**INFORMATION IN BLUE IS INSTRUCTIONAL AND SHOULD BE REMOVED FROM THE FINAL DOCUMENT. INFORMATION IN RED IS VARIABLE AND REQUIRES EDITING.**

**CHANGE THE TEXT BACK TO BLACK ONCE EDITING IS COMPLETE. REVISIONS MAY NOT BE ACCEPTABLE TO REQUIRED LANGUAGE.**

**Use wording consistent with 5th to 8th grade reading level; simple words, short sentences, small paragraphs, etc.**

# CONSENT TO PARTICIPATE IN A RESEARCH STUDY AT TEXAS A&M UNIVERSITY-CORPUS CHRISTI

**<<Study Title>>**

**WHO IS DOING THIS STUDY?**

A study team led by <<PI name>> is doing this study. Other research professionals may help them.

The following statement is required if there is a sponsor. <<Sponsor name>> is working with <institution name> to do this research study. Funding for this study comes from the <<sponsor name>>. The study team will not receive any personal payment because of your decision.

The following statement is required if there is study personnel with a declared conflict of interest in the study. <<Investigator’s name>> has a separate financial agreement with <<sponsor name>>, a sponsor of this study. To learn more about this relationship or who to call with questions, see Appendix: Conflict of Interest.

We are asking you to be a part of this research study. Please read the information below and ask questions about anything that you do not understand before you make a choice.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this research study is to <<study objectives>>.

**WHO CAN BE IN THIS STUDY?**

We are asking you to be a part of this research study because <state why, i.e. you have been diagnosed with diagnosis/condition>.

To be eligible to be in this study, you <must/must not>:

• <state basic eligibility criteria, i.e. be over the age of 18

To learn more about who can be in this study, see Appendix: Study Participants.

**WHAT WILL HAPPEN TO ME IN THIS STUDY?**

Select the following paragraphs based upon what procedures you selected. Not all may be applicable to your study.

Add a brief summary of major study procedures and duration of study participation:

Being in this study involves <<add a brief summary of study procedures>>. If you agree to be in this study, you will be in this study for << add time in hours/days/weeks/months>>.

Below are common study procedures that you can choose from or add your own.

Give a brief description in the main body of the consent. Specific details of the individual procedures of the study can be added in the appendix.

If you decide to be in this study, the following things will happen:

* Your participation will **involve collecting information about you**. See Appendix: Study Procedures- Collecting Informationto learn more.
* You will be **asked to answer some questions** by <<a brief interview, filling out questionnaire, quality of life survey>>. These questionnaires will take about <<#>> minutes to complete. See Appendix: Study Procedures- Questionnaireto learn more.
* You will have **a screening visit** where a study doctor will take your full medical history and perform a routine physical examination. See Appendix: Study Procedures – Screening Visit to learn more.
* **Blood** will be collected (about <<#>> teaspoon) from you. See Appendix: Study Procedures- Blood Collectionto learn more.
* A **biospecimens sample** will be collected. <<Biospecimen type>> will be collected from you by <<collection procedure>>. See Appendix: Study Procedures- Biospecimento learn more about how the biospecimens will be collected and what will be done with results learned from test performed on your biospecimens. • Genetic Studies: Add this paragraph if done “genetic analysis”: human cell contains thousands of genes. Genes contain the information needed to build and operate a human body. The basic structure of genes is DNA, which stands for deoxyribonucleic acid. Everyone’s genes are different. This explains differences in eye color, hair color, and blood type. Gene differences also partly explain why some people, but not others, get certain diseases. Information about gene differences among people can help researchers discover new tools to diagnose and treat inherited diseases. **DNA or genetic testing will be done on your sample collected for this study*.***
* Add this paragraph if you are creating a cell line from biospecimens: Your sample will be stored in a way that allows cells to grow and multiply. These multiplying cells may give rise to what is called a cell line. Cell lines may be kept alive for many years and can be used for multiple future studies.
* Include if using “drugs, biologics, or other products” or “medical devices”. This study involves use of a drug or device. To learn more the FDA-approved status of this <<drug/device>>, see Appendix: FDA-approved status.
* Drug Study - Add this paragraph if using “drugs, biologics, or other products” Being in this study **involves <<taking an investigational medicine for x days, x clinic visits>>.**

o Pharmacokinetic (PK) testing measures how long the study drug stays in your body after it has been given. This is measured by taking blood samples several different times after you have been given the study drug.

* Randomized Study: **You will be assigned to a study group through randomization.**

Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. You should take part in this study only if you agree to be in any of the study groups. See Appendix: Study Procedures- Randomizationto learn more the study groups, the differences between study groups, how study groups are assigned, and what you and your study doctor will know about your group assignment.

* Study Diary: You will be asked to **keep track of your symptoms** (such as vomiting/throwing up, diarrhea/loose stools) or illnesses **in a study diary**. You will be asked to do this every day for <<#>> <<day, weeks>>. Your will return the study diary and be handed a new one (except on the last visit when no new diary will be given).
* Follow-up visit - calls: The study staff will call you regularly to ask you about any symptoms or illnesses (such as a fever) you may have had.
* Follow-up visit: <<#>> of study follow-up visits are required. In the follow-up visits your study doctor will inquire if you have had any side effects and perform routine physical examinations.

