agency making the reservations and their representatives will have access to identifiable information.
	+ *NOTE: If payment to an individual could exceed $600 (not including reimbursement for parking, meals, etc. based on receipts) in a calendar year, include a statement that subjects will receive a W9 form.*
* What other choices do you have if you decide not to be in the study? *DELETE THIS SECTION IF IT DOES NOT APPLY TO YOUR STUDY*
	+ You could
		- *List appropriate alternatives here (e.g., other options for extra credit, other appropriate treatment options).*
* What could happen if you withdraw from the study early? *DELETE THIS SECTION IF IT DOES NOT APPLY TO YOUR STUDY*
	+ *In some studies, there are risks involved in a participant suddenly stopping treatment and it may be necessary to have a process in place for orderly termination. If this is a factor in your study, describe the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject including why such procedures are important to the subject's welfare.*
* Could you be taken out of the study?
	+ Alter the following as appropriate for your study
	+ You could be removed from the study if:
		- Your condition worsens.
		- The study is stopped.
		- The study drug is no longer available.
		- You cannot meet all the requirements of the study.
		- New information suggests taking part in the study may not be in your best interests.

# Can the information we collect be used for other studies?

*You must Include one of the following statements if you are collecting identifiable private information (any identifiable private information not just PHI) or identifiable biospecimens. Delete this instructional text and the statement that does not apply. DO NOT USE THIS FORM IF YOU WANT TO OBTAIN ADDITIONAL CONSENT FOR THE USE OF IDENTIFIABLE PRIVATE INFORMATION OR BIOSPECIMENS FOR UNSPECIFIED FUTURE STUDIES*

Information that could identify you will be removed and the [information you gave us/the samples we collected] may be used for future research by us or other researchers; we will not contact you to sign another consent form if we decide to do this.

-OR-

We will not use or distribute [information you gave us/the samples we collected] for any other research by us or other researchers in the future.

# What else should you know?

Include any/all of the following sections/statements if they are relevant to your study. Delete subsections that are not relevant or delete this entire section if it is not relevant to your study. Note that the term “samples” refers to biospecimens

* We are asking about N people to be in this study.

If you are collecting biospecimens include the following:

* Research tests using your sample may possibly result in inventions or procedures that have commercial value and are eligible for protection by a patent. By agreeing to the use of your sample in research, you are giving your sample without expectation of acknowledgment, compensation, interest in any commercial value or patent, or interest of any other type. However, you retain your legal rights during your participation in this research.
* The research we are doing [may/will/will not] include whole genome sequencing.

If you are collecting clinical data, include the following:

* If we find out something related to your disease or disorder will share it with you if [list conditions under which you would share clinically relevant results]. This could include [telling you about findings from our study or we may contact you about your individual results] if [list conditions under which you would contact participants about their results].

-OR-

* We will not be sharing our findings with you, this means that we will not contact you to tell you your individual results.

If the study will include exposure to radiation, please include the following:

* Radiation exposure to a woman’s reproductive organs may harm an embryo or fetus.  Also, if radioactive materials are used for certain types of scans, harm may come to an embryo, fetus, or an infant who is breast feeding.
* Pregnancy tests performed during the early stages of pregnancy do not always reveal pregnancy.  Therefore, radiation exposure that includes the reproductive organs will be limited to the first ten days after a woman who can become pregnant has begun her most recent menstrual period.

Insert the risk statement applicable to your study

If the amount of radiation exposure is the same regardless as to whether the participant elects to participate in this research study or receives standard medical care, please include the following sentence.

* The radiation dose that you will get from diagnostic tests is medically indicated for your condition and it is the same that you would get if you were not involved in this research study.

If the amount of radiation exposure is more than the participant would receive if they elected to receive standard medical care, please include the one of the following sentences.

* If additional radiation dose >350 mrem from research:  This research study includes exposure to radiation from diagnostic tests in addition to that which you would receive from standard care.  The additional radiation dose you will get is about [insert appropriate percentage] % of the average radiation dose from all sources (natural background radiation, consumer appliances, radon gas, medical tests, etc.) that a person in the United States receives each year.
* If additional radiation dose <350 mrem from research:  This research study includes exposure to radiation from diagnostic tests in addition to that which you would receive from standard care.  The risk of harm to your body from this radiation can be compared to risks from everyday activities.  For example, the risk of developing fatal cancer during your lifetime from this radiation is comparable to the risk of suffering a fatal car crash while driving [XX] miles in an automobile.  The average household in the United States drives 23,000 miles per year (2001 data).

