**Text highlighted in yellow are either instructions and/or prompts to enter protocol/sponsor-specific details.**

INFORMED CONSENT DOCUMENT

#### AGREEMENT TO BE IN A RESEARCH STUDY

**SPONSOR/STUDY TITLE:**

**PROTOCOL NUMBER:**

**PRINCIPAL INVESTIGATOR:**

**(STUDY DOCTOR)**

**TELEPHONE: (###) ###- #### (Office Hours)**

**(###) ###- #### (24 Hour)**

### **INTRODUCTION**

You (“you” refers to you or your child throughout this consent form) – *include parenthetical statement if study involves adults and minors* are deciding if you would like to volunteer for a medical research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. Do not sign this form if you have any questions that have not been answered.

The investigator is being paid by the sponsor (the company paying for this study) to conduct this research study.

**OR**

**FOR INVESTIGATOR-SPONSOR STUDIES ONLY:**

The investigator is the sponsor and is paying for this study.

You must be honest with the investigator about your health history (past and current) or you may harm yourself by participating in this study.

**Include this statement for first time in human studies:**

**THIS IS THE FIRST STUDY IN WHICH THE STUDY DRUG/FORMULATION IS BEING GIVEN TO HUMANS.**

**PURPOSE OF THE STUDY**

This study drug is an investigational drug/formulation/medical device to treat *\*type the name of the disease or illness*. **(Re-word sentence as appropriate)** "Investigational" means the study drug/formulation/medical device being tested is not approved by the (identify appropriate government authority). The purpose of this study is to *\*describe purpose in lay terms.*

In this document, you may see the terms “medication”, “treatment”, and “treatment period”; these are terms used in research studies as mentioned above and does not mean that you will be receiving medical treatment for any condition. These terms apply to the study drug and parts of the study where you will receive the investigational product.

#

# If you qualify for the study, you will receive

1. *\*describe study drug administration using bullet points for ease of reading. Include dose per day and on what study days.*

Include this statement when placebo is part of the study design.All subjects will receive placebo sometime during the study. Placebo contains no active ingredient.

Include this statement if appropriate to the study design.This is a double-blind study, which means that neither you nor the investigator will know which drug you are taking. The study staff can get this information if needed.

Include this statement if appropriate to the study design.The drug you receive will be assigned by chance, like the flip of a coin.

**HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY**

The study will last \**about # of days, weeks, months, etc. and involve up to \*# visits (or nights at the facility).* About \**#* healthy (or list certain condition) men and women, ages \*X through \*X, are expected to be in this study.

**WHEN ARE YOU ELIGIBLE TO PARTICIPATE IN ANOTHER DRUG STUDY? (Use as appropriate)**

The decision for when you can participate in another study is determined by the drug safety information gathered from the previous study. Typically, you can participate in another study as soon as 30 days after the last dose of drug received in the study you are enrolled in. This information is true for most drugs; however, some drugs may be present in your body longer and that may mean you may have to wait longer before entering another study. These results are usually only known after the last blood sample taken from you is analyzed to look for leftover drug levels. We will always make this information available to you as soon as we know. Our goal is to keep you from doing anything that may be potentially harmful to you. Your safety while participating in these studies is our primary concern.

# TO BE IN THIS STUDY

You cannot be in this study if you are in another research study or if you have been in any other research study in the last \**#* days. You cannot be in this study if you are taking any drugs of abuse (illegal and/or prescription). A urine test will be performed to check for the use of these drugs.

Subject Responsibilities:

While participating in this research study, you will need to:

* Be willing and able to follow the study directions and procedures
* Tell the study staff about any side effects or problems
* Ask questions as you think of them
* Tell the investigator or the study staff if you change your mind about staying in the study.
* [*State other applicable subject responsibilities*]

WHAT WILL HAPPEN DURING THE STUDY

Screening:

Please do not include any inclusion and exclusion criteria. These can be reviewed with the subjects during the screening or consent process.

Before the study starts, you will be asked to sign this consent form, give your health history, and tell study staff if you take any over-the-counter or prescription medicines, vitamins or herbs.