**Will I learn of research results?**

Add this section in incidental findings are possible.

Whenever a <<genetic test, MRI, CT, X-ray of the brain>> is done, there is a chance of finding something unexpected and unrelated to the research study that may have some clinical implications. These findings may provide information about you that was previously unknown (such as disease status or risk). There can be some benefits to learning such results (such as early detection and treatment of a medical condition), but there may also be risk to learning of these results (such as feeling worried about a finding where there is no available treatment or clinical significance is unknown or unclear or future problems with getting health insurance).

Add details about returning results.

If not returning results back to the individual: You will not be informed about future use or results.

If returning results back to the individual: You will be given the results of the testing done for this research study. See Appendix: Study Procedures – Returning Results to learn more.

**What about other research opportunities?**

Add this section for optional future research

There may be other research opportunities that you may qualify for. See Appendix: Study Procedures – Future Research to learn more about this option. You will be able to mark your choice in the Appendix: Study Procedures – Future Research. Your decision whether or not to participate in these optional future research studies will not affect your participation in this research study and will not affect your routine care.

**WHAT ARE THE RISKS** **OF THE STUDY?**

There are certain risks in this study. The main risk may include:

* <<list important risks>>.
* Confidentiality risk: There is a slight risk of loss of confidentiality. Your confidentiality will be protected to the greatest extent possible. See Appendix: Confidentiality Risks to learn how your information is protected.
* Allergic reaction: It is possible to have an allergic reaction to the <<vaccinations, drug>>. See Appendix: Allergic Reaction to learn more and what to do if you experience these symptoms.
* Pregnancy/breastfeeding risks: We do not know what effect the <<drug/procedure>> might have on a pregnant woman, an unborn baby, or a breastfeeding baby. There may be additional risks if you are pregnant or breastfeeding. Women who are pregnant or breastfeeding a baby should not be in this study. If you think you may have become pregnant or fathered a child while being in this study, please tell the study investigator or other study personnel. See Appendix: Pregnancy or Breastfeeding Risk to learn more.
* Genetic risk: The unauthorized disclosure of your genetic information may have an impact on your employability, insurability, immigration status, paternity suits, or social reputation. These risks include the chance of discrimination. See Appendix: Genetic Risk to learn more about the risk of discrimination and a Federal law called Genetic Information Nondiscrimination Act (GINA) that may help protect against this risk.

If you have any of these problems or changes in the way you feels, you should tell the investigator or other study personnel as soon as possible.

There may be risks we do not know about now. We will tell you about any new information that might change your decision to stay in the study.

# PROTECTING MY INFORMATION

This study is <anonymous or confidential>. Pick one or the other; can’t be both.

Include this paragraph if anonymous: The information collected from you will not include any identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers). Your identity will not be known by the research team to protect your confidentiality. Please do not include any identifiers in the study documents.

Include this paragraph if confidential: When information collected about you includes identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers), the study can involve confidential information.

For research involving the collection of identifiable private information or identifiable specimens, you must include one of the two statements (45 CFR 46.116(b)(9)):

Once data analysis is complete, your identifiers will be removed from the research data, after such removal, the <de-identified information or biospecimens> could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

OR

Once data analysis is complete, your identifiers will be removed from the research data. Your information collected as part of this research, even after identifiers are removed, will not be used or distributed for future research studies.

All research records will be kept securely. Research records will be seen only by authorized research team members. We will share your information only when we must, will only share the information that is needed, and will ask anyone who receives it from us to protect your privacy.

**Results of this study may be made public. If made public, you will not be identified in any publications or presentations.**

All studies that are FDA regulated and require registration must include:

In addition to the use of data described above, 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.

HIPAA: Use if obtaining protected health information. If not using protected health information, you can delete this section

When health information includes identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers) that link it directly to an individual, it is called protected health information (PHI). **You have rights regarding the privacy and confidentiality of your protected health information.**

Federal laws require that PHI be kept secure and private. In certain situations, federal law also requires that you approve how your PHI is used or disclosed. A research study is one of those situations.

Some people or groups who get your identifiable health information might not have to follow the same privacy rules that we follow. We will share your protected health information only when we must, will only share the information that is needed, and will ask anyone who receives it from us to protect your privacy. However, once your information is shared outside of <institution name>, we cannot promise that it will remain private.

By signing this consent form, **you are permitting the following people to have access to your medical record and use your PHI for the research purposes** described in this form.