If your study includes an additional radiation dose involving cardiac catheterization, electrophysiology studies, interventional peripheral and neuro-radiology procedures, you should consult with a medical physicist to determine if additional statements covering any deterministic effects—such as erythema or epilation—may be required.

# How will your information be used and shared?

* If you agree to be in this research study and sign this consent form, you give your permission to: *enter the name(s) of the investigators, and others who will use or disclose PHI for the study. -OR-Enter the class of persons [e.g., investigators, study team, health care providers] to* use or share your health information for this research study.
* The health information that we may use or share for this research includes:  *Describe the information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, medications, demographic information, etc.*
* A description of this clinical trial will be available at <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
* The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law known as the Privacy Rule or Health Insurance Portability and Accountability Act (HIPAA).
* We cannot use or share your information for this research study without your permission.
* If you have any questions about the Privacy Rule you can speak to the investigator or the Privacy Officer at 956-665-5843.
* We will use your information only for the study described in this document.
* We will do our best to make sure your information stays private. Let us know if you have questions about this.

# What happens if I say no or change my mind?

* You can say you do not want to be in the study now or if you change your mind later you can stop participating at any time.
* We will not collect, use, or share your information for this study. Choose the appropriate term(s)
* No one will treat your differently. You will not be penalized.
* You will not lose any benefits.

OR

 *[For studies with the prospect of direct benefit,]*

While you will not get the possible benefit of being in this study, you will not lose any other benefits.

* If you say yes, but later change your mind, you can tell us to stop using any information that can be traced to you. We will stop, except in very limited cases if needed to comply with law, protect your safety, or to make sure the research was done properly.
* If you want us to stop using your information, you need to tell us in writing. *Write or e-mail [insert name, phone # address and email]*
* If you stop, the care you get from your doctor will not change.

# How will my privacy be protected?

* *As appropriate, describe how information about participation in the study and the data generated from the study will be kept confidential or anonymous. If data will be collected anonymously, explain how this will be done. If the data will be confidential, provide details about how this will be maintained (e.g. secure storage of files, informed consent and data stored separately, destruction of identifying information once all data has been collected, use of coded data with a code book stored separately to link participants with their coded data. Indicate how long data will be kept and who will have access to any identifiable data. You may use the following text/image if applicable.*
* Your information will be stored with a code instead of identifiers (such as name, date of birth, medical record number, social security number).
* All information used by this project will be protected so that it can only be accessed by authorized people. Still, no one can guarantee that computer security will be perfect.
* No published scientific reports will identify you directly.
	+ The figure below is an example only. It is applicable for when the investigators won’t have the key to the code. Delete if not applicable

###

* *If it is possible that data may reveal illegal behavior that must be reported according to state law (e.g. abuse, intent to harm self or others), you should state that disclosure of such information will be reported to the extent required by law.*
* *Research using electronic communication cannot be promoted as anonymous, even if attempts are made to secure the transmission of data. In addition to interception of data, there exists the possibility of spyware that can track keystrokes on computers and/or electronic surveillance of employee computer use.*
* *If you have obtained a Certificate of Confidentiality, you should state this here and indicate its purpose and limitations. If you are accessing or using educational or medical records in your research, you should be aware of HIPAA and FERPA regulations regarding their use and should address any pertinent issues in the informed consent form.*

# Who is paying for this study?

* *If there is no external funding source:* The [Department/School/Division) of XXXX at The University of Texas Rio Grande Valley is funding this research.
* *OR*
* The National Institutes of Health is providing funding for this study.
* *OR*
* *For industry sponsored studies:*
* This study is supported by the SPONSOR. SPONSOR is a drug company that makes the drug being studied in this research project. SPONSOR is giving money to UTRGV for some of the costs of the study. The results of the study will be reported to SPONSOR. If the study shows that the STUDY DRUG/DEVICE/INTERVENTION may be useful for a new purpose, this could benefit SPONSOR financially.
* Please ask Dr. XXXX if you have any questions about how this study is funded.
* *Include any disclosures or management plans mandated by the COI Official or the IRB.*