The investigator will do some tests to find out if you can be in the study. These tests include: *\*describe each procedure as a bullet point for ease of reading. (Choose from the list and/or add other screening tests)*

* Physical exam, including vital signs (blood pressure, temperature, heart and breathing rates), height and weight
* Lab tests (blood and urine)
* Blood test for HIV and hepatitis B and C
* Urine test; required at screening and before every dosing period to test for drugs of abuse (illegal and/or prescription)
* (Blood/Urine) pregnancy tests for female subjects at screening and before every dosing period

**Required wording when heart monitors are required per protocol (adjust wording as per protocol):**

You will be given a small portable heart monitor to wear. This monitor will record your heart rate for 24 hours. The monitor is connected by wires that are stuck to your chest, using tape or stickers. To attach the monitor wires, a small section of your chest might have to be shaved. You must return the monitor to the study staff.

Required wording for female subjects when a pelvic exam is required:

The study exam and lab tests are not meant to take the place of your yearly women’s pelvic exam. You will not be tested for sexually transmitted diseases. If you think that you might have a sexually transmitted disease, you should see your private doctor.

Required wording when mammograms are required:

A mammogram is an x-ray of the breast used to help find small lumps in the breast. The mammogram for this study will expose you to a small amount of radiation. The long-term effects of low-level radiation are not known.

**Required wording when sebum will be collected:**

We will collect your facial oil during this study. You will wear a headband to collect the facial oil.

*\*If the study design requires a washout period, describe, in lay terms, the meaning of washout.*

Study Procedures:

*\*Describe procedures in chronological order.*

*Sentences should be no more than 8 to 10 words long and words should be less than 3 syllables when possible.*

**Include this statement in studies requiring self-dosing:**

Do not give the study drug to other people and keep it out of the reach of children.

**Required wording when endoscopy procedures will be performed.** A gastrointestinal endoscopy is a way to look at the inside of the digestive tract using a flexible tube that has a light and camera on the end, called an “endoscope”. The instrument may also be used to take samples (biopsies) or cultures or make repairs. A snake-like tube is usually passed through the mouth or rectum, and the exam is usually performed while you are under sedation (which will make you relaxed, or sleep).

Blood Samples:

If multiple blood draws are required, identify the number of blood draws and the total amount of blood (e.g., approximately 1 cup).

Blood samples will be taken by single needle-sticks or by a tube that is left in your arm. You cannot choose how the blood is taken.

There will be about \*# blood draws***.*** The total amount of blood drawn will be about *\*# ml or # cups*. For comparison, the standard blood donation is about 480 mL (two cups).

**Required wording if blood volume is greater than 450 mL in 30 days. This should follow theparagraph which describes the total amount of blood to be drawn:**

A blood loss in this amount may cause anemia (low red blood cell count). Anemia may make you feel tired. Some people may need iron supplements to compensate for the blood loss resulting from the procedures done during this study. Please make sure that you discuss this with the investigator or your personal doctor. Also, you may not want to donate blood for several months.

**HIV AND HEPATITIS TESTING**

**Provide language as per your State Department of Health and/or state law or include the following:**

If addressed in the protocol, begin paragraph with, “As required by the study and…”

If any person is exposed to your blood, you must have your blood tested for the hepatitis viruses and for HIV. HIV is the virus that causes AIDS. If the HIV test is positive, a follow-up test will be done. If the follow-up test is also positive, you will be told in private and you will also be told about counseling. It may take weeks or months after being infected with HIV for the test to be positive. The HIV test is not always right.

Positive test results may be required to be reported to the State Department of Health. If you have any questions about what information is required to be reported please ask the investigator or study staff. Although this testing is supposed to be private, this cannot be guaranteed. For example, it is possible for a court of law to get health or study records without your permission.

# POSSIBLE SIDE EFFECTS AND RISKS

**If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.**

Because this drug/formulation/device/procedure is investigational, all of its/the/their side effects may not be known. There may be rare and unknown side effects. Some of these may be life threatening.

You must tell the investigator or study staff about all side effects that you have. If you are not honest about your side effects, you may harm yourself by staying in this study.