**You are also permitting your PHI to be shared with everyone** listed below:

* The research team, which includes the study personnel listed on this form and other persons involved in this study at <<institution name>> ;
* The <<Sponsor name>> and the people or groups it hires to help perform this study;
* The Institutional Review Board;
* Other researchers, hospitals, and institutions that are part of this study and their Institutional Review Boards;
* Insert if study uses DSMB or DSMC: A Data Safety Monitoring Board, a group that oversees the data (study information) and safety of this research;
* People from organizations that provide independent accreditation and oversight of hospitals and research;
* Government/regulatory agencies (both US and international), such as the Office for Human Research

Protections <<the Food and Drug Administration, or international equivalent, the National Cancer Institute and/or other National Institutes of Health offices >> who protect human subjects and oversee the conduct of research; and

* Insert name of any other person or agency as required

The research record is separate from your medical record. Information about you that is obtained during this study will be recorded in a research record and may also be recorded in your medical record. A research record will be created and kept in the <<internal location where research records are stored such as department name>> research office. The research record may include documents that have your <<name, assigned study ID number, home street address, telephone number, medical record number, hospital account number, insurance number, social security or individual taxpayer identification (ITIN) number, date of birth, dates of service, medical device number, fax number, email address, certificate/license numbers, vehicle identifier/license numbers, web or internet address, finger or voice prints, full face photographs, or list other unique personal identifier>>. All research records will be maintained in a confidential manner.

Add following paragraph if limited PHI is kept by the study team in a research database separate from the remaining research record:

There will be a separate database, in which all study information is collected. This database will be used to analyze the study information and find out the study results. Information in this database will include your <<assigned study ID number, initials, date of birth, and dates of service>>.

Add following paragraph if sharing research information with outside party:

Portions of that research medical record will be sent to <<outside party such as sponsor>>. This information sent to <<outside party such as sponsor>> will include your <<name, assigned study ID number, home street address, telephone number, medical record number, hospital account number, insurance number, social security or individual taxpayer identification (ITIN) number, date of birth, dates of service, medical device number, fax number, email address, certificate/license numbers, vehicle identifier/license numbers, web or internet address, finger or voice prints, full face photographs, or list other unique personal identifier>>.

**By signing this consent form, you are allowing your health information to be recorded in the research record.**

**What if I do not want to allow use of my protected health information?**

You may choose not to sign this consent form and not be in the study.

**What if I change my mind?**

You may cancel your permission to use and share your confidential information at any time by contacting the study personnel. You may also contact <institution name of medical record department> in writing. If you cancel your permission, you may no longer participate in this study.

Your PHI that has already been collected for the study may still be used; however, no new information will be collected except information related to adverse events or other safety issues.

If you do not cancel your permission, your PHI may continue to be recorded until the entire study is finished. This may take years. Any study information recorded in your medical record will be kept forever. Unless stated elsewhere in this form, you may not have access to your research record or research test results.

**WHAT ARE THE BENEFITS OF BEING IN THIS STUDY?**

Choose one of the two following paragraphs:

There may be no direct benefit to you from being in this research study. By being in this study, you may help researchers learn more about <study topic> in the future.

There may be direct benefit to you from being in this study. Possible benefits may include <Describe benefits. Be sure not to overstate benefits>. By being in this study, you may help researchers learn more about <study topic> in the future.

**WHAT ABOUT EXTRA COSTS?**

No costs to subjects.

Participation in this study will not result in any extra costs to you. You will not have to pay anything extra if you are in this study aside from the personal time and travel costs it will take to come to all of the study visits.

There are no extra costs to your insurance company from being in this study. Insurance may still be billed for routine care. Your research visit may be combined with a routine care visit. Although study funds may pay for certain study-related items and services, your insurance company will still be required to pay for all of your routine care that would have occurred if you were not part of this research study. These charges may include <<your clinic visit(s), any continuing medical care and/or hospitalizations, all clinical and laboratory evaluations, imaging scans, chemotherapy treatments (if needed), surgeries (if needed), and radiation treatments (if needed)>>.

Potential costs to subjects.

Taking part in this study may lead to added costs to your health insurance company. There are no plans for the study to pay for these costs.

Insurance may still be billed for routine care. Your research visit may be combined with a routine care visit. Although study funds may pay for certain study-related items and services, your insurance company will still be required to pay for your routine care that would have occurred if you were not part of this research study. These charges may include <<your clinic visit(s), any continuing medical care and/or hospitalizations, all clinical and laboratory evaluations, imaging scans, chemotherapy treatments (if needed), surgeries (if needed), and radiation treatments (if needed)>>.

Please ask the study team about additional costs you could incur from you participating in this study.

**WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?**

Not providing payments, tangible property or reimbursement, you can remove this entire section

Payments provided

You will receive <<List out payment and schedule be sure it is consistent with protocol>>. Maximum compensation for participating in the study is <<$>>. See Appendix: Payments to learn more about payments, payment schedule, and tax consequences for receiving payments.

Tangible Property provided

You will receive <<List out items you will provide in protocol>>.

**WHAT IF I’M HARMED OR GET ILL BECAUSE I’M IN THE STUDY?**

Recommended Sponsor statement (must be in compliance with contract): If you has an illness, adverse event, or injury that is the result of a medication, intervention, procedure, or test required for this study, the study sponsor, <<name>>, will pay usual and customary medical fees for reasonable and necessary treatment.