# What should you do if you are hurt or injured during this study?

* *You may delete this section for minimal risk studies*
* *Wording for non-industry-funded studies*
* If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. UTRGV does not offer financial compensation or payment for injuries due to participation in this research.
* You and your insurance company will be billed for the costs of any care or injuries.
* If you think you have been injured from taking part in this study, call Dr. XXXX at (xxx)-xxx-xxxx. He/she can go over things with you, let you know of resources that may be available and give you information on what you need to do.
* In case of injury resulting from this study, you will not lose any legal rights by signing this form.
* *Wording for industry-funded studies*. Do not modify.
* If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency care. Treatment may be billed to you or your insurer. If your injury is caused by a research procedure or the experimental drug/device/intervention, SPONSOR may pay for treating the injury. This does not mean that a mistake happened.
* UTRGV does not offer financial compensation or payment if you are injured as a result of participating in this research.
* If you think you have been injured from taking part in this study, call Dr. XXXX at (xxx)-xxx-xxxx. He/she can go over things with you, let you know of resources that may be available and give you information on what you need to do.
* In case of injury resulting from this study, you will not lose any legal rights by signing this form.

# What you need to know about our sharing of data with NIH (the National Institutes of Health)

* *Only include the following section if the study is funded by the NIH and is subject to the 2014 Final NIH Genomic Data Sharing Policy.*
* Why will my data be shared with the National Institutes of Health (NIH)?
	+ The NIH is funding this study. The NIH’s goal is to maximize the benefits that come from the research.
	+ The NIH repository stores genetic information and phenotypic data from many studies. The NIH then shares that information with researchers. We will send the information about you and the other participants to a repository at the NIH. The information will be de-identified (no names or other direct information about you will be included). The NIH will not be able to re-identify you or any other individual.
	+ The NIH intends to share the collected information with other researchers. The researchers who receive data must promise to keep the data confidential and to use it only for the purpose approved by NIH. They must also promise to not try to re-identify anyone.
	+ The goal of genetic studies is to look for genetic connections that may explain how to identify, prevent, and treat health problems. For example, genetic data may be used to find out:
		- Who is more likely to develop a certain illness, such as asthma, cancer, or diabetes, or a condition like high blood pressure or obesity;
		- What genes affect the progress of a certain disease or condition; and
		- What genes may affect treatments which now may or may not work in certain people.
* Risks Associated with Sharing Data with the NIH
	+ There are risks associated with sharing your data with the NIH but they are very unlikely to occur. There is only a very small chance that someone could find out that the data came from you. If that happened, it’s possible that someone could deny you a job or health insurance. Or you could experience stress, anxiety or embarrassment.
* Benefits Associated with Sharing Data with the NIH
	+ Sharing your information for future research will not directly benefit you. It is hoped that it will lead to a greater understanding of the interaction between genes and health. This knowledge could help others in the future.
* *Controlled or Unrestricted Access*
	+ *The data about you can either be made available by the NIH through controlled access or unrestricted. Controlled access means the data are made available for other research only after investigators have obtained approval from NIH to use the requested data for a particular project. Data for unrestricted access are publicly available to anyone (e.g., The 1000 Genomes Project).*
* Consent to Share Data with the NIH
	+ Please indicate whether you will allow us to share your information with the NIH by putting your initials next to one of the following choices:
	+ \_\_\_\_\_(initials) No, I do not consent to sharing my de-identified information with the NIH
	+ \_\_\_\_\_ (initials) Yes, I do consent to sharing my de-identified information with the NIH for controlled access
	+ \_\_\_\_\_ (initials) Yes, I do consent to sharing my de-identified information with the NIH for unrestricted access

# Do you want us to tell your doctor you are participating in this study?

Please indicate whether you would like us to inform your doctor(s) of your participation in this study.

 \_\_\_\_\_ (initials) No, I request that my doctor(s) not be informed of my participation in this study.

 \_\_\_\_\_ (initials) Yes, I request that my doctor(s) be informed of my participation in this study.

# Who to Contact Regarding Your Rights as a Participant

This research has been reviewed and approved by the University of Texas Rio Grande Valley Institutional Review Board for Human Subjects Protections (IRB). If you have any questions about your rights as a participant, or if you feel that your rights as a participant were not adequately met by the researcher, please contact the IRB at (956) 665-3598 or irb@utrgv.edu.

# Signatures

By signing below, you indicate that you are voluntarily agreeing to participate in this study and that the procedures involved have been described to your satisfaction. The researcher will provide you with a copy of this form for your own reference. *Include the following text, unless the research involves children (under which circumstances a parental permission form and possibly child assent is needed):* In order to participate, you must be at least 18 years of age. If you are under 18, please inform the researcher.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

Participant’s Signature Date

1. Omit if minimal risk study; otherwise emergency contact should be a phone number accessible 24 hours (i.e. pager, cell) and answered by someone knowledgeable about the study. [↑](#endnote-ref-1)