Do not use medical terminology to describe side effects - only use lay language. **Do not list side effects solely by alphabetical order.**

Below is a list of the most common side effects of *\*type name of investigational drug/device: \*Describe the most common side effects as identified in the protocol, investigator’s brochure and/or package insert.* ***FOR EASE OF READING, PLEASE BULLET EACH KNOWN SIDE EFFECT.***

Below is a list of less common side effects of *\*type name of investigational drug/device*: *\*Describe less common side effects as identified in the protocol, investigator’s brochure and/or package insert.* ***FOR EASE OF READING, PLEASE BULLET EACH KNOWN SIDE EFFECT.***

Below is a list of rare side effects of *\*type name of investigational drug/device*: *\*Describe rare side effects as identified in the protocol, investigator’s brochure and/or package insert.* ***FOR EASE OF READING, PLEASE BULLET EACH KNOWN SIDE EFFECT.***

Below is a list of very rare side effects of *\*type name of investigational drug/device*: *\*Describe very rare side effects as identified in the protocol, investigator’s brochure and/or package insert.* ***FOR EASE OF READING, PLEASE BULLET EACH KNOWN SIDE EFFECT.***

Required wording for studies involving the testing of birth control pills:

The most common side effects of birth control pills are:

* Nausea, vomiting and changes in appetite
* Stomach cramps and bloating
* Abnormal vaginal bleeding or spotting
* Changes in menstrual flow or no menstrual flow
* Vaginal yeast infection
* Tender or enlarged breasts
* Weight gain
* Change in skin color and skin rash
* Loss of scalp hair
* Migraine headaches
* Nervousness and change in mood (depression)

• Dizziness

Less common, but more serious side effects are:

* Blood clots
* Stroke
* Heart attacks
* Gallbladder disease
* Liver tumors
* Changes in pap smear results
* Cancer of the sex organs

The risk of blood clots, heart attacks, and strokes are increased if you have:

* High blood pressure
* Diabetes
* High cholesterol
* Blood clotting disorders
* Chest pain
* Cancer of the breast or sex organs
* Liver disease
* Smoked cigarettes

Required wording when using a combination of drugs:

When you take more than one drug at a time, the side effects can be worse or different than if you take either drug by itself.

Required wording when drugs are involved:

Until you know how the drug(s) will affect you*,* you should use caution by avoiding stairs, not driving a car or working with machinery.

Required wording for drugs that can form antibodies:

You may form antibodies to the study drug. An antibody is a type of protein that helps protect the body against attack by bacteria and viruses. There is also a chance that if you have these antibodies, this study drug or similar drugs will not work for you in the future.

**Required wording for radio labeled studies:**

This study involves exposure to radiation. The risk from radiation exposure in this study is small when compared with other everyday risks. Female subjects must not be pregnant. Female subjects who have not been surgically sterilized must have a negative pregnancy test to be in this study.

The risks of receiving the very low doses of radiation are thought to be low, but are unknown.

**ADDITIONAL RISKS OR DISCOMFORTS**

*Include a description of any reasonably foreseeable risks or discomforts to the subject other than side effects caused by the study drug/device or procedures.*

**Required wording for confinement of 2 weeks or more:**

The long time you have to spend at the study site may make you uncomfortable.

Blood Samples (taken by single needle-sticks or by a tube that is left in your arm):

There may be side effects of having blood drawn such as:

* Fainting
* Redness
* Pain
* Bruising
* Bleeding
* Infection
* Nerve damage
* Blood clots, which may cause inflammation, swelling and pain

If you feel faint tell the study staff right away.

Risks of Using an Intravenous (IV) Catheter:

         Infection

         Pain

         Redness

         Bruising

         Vein irritation from the fluids or medication being given

         Local swelling due to IV fluid accidentally entering the tissue rather than the vein

         Blood clots, which may cause inflammation, swelling and pain

* Nerve Damage

## Electrocardiogram (ECG):

## The ECG test is a recording of the electrical activity of your heart. The sticky pads used may be cold when applied and sometimes cause some discomfort such as redness or itching. If the hair under the patches needs to be shaved, irritation from shaving also could occur.

Endoscopy:

Some of the possible risks of this procedure are:

* Pain
* Vomiting
* Inhaling stomach fluid into the lungs (aspiration)
* Infection
* Bleeding
* Tearing of the wall of the stomach or intestines (perforation), which could cause infection
* Injury to other organs near the intestines
* Reactions to medications

You may be given medications before the procedure for sedation. Do not drive or operate machinery after this procedure until the next day.