You should seek treatment, then notify the study doctor as soon as possible when you believe that an illness, adverse event, or injury has occurred. The study doctor will decide if the adverse event or injury was a result of your participation in the study.

The sponsor is not responsible for expenses that are due to medical conditions you had before the study, or intentional wrongdoing by any person. Providing this treatment or care is not an admission by the hospital or the Sponsor that they are responsible for such injury or illness. No funds have been set aside by <institution name> to pay research participants if the research results in injury. You do not give up any legal rights as a research participant by signing this form.

When there is no sponsor or the sponsor is a granting/government or other agency (or emergency use), the following language is to be used: In the case of illness or injury resulting from this study, treatment is available at <institution name>, but will be provided at the usual charge. Payment for this treatment will be your responsibility. The <institution name> does not have funds set aside to pay research participants if the research results in injury. By signing this form, you are not giving up any legal rights to seek compensation for injury.

When the study is non-interventional and limited to data collection only:

This study involves data collection only. As detailed in the “What About Confidentiality?” section, your information will be kept secure and confidential to the greatest extent possible. Possible risks may be the unintentional use of your information. If an unintentional use of your information occurs, there are no funds set aside to pay you. By signing this form, you are not giving up any legal rights to seek damages for harm.

**WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?**

If study does not involve treatment, the alternative is not to participate - Instead of being in this study, you may choose not to participate.

Instead of being in this study, you may <<list alternatives to participation>>.

**WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?**

**Being in a research study is voluntary.** If you choose not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled.

**What if I change my mind?**

**You may withdraw from the study at any time** without penalty or loss of benefits to which you are otherwise entitled.

We will inform you of any new information that develops during this study. This information may affect your decision to stay in the study. If you choose to withdraw from the study, you must tell the study team as soon as possible. See Appendix: Withdraw for more information about what to expect if you withdraw.

<<PI name>>, the <<sponsor name>>, the Institutional Review Board or the FDA>>may stop the study at any time. The study doctor, your medical doctor, or the <<sponsor name>> may remove you from the study at any time without your permission.

**WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

<<PI name>> is in charge of this research study. **You may call <<PI name>> at << PI contact number>> with questions at any time during the study.**

You **may also call << lead study coordinator name>>, the study coordinator, at << study coordinator contact number>> with any questions you may have.**

You should call Dr. << Name>> if you believe that you have suffered injury or do not feel well as a result of being in this research study.

You may also call Texas A&M University-Corpus Christi Institutional Review Board (IRB) with questions or complaints about this study at irb@tamucc.edu or 361-825-2497. The IRB is a committee of faculty members, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

# CONSENT TO PARTICIPATE

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. A copy of this signed form will be given to me.

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

Signature of Participant Date

# STUDY PERSONNEL

(Personnel performing the consent process MUST be listed as study personnel. Double check your IRB application that you’ve included all personnel who may be obtaining consent in this study)

I have explained the purposes, procedures, and risks involved in this study in detail to:

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

Print name of Participant

Any questions that have been raised have been answered to the individual’s satisfaction.

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

Signature of Person Obtaining Consent Date Time

Print Name of Person Obtaining Consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**TESTIGO/*WITNESS***

Required for phone consent process, when consenting non-English speaking persons with the short form method, or if the IRB has required a witness or patient advocate for the study. Delete this section if not applicable. If using for phone consent, you can delete the Spanish translation provided.

He presenciado el proceso del consentimiento y firma(s) para esta investigación científica. *I have witnessed the consent process and signature(s) for this research study:*

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

Firma del Testigo Fecha

Signature of Witness Date

Escriba el nombre del Testigo/*Print Name of Witness*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(También debe firmar el documento traducido/*Must also sign the translated document*)

**INTÉRPRETE/*INTERPRETER***

Delete this section if you are not enrolling non-English speaking persons. The following is required if you elected to recruit non-English speaking persons. You will secure an IRB approval for the English version first. Then add the translated version to the study as an amendment.

Yo estuve presente y presté servicios de interpretación durante la firma de este documento. *I was present and provided interpretation services during the signing of this document.*

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

Firma del Intérprete Fecha

*Signature of Interpreter Date*

Nombre del Intérprete en Letra de Molde/ *Printed Name of Interpreter*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (También debe firmar el documento traducido/*Must also sign the translated document*)

Relación del intérprete al Sujeto:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Relationship of Interpreter to Subject*

This section includes appendixes that if referenced in the main body needs to be included here. Appendixes provided additional information to those subjects who want more details. If appendixes are not relevant, then delete.

# Appendix: Conflict of Interest

If multiple investigators have a conflict declared, they must have separate paragraphs for each. <Investigator name> personally receives income from the study sponsor for <<Financial disclosure: relationship, i.e. consultant, board member, equity owner>> work. The hospital and the IRB have reviewed this arrangement and determined that this relationship presents a potential conflict of interest for << Investigator name>>. Therefore, << Investigator name>>’s relationship is being disclosed to you.

