# CONSENT TO TAKE PART IN RESEARCH

***Consent Template Version: January 2019.***

***This is a template – please replace all the text in blue with study specific information.***

**Simple Study Title:** <use [www.clinicaltrials.gov](http://www.clinicaltrials.gov) title, if the study not registered use iRIS study alias>

**Full Study Title:** <use the full protocol title>

**Study Sponsor:** <if the study is not sponsored, delete this line>

**Principal Investigator:** <PI name, credentials; e.g. John Smith, MD, Professor, Internal Medicine, UTHealth>

**Study Contact:** <include the name and phone number; e.g., Jane Doe, RN, Research Nurse,

XXX-XXX-XXXX>

The purpose of this study is to <briefly state the purpose of the study>.  If you choose to participate in this study, you will be asked to <please briefly describe the study procedures in a sentence or two>.  The total amount of time you will be in this study is <briefly describe the time commitment>.

There are potential risks involved with this study that are described in this document.  Some known risks include <briefly describe the most common risks>.  There may be potential benefits to you such as <please add potential direct benefits to the subject here>.

There are alternatives <procedures or courses of treatments> to participating in this research study, such as <briefly describe alternatives procedures or courses of treatments>.

Participation in this research study is voluntary.  You may choose not to take part in this research study or may choose to leave the research study at any time.  Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth), Memorial Hermann Healthcare System, or Harris Health System.

If you are interested in participating, please continue to read below.

**What is the purpose of this research study?**

The purpose of this study is to see how well <name the study intervention> works at treating people with <name the study condition>. This study will test the safety of the <name the study intervention>. This <name the study intervention has/ has not been> approved by the Food and Drug Administration (FDA); therefore it is called an investigational drug/device.

Include only if the study has funding:

<State the name of the sponsor or funding agency> is paying UTHealth for their work on this study.

Include only if any of the study personnel has a financial conflict of interest related to this study:

The <state the name of the individual with the conflict> <state the conflict – e.g. owns equity, receives payment for consulting or other services, is an inventor of the drug/compound/device> <state the name of the company> which is paying for this research. You may ask <state the name of the PI> for more information about this financial interest.

Include only if the trial must be registered under U.S. Law:

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 website will include a summary of the results. You can search this website at any time.

Include only if the trial will be registered even though not required by U.S. Law:

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/). This Web site 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.

**Who is being asked to take part in this study?**

You are being asked to take part in this research study because you have <XXXX>. This study is being conducted at <state the number of sites, if only UTHealth, state UTHealth>. About <XXXX> people will take part in the study <worldwide/in this country/in this city> including approximately <state local enrollment target> at UTHealth, Memorial Health System, and/or Harris Health System.

**What will happen if I take part in this study?**

Explain what will be done as part of study procedures. State the information in simple short sentences. State the study disease/condition in lay terms: e.g. heart attack instead of myocardial infarction. Clearly state the use of experimental drugs, devices, treatment, etc. If this is a registry where clinical information is taken from the medical record, please describe the type of information that will be collected.

If randomized to a treatment:

If you agree to take part in this study you will be randomized (similar to flipping a coin) to receive <study drug> or placebo (a tablet that contains no active ingredient). It is not known whether <study drug> will be of benefit. For this reason, some study participants must receive a placebo. This will allow a careful comparison to study the benefits and side effects of the investigational drug. There is a 50% chance you will receive <study drug> and a 50% chance that you will receive placebo. Neither you nor your doctor will know if you are receiving <study drug> or placebo, as both will look the same.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects. <A patient study calendar is attached at the end of this document. It shows how often these <insert appropriate words, e.g., exams, tests, and/or procedures> will be done.>

For venipunctures for blood samples –

You will have about <state in tsp., tbsp. or oz.> of blood drawn from a vein in your arm (state frequency). The total amount of blood withdrawn during your participation will be about <state in tsp., tbsp. or oz.>.

**How long will you be in the study?**

If you agree to take part, your participation will last for <state duration in days, weeks, months, or years> and will involve <state the number of visits>.

**What choices do you have other than this study?**

You may select other options than being in this research study. <Discuss the usual approaches for treatment of patients with this condition in a few sentences. If the study intervention is available outside of the study, please state.>

**What are the risks of taking part in this study?**

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

If you choose to take part in this study, there is a risk that the <study intervention> may not be as good as <the usual approach> in treating your condition.

There is also a risk that you could have side effects from the <study intervention>. These side effects may be worse and may be different than you would get with the usual treatment.

Some of the most common side effects that the study doctors know about are:

In a bulleted list, identify the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a patient how sick the study intervention will make them, but with a particular emphasis on how those risks are changed by participating in the study. This should be a brief list (generally around 5 although more may be necessary), including the most important reasonably foreseeable risks and discomforts.

Some of the less common side effects that the study doctors know about are:

In a bulleted list, identify the less frequent risks. This should be a brief list including the most important reasonably foreseeable risks and discomforts.

There may be some risks that the study doctors do not yet know about.

**Use and adapt** the following text when the study intervention may pose risks to fetus. Include additional detail as required:

**Female:**

If you are a woman able to become pregnant, a blood or urine pregnancy test will be done, and it must be negative before you can take part in this study. The <specify intervention> used in this study could be harmful to an unborn baby. The <specify intervention> may hurt an unborn baby in ways we do not currently know. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study and for <specify time> months afterward. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for <insert time in months/years> after you have completed the study. If you become pregnant while taking part in this study or if you have unprotected sex, you must inform the study doctor immediately.