Magnetic Resonance Imaging (MRI):

An MRI is a way of looking at the soft tissues of the body. You will lie down on a large magnet. A magnetic signal will be sent through your body and then received back. Subjects with metal near important organs may not receive an MRI. The metal may be drawn away from the body and towards the large magnet, which could cause injury.

CT Scan:

A CT scan is a computerized series of detailed pictures of areas inside the body taken from different angles. You may feel some discomfort or anxiety when lying inside of the CT scanner. The dye (contrast agent) that is injected into your body may cause a metallic taste in your mouth, to make you feel warm, or cause nausea and vomiting. The dye may also cause an allergic reaction that could be mild or it could be serious and life-threatening. If you know that you have had an allergic reaction to IV contrast agents in the past, please tell the study staff. You will be exposed to a limited and medically acceptable dose of radiation during the scan. There is always a risk of damage from being exposed to any radiation.

18FDG-PET/CT Scan:

A PET Scan is a computerized image that looks at the activity of tumor cells in your entire body and that requires injection of a special radioactive marker (tracer) into your vein. You will be asked to fast (no food) for about 4 to 6 hours before the scan. A small amount of radioactive sugar (tracer) will be injected into your blood about 1 hour before the scan. The injection of the radioactive tracer may cause some slight discomfort. Allergic reactions to the tracer are rare but may occur. You may experience discomfort related to lying still in an enclosed space for a long period. The camera will record the tracer’s signal as it travels through your body. You will be exposed to a limited and medically acceptable dose of radiation during the scan. There is always a risk of damage from being exposed to any radiation.

Bone scans:

A bone scan uses x-rays where a small amount of radioactive chemical (tracer) is injected into your veins and travels through the bloodstream. It collects in the bones and is picked up by the scanner. There is a risk of allergic reaction to the chemical used in the test. You could also have swelling, soreness, or infection at the site where the tracer is injected into your vein. The radiation exposure of this test is very low, and not likely to cause any damage to you. The injection of the radiotracer may cause some discomfort. Allergic reactions to the radiotracer are rare.

X-rays:

The x-ray will provide information about the status of your lungs, heart and chest wall. There is always a chance of excessive exposure of radiation with x-rays; however, the effective radiation dose from this procedure is about the same as the average person receives from background radiation in 10 days.

Echocardiogram:

During the echocardiogram, electrodes will be placed onto your chest to allow for an ECG to be performed. Then a transducer (a device that looks like a computer mouse) will be applied. You may feel slight pressure on your chest from the transducer. In addition, you may be asked to breathe in a certain way or to rest on your side during the test.

Multiple Gated Acquisition (MUGA) scans:

This test measures how well your heart is pumping. A MUGA is a special type of x-ray machine used to take a rapid series of pictures of the heart. This procedure involves getting radiation (like x-rays). A radioactive substance called a tracer is given through an IV, which helps to create the pictures that are taken. The amount of radiation involved is about the same amount as two regular chest x-rays. There is a minimal amount of pain with this test. The tracer is passed out of the body through the urine within 24 hours after the test is completed. This test takes about 2 to 3 hours to complete. The injection of the radiotracer may cause some discomfort. Allergic reactions to the radiotracer are rare.

Biopsy:

If you undergo a biopsy, there may be side effects such as:

* Pain
* Bruising
* Bleeding
* Infection

Bone Marrow Biopsy or Bone Marrow Aspirate:

A small sample of bone marrow is usually taken from the hip (pelvis) bone. You are given a small injection to numb the area. A needle is passed through the skin into the bone. A small sample of the bone marrow is then drawn into a syringe. It may be painful, but this only lasts for a short time. You may be offered medication to reduce any pain or discomfort during the test.