The following statement is required if there is a conflict of interest and there is a remedy statement or management plan. In addition to informing you of this conflict of interest, <<Investigator’s name>> will not <<List items in the COI management plan: be involved in the recruitment of or enrolling study participants, will not participate in data and safety monitoring activities, will not be engaged in the recording of research data>>.

If you have questions, contact the <Office name and contact information>.

# Appendix: FDA-Approved Status

<<drug>> is a <<describe drug, i.e. broad spectrum antibiotic (an antibiotic that kills many different types of bacteria)>> approved by the United States Food and Drug Administration (FDA) for the treatment of <<disease/condition>>. It is approved in the form of <<approved form, i.e. tablets or as an injection into a vein>>. The study sponsor <<sponsor name>> is studying the possibility of using <<drug>> as <<unapproved route, i.e. an inhaled medication through a device called a nebulizer>>.

The Food and Drug Administration (FDA) is responsible for the protection and overseeing of products that can affect public health. FDA approval or clearance is necessary to make sure patients using certain medical devices will be safe while utilizing the product. Devices go through rigorous study and examination before being allowed to be cleared or approved into the health care market.

The <<device>> is an FDA <<approved/cleared>> device currently used <<state approved conditions, i.e. in adults>>. However, the model used in this study has been changed slightly. <<State how, i.e., it is modified, it is being used in a different population than label, it is being used differently, etc.>> Therefore, it is called an investigational device for this study because we are still learning about its use in this new design. “Investigational” means that it is still experimental and has not been approved yet for this use by any regulatory agency, including the FDA.

Approved in adults but not children: <<drug>> has been approved by the FDA and in many other countries to treat <<disease/condition>> in adults. In children, however, <<drug>> is still experimental and is not approved by any regulatory agency, including the FDA.

Not FDA approved: <<drug >> has not been approved for use by the FDA and is considered an investigational drug. “Investigational” means that it is still experimental and has not been approved yet for this use.

Not FDA approved for this use: <<drug >> has not been approved for use by the FDA for this use and is considered an investigational drug. “Investigational” means that it is still experimental because it has not been tested for <<state the particular use not approved for>>.

# Appendix: Study Participants

Up to << # of subjects>> will be in this study at about << # of sites>> different places. Up to << # of subjects>> will be asked to be in this study at <institution name>.

<Add any additional information about who can participate>.

# Appendix: Study Visit Schedule

Charts or tables to visually display the study visits and what procedures can be anticipated at each visit is an easy way to describe to subjects what will happen. This is also a handy reference for them to keep for future reference.

|  |  |  |  |
| --- | --- | --- | --- |
|   | [Procedure]  | [Procedure]  | [Procedure]  |
| Study Visit 1  | X  |   |   |
| Study Visit 2  | X  |   |   |
| Study Visit 3  | X  | X  |   |
| Study Visit 4  | X  | X  | X  |
| Study Visit 5  |   |   |   |
| Study Visit 6  |   |   |   |
| Study Visit 7  |   |   |   |

# Appendix: Study Procedures - Collecting Information

Your participation will involve collecting information. The following information will be

* You do not have to give any information to the study that you do not want to give. By signing this form you are authorizing the collection and use of the information outlined in this form.
* We will ask for your contact information, including your telephone number, so that we can call you after <<each study visit>> to see how you are doing.
* Add this paragraph if you selected “review of existing data/records…” in Section 2.0.1: If you choose to participate, the study team will collect information from your medical record. The information collected will include the following:

o <<Summary of information collected, i.e. diagnosis, lab results, medications).

* We will ask you questions about your medical history, health, and the medicines your are taking to see if you can be in the study. Your medical records may be reviewed to assess his or her health.
* Add if applicable: If you agree, the study team will access your medical record from time to time to update the information collected. This will happen because researchers may need to know how your health has changed over time.
* Information above collected for this study will be shared with <<recipient investigator/sponsor>>.

# Appendix: Study Procedures- Questionnaire

You will be asked about: <<general list topics>>. Some questions may be embarrassing or uncomfortable to answer. Sample questions that you may be asked are:

• <add some sample questions that give subjects a flavor of what they will be asked>.

You do not have to answers questions you do not want to.

# Appendix: Study Procedures- Screening Visit

The screening visit will take approximately <<#>> hours. The screening visits will include:

* Checking your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, and take your temperature.
* Taking height and weight measurements.
* A pregnancy test if you are female and of childbearing potential.
* A review of how you are feeling (whether you feel okay, different from normal or unwell).
* A review of your study diary.
* A review of your current medications.
* Blood tests, chemistry, and inhibitor testing and blood values. Approximately <<#>> tablespoons will be taken each time.

Tests done will not benefit you directly or change how your disease is treated.

# Appendix: Study Procedures- Blood Collection

Blood will be taken by needle stick from a vein in your arm. There will be a total number of <<# of blood samples>> blood draws of about <<# of teaspoons>> teaspoons taken for the study. Several blood samples will be drawn during the study and you will give a total of about <<add volume>>.