**Male:**

If you are a man, taking part in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. If you are sexually active, it is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for <specify time> months afterward. If your partner becomes pregnant while taking part in this study or if you have unprotected sex, you must inform the study doctor immediately.

**What are the benefits to taking part in this study?**

There is some evidence in people with <state name of condition> that the <study intervention> can <list potential benefits>. However, we do not know if this will happen in everyone with <state name of condition>. This study may help the study doctors learn things that may help other people in the future.

**Can you stop taking part in this study?**

You may decide to stop taking part in the study at any time. To withdraw from the study, please contact <PI Name> at <XXX-XXX-XXXX>.

Your doctor or the sponsor can stop the study at any time. Your doctor or the sponsor may stop your participation in the study if your condition worsens, the study is stopped, the study drug is no longer available, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

**What happens if you are injured during the study?**

When the study has no provision for treatment, Option A:

If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You should report any such injury to <insert PI name and phone number>. You will not give up any of your legal rights by signing this consent form.

When the study has no provision for treatment, Option B:

If you are injured or have any harmful effects during the course of the research study, treatment will be available to you. You or your insurance company will be billed for any treatment. You should report any such injury to <insert PI name and phone number>. You will not give up any of your legal rights by signing this consent form.

When the study is **sponsor initiated**, and there is a provision of treatment (please note that this language is mandatory for pharmaceutical company sponsored protocols) Option A:

If you suffer any injury as a result of taking part in this research study the sponsor of this study, <insert sponsor's name>, will pay for reasonable and necessary medical expenses if the injury is a direct result of taking the study medicine or undergoing study procedures, and not due to the natural course of any underlying disease or treatment process. You should report any such injury to <insert PI name and phone number> and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form.

When the study is **sponsor initiated**, and there is a provision of treatment (please note that this language is mandatory for pharmaceutical company sponsored protocols), Option B:

If you are injured or have any harmful effects during the course of the research study, treatment will be available to you. You will not have to pay any charges for treatment for injuries resulting due direct result of study medicine or device or study procedures that would not have otherwise been done as part of your regular care. You or your insurance will be billed for all treatment for injuries due to the natural course of the disease or due to treatments; you may have received even if you were not part of the research study.

Add if either **sponsor initiated** Option A or Option B is used add:

If you are treated for a research injury that is paid for by <Study Sponsor>, <Study Sponsor> or its representative will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. If you are a Medicare beneficiary, <Study Sponsor> will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services, in accordance with CMS reporting requirements. <Study Sponsor> will not use this information for any other purpose.

**What are the costs of taking part in this study?**

The sponsor will pay for the special tests and examinations that are required by this study and not otherwise part of your standard medical care.

Include if study also involves standard of care procedures:

However, many of the tests, procedures, and exams you will receive are believed to be part of standard medical care, and may or may not be covered by your medical insurance. If your medical insurance does not pay for your care you will be responsible for the cost of the medical care related to your condition including laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures.

If you receive a bill that you believe is related to your taking part in this research study, please contact <PI Name>, or research staff at <XXX-XXX-XXXX> with any questions.

You will receive $XXXX for each study visits, with payment at each visit even if you do not complete the entire study. You will be issued gift card (if applicable), following completion of each visit. All information is stored in a secure fashion and will be deleted from the system once the study has been completed.

Include if compensation will exceed $600 in a calendar year:

If you receive payment for taking part in this study, please be informed that you will be asked to complete a copy W-9 form that will be forwarded to the accounting department as a requirement by the Internal Revenue Service. You will also be issued a 1099-Misc form from this study for tax reporting purposes.

**How will privacy and confidentiality be protected?**

Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth, Memorial Hermann Healthcare System, or Harris Health System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes <Provide a description of 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, or certain health information indicating or relating to a particular condition>. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Use for Investigator Initiated Studies:

Personal identifiers such as your name and medical record number will be removed from the information and samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

Use for Industry Sponsored Studies:

Please understand that research study data will be sent to the sponsor of this research study, <Study Sponsor>. The data that will be sent to the sponsor will not include your name but may include your initials, date of birth, date of study visits, and date of study procedures.

Use for Collaborative Research Studies:

Please understand that research study data will be sent to the research collaborators at other Universities. The data that will be shared will not include your name but may include your initials, date of birth, date of study visits, and date of study procedures.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

* Representatives of UTHealth and/or Memorial Hermann Health System and/or Harris Health System
* Representatives from the U.S. Food and Drug Administration (FDA)
* Representatives of the sponsor of this research including contract research organizations
* Members of Data and Safety Monitoring Boards (an independent group of experts that reviews this study’s data to make sure participants are safe and the research data is reliable)
* Companies engaged with the UTHealth for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth and Memorial Hermann Health System or Harris Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact <PI Name> in writing at <PI campus mailing address>.

This Authorization will expire 15 years after the end of the study.

**Whom can you contact if you have questions about the study?**

If you have questions at any time about this research study, please feel free to contact the <insert the PI or study coordinator name> at <insert 24 hour phone number>, as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

<Checkboxes for options may be included here. See the document “Additional Informed Consent Elements” for suggested language.>

**SIGNATURES**

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

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| Printed Name of Legally Authorized Representative |  | Signature of Legally Authorized Representative |  | Date Time |
| Printed Name of Person Obtaining Informed Consent |  | Signature of Person Obtaining Informed Consent |  | Date Time |