There may be side effects of having a bone marrow aspiration and biopsy such as:

* Pressure and/or pain when the needle is inserted, as well as when the bone marrow is removed with a syringe (aspiration)
* Bleeding where the needle is inserted into the skin and tissue over the bone
* Bruising where the needle is inserted into the skin and tissue over the bone
* Pain where the needle is inserted into the skin and tissue over the bone
* Infection where the needle is inserted into the skin and tissue over the bone

Rare side effects may include:

* Infection of the bone
* Extensive bleeding at the biopsy site

## Risks of Intramuscular (IM) Injection:

## Infection

* Pain
* Redness
* Bruising
* Irritation from the fluids or medication being given
* Local swelling
* Accidental intravenous (IV) injections

## Fainting

## Risks associated with the use of a urinary catheter are:

* Urinary tract or kidney infections
* Blood in the urine (hematuria)
* Blood infections (septicemia)
* Kidney damage (usually only with long-term, indwelling catheter use)
* Urethral injury
* Bladder stones
* Balloon rupture (the balloon is what holds the catheter in place in the bladder)

The risk of complications increases with prolonged use.

Risk associated with the use of (list drug) which may cause positive drug test: (such as opioids and opiates)

For a short time following the study you may test positive for drugs of abuse.

## INCIDENTAL FINDINGS Include as applicable

During the study, we may find an abnormality that is unrelated to the research study or to the study drug, but that may affect your health. This is called an “incidental finding.” We will contact you to let you know if we see such an incidental finding. You do not have an option to decline information about an incidental finding. It will be up to you to decide if you want to follow-up with your personal doctor. If you need assistance obtaining medical care for an incidental finding, we will help you coordinate this care. An incidental finding may cause you to feel anxious. Since an incidental finding will be part of your medical record, it may affect your ability to get health or life insurance. The costs of any care associated with an incidental finding are not paid for by this study. These costs are your responsibility.

## BIRTH CONTROL, DANGERS OF PREGNANCY AND BREASTFEEDING

**Include for studies involving risks to females only:**

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control listed below.

**Include for studies involving risks to females & males (when the compound is known to be or is possibly teratogenic):**

If you are a female, you must not get pregnant while in this study. The only certain way to not get pregnant is to not have sex. If you are a female and choose to have sex, you must use a type of birth control listed below.

If you are a man, you must use birth control if you choose to have sex with women while in this study. You must also not donate sperm during the study and for at least (insert number of weeks/months) after completion of the study.

**OR**

(if not mandated by the protocol) If you are a man, it is suggested that you use birth control if you choose to have sex with women while in this study. You must also not donate sperm during the study and for at least 4 weeks after completion of the study.

Methods of birth control for this study include: *\*Type acceptable methods of birth control as identified in the protocol.*

Even if you use birth control during the study, there is a chance you or your partner could become pregnant. If you or your partner are pregnant or become pregnant during the study, the study drug/device or procedure may involve unforeseeable risks to the unborn baby. A pregnancy test is not always right, especially in the early stages of pregnancy.

You cannot be in the study if you are breastfeeding. It is not known whether the study drug/device can be given to breast fed babies. Therefore, if you are breastfeeding a child you cannot participate in the study.

## POSSIBLE BENEFITS OF THE STUDY (You can remove if included in summary on page 1)

You will get no medical benefit from this study, other than the benefit of free medical tests.

OR

You may receive a chance to be in a research study that may help others.

**Include for a treatment study**:

There is no promise that your condition will get better. It might stay the same or it might get worse.

**Include this statement when placebo is part of the study design:**

There is no promise that your condition will get better. It might stay the same or it might get worse, especially if you get the placebo.

## ALTERNATIVES TO PARTICIPATING IN THE STUDY (You can remove if included in summary on page 1)

Since this study is for research only, the only other choice would be not to be in the study. **(For Phase I normal healthy studies only)**

OR

*Identify specific alternative procedures, courses of treatment, or drugs/devices that may be available as well as their important potential benefits and risks.* **(For Treatment Studies)**

 **CONFIDENTIALITY**

 *If HIPAA Authorization wording is integrated into the informed consent, please ensure all elements of HIPAA are included; otherwise, Bluebonnet will insert template language to ensure elements are included.*

Your records of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

* The investigator
* Sponsor company or research institution [including monitor(s) and auditor(s)]
* The United States Food and Drug Administration (FDA) must be included for FDA regulated studies but not required to delete if the study is not FDA regulated
* Other country**(include if outside of the US)**, state or federal regulatory agencies
* Bluebonnet Ethical Review (the IRB)

**Include one of the following when collecting Private Information or identifiable biospecimens for future research.**

After the research, identifiers might be removed, and your de-identified information or bio-specimens may be used for future research without additional informed consent.