Add this sentence if applicable:The study staff will collect blood specimens left over from previous tests. This will happen only if blood was already drawn from you as part of their care.

Add this sentence if blood collection from catheter or heparin lock. Blood will be taken through the catheter placed in your arm for your medical care. If the IV stops working and blood samples needed for this study can no longer be drawn, you may have another IV started or blood may be drawn by needle stick.

Add if collecting blood but not performing genetic testing: No human genetic tests will be performed on your blood sample.

Blood draw risks – Risks of drawing blood from your arm include discomfort and/or bruising. Numbing cream will help ease the pain of needle sticks. There is a very low risk of infection, bleeding, clotting, or fainting.

# Appendix: Study Procedures - Biospecimen

<<Biospecimen type>> will be collected from you by <<collection procedure>>.

Add this paragraph if the study includes the use of samples (whether as part of the main study or as part of optional research): Your samples will be used only for research and will not be sold. You should know that research sometimes results in discoveries that may one day have commercial value. For example, discoveries could eventually lead to new tests, drugs, or other products. Development of new products relies on the study of samples from hundreds or thousands of people, not on any one person. If this happens, you <would/would not> share in any financial recovery. You will not receive money or other compensation for use of these samples.

# Appendix: Study Procedures- Randomization

This study will place participants into one of the <<#>> study groups. The groups will be:

* Group <<name>>:
* Group <<name>>: Placebo group: A placebo is an inactive pill, liquid, or powder that has no medication in it. Experimental treatments are often compared with placebos to find out how effective the experimental treatment is.

<<describe groups and differences between the groups in procedures experienced>>.

You or your study doctor cannot decide which group you will be assigned to. You should take part in this study only if you agree to be in any of the study groups.

How are groups determined? <<describe how groups are assigned, i.e.,

The group to which you will be assigned will be decided randomly, like tossing a coin. There is an equal chance of you being assigned to either group.

You will be assigned a study number. That number is entered into a computer program that randomly assigns your number to a study group.>>

Double Blinded: You and the research team will not know which group you have been assigned to.

Single Blinded: You will not know which group you have been assigned to.

Not blinded: This study is “open-label,” which means that both you and the research team will know which group you were assigned to.

# Appendix: Study Procedures – Returning Results

Add details about returning results.

If not returning results back to the individual: <state reason for why test results will not be returned, i.e., The validity of test results are often still being tested. Tests done will not benefit you directly or change how your disease is treated.> You will not be informed about future use or results.

If returning results back to the individual: You will be given the results of the testing done for this research study. These tests include <<blood work obtained, pregnancy testing, urine testing, and urine drug screen testing>>. <State how results will be returned and under what conditions, i.e., If clinically relevant results are found, the study doctor will contact your primary physician to discuss these results with you.>

Incidental Findings not being disclosed –The <<genetic test, MRI, CT, X-ray of the brain>> used in this study is still under development and is not the same quality as a <<genetic test, MRI, CT, X-ray of the brain>> that you may have as part of your health care. <<State reason why: The images from the <<MR, CT, X-ray>> will not be reviewed by a physician who normally reads such images (such as a neuroradiologist). The genes this study is looking at has not been definitively linked to a disease.>> As a result, you will not be informed of any unexpected findings. If you believe you are having symptoms that may require <<clinical imaging, genetic tests>>, you should contact your primary care doctor. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

Disclosure of Findings of Clinical Significance Only – Whenever a <<genetic test, MRI, CT, X-ray of the brain>> is done, there is a chance of finding something unexpected and unrelated to the research study that may have some clinical implications. Unexpected findings can have a clear clinical significance to you or uncertain clinical significance. Clear clinical significance means that the <<genetic test, MRI, CT, X-ray of the brain>> shows a problem that may be treatable and we have an understanding of the risks of not treating the problem. Uncertain clinical findings are when the <<genetic test, MRI, CT, X-ray of the brain>> shows something unusual but we do not know if it might affect the health of you or treatment may not be available or possible. On this study, you will be informed of any findings of clear clinical significance discovered during the research, but you will not be told of findings of uncertain clinical significance. To help us decide if the findings are of clinical significance to you, we are also seeking your permission to review your medical record. If such findings are found, <<study staff may contact you by telephone to recommend a visit for you. You will be notified by mail to contact your physician.>> If notifed by mail: Notification will be sent to the last address you provided to us. <Institution name> will not release specific research findings over the telephone. Your physician will arrange for you to meet with him or her and/or a genetic counselor or other appropriate health care provider at <Institution name> to review the research information.

Disclosure of findings: subject’s choice: Whenever a <<genetic test, MRI, CT, X-ray of the brain>> is done, there is a chance of finding something unexpected and unrelated to the research study that may have some clinical implications. These findings may provide information about you that was previously unknown (such as disease status or risk). There can be some benefits to learning such results (such as early detection and treatment of a medical condition), but there may also be risk to learning of these results (such as feeling worried about a finding where there is no available treatment or clinical significance is unknown or unclear or future problems with getting health insurance). Unexpected findings can have a clear clinical significance to you or uncertain clinical significance. Clear clinical significance means that the <<genetic test, MRI, CT, X-ray of the brain>> shows a problem that may be treatable and we have an understanding of the risks of not treating the problem. You will be notified if we find any unexpected finding that has clear clinical significance. There is a remote chance that the <<genetic test, MRI, CT, X-ray of the brain>> shows something of uncertain or unknown clinical significance. Uncertain clinical findings are when the <<genetic test, MRI, CT, X-ray of the brain>> shows something unusual but we do not know if it might affect the health of your or treatment may not be available or possible. Whether or not you want to be informed of findings of uncertain or unknown clinical significance is up to you. Please indicate your choice by marking your preference and initial below:

|  |
| --- |
|  Please inform me of unexpected findings. \_\_\_\_ Initials   Please inform my doctor of unexpected findings. \_\_\_\_\_\_\_ Initials  Name of primary physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Clinic of primary physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone number of primary physician: \_\_\_\_\_\_\_\_\_\_\_   Please **do not** inform me or my doctor of unexpected findings. \_\_\_ Initials  |

# Appendix: Study Procedures – Future Research

Disclosure to sponsor: You also have the option to share your contact information with <<sponsor name>>. By giving your contact information to << sponsor name>>, you will also have the option to learn about << other studies you may qualify for and get updates about what researchers have learned from this study>>. You do not have to agree to share your contact information or be contacted in the future in order for you to be in the main part of this study. If you choose not to give your contact information to << sponsor name>>, then you will not be contacted with the results of this research.

|  |
| --- |
| Please read each sentence below and think carefully about your choice. After reading each sentence, circle “Yes” or “No” and initial each item.  I agree that that my <<samples and clinical information>> can be shared with <<sponsor name>>.   Yes No \_\_\_\_\_ Initials  |

Add this paragraph if keeping all or some of the specimens for future research. Note: To use this option to roll-over specimens from a study into a repository, you will need to have an IRB-approved repository.

In addition to the main study already described, there is additional research in which you can participate. We would like to use any left-over samples from the main study for futureresearch. These samples will be used to learn more about <<disease/condition>>.

No additional risks are expected because the samples are already being collected.

There will be no direct benefits to you for the storage and future research use of your samples. From studying your samples, we may learn more about <<disease to be studied>>.

If you say no to this additional research, the left-over samples will be destroyed once all study procedures are completed. Your decision will not affect your medical care in any way. If you say yes, the

<<information/sample>> will be stored at <<location>> for use in <<describe nature of future studies>> once the <<information/sample>> are collected. <<Information/sample>>collected could be stored for <<time period>>.

You may change that decision at any time. If you change your mind, you should contact the study team for <institution name> at <contact information>. However, if some of the research with your sample has already been completed, the information from that research may still be used.

|  |
| --- |
| Please read each sentence below and think carefully about your choice. After reading each sentence, circle “Yes” or “No” and initial each item.  I agree to allow my <samples/information> collected as part of this study to be used for future research on <<describe nature of future studies>>:   Yes No \_\_\_\_\_ Initials  I agree that my sample collected for this study may be stored at <<repository name>> for an indefinite amount of time and may be used in future research studies regarding <<repository purpose, i.e. DNA and genetic studies>>. I understand that the sample that is stored still contains information that may identify me.  Yes No \_\_\_\_\_ Initials  I agree that <<institution name>> may contribute <<anonymous test results and clinical information>> about me to a public database <<describe. Example: The database is part of the National Institute of Health’s effort to improve understanding of genetic differences in people>>.  Yes No \_\_\_\_\_ Initials  |

Optional future contact: Include this section if you would like to use identifiable information collected as part of this study to be used to recruit for future studies.

**Optional Future Research Contact:** You also have the option to learn about future research our institution is doing. By giving permission to use your contact information for future research, you will have the option to learn about <<research results or other studies you may qualify for>>.You do not have to agree to share your contact information or be contacted in the future in order for you to be in the main part of this study. If you choose not to give your contact information, then you will not be contacted with the results of this research.

|  |
| --- |
| Please read each sentence below and think carefully about your choice. After reading each sentence, circle “Yes” or “No” and initial each item.  Someone from the study team may contact me in the future to ask about me participating in future research studies.  Yes No \_\_\_\_\_ Initials  I agree that a member of the research team may use my <<contact information, email address>> to contact me in the future about <<research results or other studies I may qualify for and get updates about what researchers have learned from this study>>.   Yes No \_\_\_\_\_ Initials I would like to receive updates by e-mail about this study.   Yes No \_\_\_\_\_ Initials   Email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |

Optional PK Testing: Pharmacokinetic (PK) testing measures how long the study drug stays in your body after it has been given. This is measured by taking blood samples several different times after you have been given the study drug. PK testing is an optional part of this research study.

|  |
| --- |
| Please read each sentence below and think carefully about your choice. After reading each sentence, circle “Yes” or “No” and initial each item.  I agree to participate in the optional pharmacokinetic (PK) testing:   Yes No \_\_\_\_\_ Initials  |