OR

Your information or bio-specimens will not be used or distributed for future research studies even if identifiers are removed.

**[Any study that is considered an "applicable clinical trial" (e.g., Trials of Drugs and Biologics:  Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation; Trials of Devices:  Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies) by the FDA and required to be registered in the Clinicaltrials.gov database must also include the following paragraph in the informed consent:]**

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.

The Institutional Review Board (IRB), Bluebonnet Ethical Review, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

**For research involving bio-specimens**:

**RESEARCH INVOLVING BIOSPECIMENS**

Your bio-specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit. If sharing in commercial profits modify previous sentence and describe the process.

The research results, including individual research results, will/will not be provided to you. If research results will be shared describe under what conditions.

This future research will/might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Future Research of Biomarker Samples:**

Loss of confidentiality is the primary risk of testing, collecting, and storing tissue/blood samples. It may be possible for DNA to be extracted (through various testing methods) from the donated tissues/blood, which would allow knowledge about you, that you may not want known, to be gained. Your test results are confidential. The sponsor will make every effort to protect any information about you generated from their testing and analysis of your samples except those people or companies you read about in this form. We believe that the benefits of learning more about human genetic variation and how it relates to health and disease outweigh the current and potential future risks, but this is something that you must judge for yourself.

There are also current limited protections afforded to you by a U.S. Federal law, the Genetic Information Non-discrimination 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. All health insurance companies and group health plans provided by employers with 15 or more employees must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long term-care insurance, nor does it prohibit discrimination on the basis of a genetic disease or disorder that you already know about.

## IN CASE OF STUDY RELATED INJURY

*Complete this section by providing the following information. If you have a contract/agreement with the sponsor that addresses provisions to pay for research-related injury, this wording must agree with the wording in the contract/agreement.*

*If compensation for injury is available, give an explanation as to what it consists of, or where further information might be obtained. If no compensation is offered aside from medical treatment, you may include a statement such as, “****No other form of compensation is offered****.”*

*Give an explanation as to whether any medical treatment is available if injury occurs and, if so, what it consists of, or where further information might be obtained.*

**If the cost of medical treatment for a research-related injury will be the responsibility of the subject or their insurance company, include the following statement:**

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

**LEGAL RIGHTS**

You will not lose any of your legal rights by signing this consent form.

## CONTACT INFORMATION

If you have questions, concerns, or complaints about this study or to report a study related injury, contact the study doctor at the telephone number listed on the first page of this consent document.

**If you are unable to reach anyone at the number(s) listed on page one and you require immediate (life threatening) medical attention, please go to the nearest emergency room.**

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

* By mail: Study Subject Specialist

 Bluebonnet Ethical Review

 4005 US Hwy 183 N

 Lockhart, TX 78644

* or call: 512-585-4323
* or by **email**: support@bbirb.com

Please reference the following number when contacting the Study Subject Adviser: BBIRB XXXXX.

**PAYMENT FOR BEING IN THE STUDY**

Describe the prorated amount (amount of payment per visit, per procedure, etc.) and the total amount of payment for completing the study. Include any additional payments that may be offered. You may use a table format for clarity. Payment cannot be contingent upon successful completion of the study, as this would be coercive per 21 CFR 50.20, 50.25(a)(6), and ICH Guideline 3.1.8.

You may receive up to \*$.00 for being in the study.

**If receiving the same compensation per visit add:**

You will be paid $$Comp$$ per completed *\*(visit, procedure, etc.)*.

 **OR**

**If receiving different compensation per visit add:**

You will be paid per completed visit as follows:

|  |  |
| --- | --- |
| **Visit** **(LIST OUT EACH VISIT)**  | **Compensation (amount)** |
|  | $.00 |
|  | $.00 |
|  | $.00 |
|  | $.00 |

If you choose to leave or are withdrawn from the study for any reason before finishing all \**(visits, procedures, etc.)* you will be paid for each completed *\*(visit, procedure, etc.)*. You will receive payment within \*(*number of days, weeks, etc.)* after your last study visit, or if you choose to leave or are withdrawn from the study for any reason, you will receive payment within \*(*number of days, weeks, etc.*) [**If the compensation time frames listed above are the same, combine the two statements.**]

**Required for all Phase I normal, healthy studies or for studies compensating subjects more than $600:**

You may be required to report the payment received for this study to the Internal Revenue Service as taxable income.