Add this paragraph if you intend to contact subjects to disclose research results to a government sponsored public database:

Optional NIH database submission:

As part of this study, the <<sponsor name>> will submit clinical information and test results to the National Institute of Health (NIH) database. This database is a Health Insurance Portability and Accountability Act

(HIPAA) compliant, de-identified public database as part of the National Institutes of Health’s effort to improve understanding of <<study purpose>>. Confidentiality and security of the information is maintained. Subjects may request to opt-out of this scientific effort by indicating your choice below or by calling <<study coordinator name>>.

|  |
| --- |
| Please read each sentence below and think carefully about your choice. After reading each sentence, circle “Yes” or “No” and initial each item.  I agree to participate in the optional NIH database submission:   Yes No \_\_\_\_\_ Initials  |

**Appendix: Other Risks**

Add if Allergic reaction is a risk:

# Appendix: Allergic Reaction Risk

While allergic reactions are possible, these reactions are rare.

Allergic reactions usually happen right away after taking the oral medicine and symptoms include hives, swelling of the throat, and trouble breathing. You will remain in the clinic <#> hours after dosing to watch you for these reactions. Medications for immediate treatment of severe allergic reactions and trained personnel will be available in the clinic where the <study drug/vaccination> is given.

If you experience any of the following systems after you have left the clinic, contact the study team at <contact information> immediately:

• <list allergic reaction symptoms>

Add if Pregnancy/breastfeeding risks:

# Appendix: Pregnancy or Breastfeeding Risk

We do not know what effect the <<drug/procedure>>might have on a pregnant woman, an unborn baby, or a breastfeeding baby.

Participants who could get pregnant or father a child should use birth control such as birth control pills or condoms, or not have sex. You will be asked about this at your study follow-up visits.

# Appendix: Genetic Risk

A risk of having genetic testing is the chance for genetic information to be used to discriminate (make an unjust or prejudicial distinction in the treatment of different categories of people or things based your genetic information).

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate based on genetic information. This law generally will protect you in the following ways:

* Health insurance companies, group health plans and employers with 15 or more employees may not request your genetic information that we get from this research, except in very limited circumstances.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility, benefits or premiums.
* Employers with 15 or more employees may not use the genetic information that we get from this research when making a decision to hire, promote, or fire you now, or in the future, or when setting compensation or the terms or privileges of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

# Appendix: Payments

Charts or tables to visually describe to subjects what will happen. This is also a handy reference for them to keep for future reference.

|  |  |  |  |
| --- | --- | --- | --- |
|   | Reimburse for <X> expense  | Payment  | Notes  |
| Study Visit 1  | X  | $ <amount>  |   |
| Study Visit 2  | X  | $ <amount>  |   |
| Study Visit 3  | X  | $ <amount>  |   |
| Study Visit 4  | X  | $ <amount>  |   |
| Study Visit 5  |   | $ <amount>  |   |
| Study Visit 6  |   | $ <amount>  |   |
| Study Visit 7  |   | $ <amount>  |   |

Reimbursement (use this sentence only if you are collecting receipts and giving subjects the exact amount they spent.) To reimburse you for study related expenses such as << taxi fare, hotel, meals>> you will need to provide a receipt showing your expenses and that amount will be provided to you by the study team. These payments are not considered to be taxable income.

Payment: You will receive <payment amount, i.e. <X> dollars per visit>.

If you do not complete the study, you will be compensated for the visits that were completed. You will not be compensated for any unscheduled visits*.*

What are the tax consequences for receiving payment to participate in research?

If the total value of <<payments/property provided>> (pick one) to you from <institution name> totals more than $600 in any calendar year, <institution name> must report this to the IRS on a Form 1099 with the recipient’s social security number (SSN) or individual tax identification number (ITIN). You will receive a copy of this tax form. Accepting <<payment/property>> (pick one) for taking part in the study may affect eligibility for Medicaid or other programs.

<institution name> can only <<make payments/provide property>> (pick one) if we have your SSN or ITIN Number. If you do not provide this number, you can still participate in the research study; however, you will not receive <<payment/property>> (pick one). Your SSN or ITIN Number will be maintained in a secure manner.

# Appendix: Withdraw

Inform the subjects what will occur with the data/samples collected about them up to the time of withdrawal.

If you withdraw from the study early for any reason, the information that already has been collected will be kept in the research study and included in the data analysis. No further information will be collected for the study.

Add if applicable: The information that already has been collected will be de-identified (the information cannot be traced back to you individually). Because you cannot be identified from the information there is no further risk to your privacy. This information will continue to be used even after you withdraw.

If FDA-regulated: If you withdraw from the study early for any reason, the information that already has been collected will be kept in the research study and included in the data analysis.

Withdrawal may have consequences. Consequences might be <<list consequences of withdrawal>>.

If you withdraw or you are removed from the study for any reason, the study doctor may ask you if they may continue to follow you for monitoring. This visit could include any of the assessments/tests mentioned earlier and any other procedures that the study doctor feels are necessary for your safety.