**OR**

You will not be paid for being in this study.

## VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. You can still get healthcare in the future. *–* ***Delete statement for non-treatment studies.***

**REQUIRED BY BLUEBONNET: Include appropriate wording below for the following vulnerable populations that are allowed to participate in the study:**

**Employees of the investigator/sponsor: Keep highlighted for master IC’s**

Employees of the investigator or sponsor are allowed to participate in this study. If you are an employee:

* The decision to participate or not will not affect your performance evaluation.
* The decision to participate or not will not affect possible promotions.
* The decision to participate or not will not affect your pay.

**Students:**

Students of this institution are allowed to participate in this study. If you are a student:

* The decision to participate or not will not affect your grade, recommendations, employment or the like.
* For mandatory participation or for extra credit, you will be given other options for fulfilling the research requirement, such as writing short papers or book reports, special projects, and brief quizzes on additional reading.
* Failure to participate will not have a negative effect on your relationship with the investigator or the faculty.

The investigator, the sponsor company, or the FDA, if applicable, may take you out of the study without your permission, at any time, for the following reasons:

* If you do not follow the investigator’s instructions
* If we find out you should not be in the study
* If the study is stopped
* If it becomes harmful to your health

*List any additional anticipated circumstances in which the subject’s participation might be terminated.*

If you leave the study or if you are taken out of the study, you may be asked to return for a final visit to have some end of study evaluations or tests. If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used. ***OR*** *Describe the additional procedures for orderly termination or withdrawal by either the investigator or the subject and include the options for data collection and/or analysis.*

## ADDITIONAL COSTS

*\*Describe any costs to the subject for study-related procedures, drug, etc., when appropriate. \*This section is not required if there are no additional costs to the subjects.*

## NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation we will tell you. You can then decide if you still want to be in the study.

REQUIRED FOR CALIFORNIA SITES ONLY [NOTE: CA Bill of Rights are not required for social/behavioral science research and do not need to be included.]:

SUBJECT’S BILL OF RIGHTS

You will be given a separate copy of the California Experimental Research Subject’s Bill of Rights. If you have not received a copy of this document, please notify study staff.

STATEMENT of consent

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Printed Name of Adult Study Subject

Signature of Adult Study Subject Date

##

STATEMENT OF PERSON OBTAINING INFORMED CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

Printed Name of Person Explaining Consent Form

## Signature of Person Explaining Consent Form Date

## The signature lines below are required when adult subjects are not able to legally give consent.

Printed Name of Guardian or Legally Authorized Representative

#### Signature of Guardian or Legally Authorized Representative Date

#### You (and/or your legally acceptable representative) will receive a signed and dated copy of this consent form to keep.

**OR**

Applicable for studies with waiver of documentation of IC

#### Keep a copy of this consent form your records.

#### ASSENT FORM FOR MINOR STUDY SUBJECTS

7 – XX years of age

(Bluebonnet will complete the age range per PI’s state law on age of consent)

You are being asked to be in a research study about \****[describe purpose in simple language]***. A research study is a way to learn more about the study drug(s)/medical device and its uses.

If you decide that you want to be a part of this study, you will be asked to *\*[****description, procedures, including time involved].***

There are some things about this study that you should know. They are ***\*[things that take a long time, other risks, discomforts, etc.].***

At each study visit, you will:

This study will last about *\**# *days/weeks/months* and will include up to \*# visits to the investigator’s office.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be \****[description]*.**

If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you. **[This statement applies to research projects that offer treatment or intervention.]**

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. You can say no and no one will be mad at you. If you decide to stop after we begin, that's okay too.

**Statement of Assent**:

I have read or someone has read to me this assent form. My parent(s) or my legally authorized representative (if applicable) and the investigator have explained the study to me and have answered my questions. I agree to be in this study.

Printed Name of Minor Study Subject

Signature of Minor Study Subject Date

Printed Name of Person Explaining Assent Form

Signature of Person Explaining Assent Form Date

Signature line for Person Explaining consent are not require for studies that include waiver of documentation

You (and/or your legally acceptable representative) will be given a signed and dated copy of this consent form to keep.

OR

Applicable for studies with waiver of documentation

#### Keep a copy of this consent form your records.

CONSENT FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read.  The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Impartial Witness

Signature of Impartial Witness\* Date

\*Impartial Witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information provided to the subject.

#### You (and/or your legally acceptable representative) will receive a signed and dated copy of this consent form to keep.

*INSTRUCTION TO SITE: PLEASE US THE FOLLOWING AS GUIDANCE:*

## HIPAA Authorization

***If HIPAA Authorization wording is integrated in this informed consent document, please ensure the following are included:***

* A specific and meaningful description of the PHI to be used or disclosed
* The identification of the persons or class of persons authorized to make the use or disclosure of PHI (who do you want to get information from including your own hospital, practice group, etc.?)
* The identification of the persons or class of persons to whom the covered entity is authorized to make the disclosure (what internal or external persons or entities will be getting the information?)
* Description of each purpose for which the specific PHI identified earlier is to be used or disclosed
* An expiration date or, an authorization for a research purpose, may state that the authorization does not expire; that there is no expiration date or event; or that the authorization continues until the “end of the research study”.
* The individual’s signature and date, and if signed by a personal representative, a description of his or her authority to act for the individual
* A statement that the individual may revoke the authorization in writing, and instructions on how to exercise such right (who does the individual need to write, name and address?)
* A statement about the potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule

Signature of Study Subject or Legally Authorized Representative Date

Description/Relationship of Legally Authorized Representative

PHOTO RELEASE FORM

You give the company paying for this research study the right to use, copy, and give out the pictures taken of \*(insert type of pictures to be taken)*.* The purpose for taking the photos is \*(describe purpose).

Your pictures may be used for \*(provide examples of where the pictures may be used).

We will try to hide your identity. Your name will not be on the pictures. You have the right to review your pictures and cancel this Photo Release Form.

**Statement of Consent**:

I have read this release and understand its meaning. I understand I do/do not need to sign this Photo Release Form in order to be in the study.

Printed Name of Adult Study Subject

Signature of Adult Study Subject Date

Printed Name of Person Explaining Release Form

## Signature of Person Explaining Release Form Date

Signature line for Person Explaining consent are not require for studies that include waiver of documentation

## The signature blocks below are also required when adult subjects are not able to legally give consent.

Printed Name of Guardian or Legally Authorized Representative

Signature of Guardian or Legally Authorized Representative Date

You (and/or your legally acceptable representative) will be given a signed and dated copy of this release consent form to keep.

OR

Applicable for studies with waiver of documentation

**Keep a copy of this consent form your records.**

#### PHOTO ASSENT FORM FOR MINOR STUDY SUBJECTS

7 – XX years of age

(Bluebonnet will complete the age range per PI’s state law on age of consent)

You are being asked to let us take pictures of \**(insert type of pictures to be taken).* You are also being asked if we can make copies of these pictures and let other people see them.

We will not put your name on the pictures. We will not put anything on the pictures that would let anyone know who you are. You can look at your pictures whenever you want to.

The reason we would like to have your picture is to show other people what happened during this research study. This might help doctors and other people learn more about \**(insert name of drug or device)* in the future.

You can also decide that you do not want us to take your picture, and that will be okay with us. It is up to you to decide if you want your picture taken or not. You can still be in this research study, no matter what you decide to do. You do not have to sign this piece of paper to be in the study.

(or)

We will take pictures of everyone who is in this study. If you decide to be in this study, we will need to know if it is okay for us to take your picture. If you sign this piece of paper, it means that it is okay with you for us to take your picture as part of being in this study.

**Photo Assent Statement**:

I have read or someone has read to me this photo assent form. My parent(s) or my legally authorized representative (if applicable) and the investigator have explained it to me and have answered my questions. I agree to let my pictures be taken and used as described above.

Printed Name of Minor Study Subject

Signature of Minor Study Subject Date

Printed Name of Person Explaining Photo Assent Form

Signature of Person Explaining Photo Assent Form Date

You (and/or your legally acceptable representative) will be given a signed and dated copy of this assent form to keep.

OR

Applicable for studies with waiver of documentation

#### Keep a copy of this consent form your records.