**Remove all instructional text and red color-coding from this document once complete.**

## Title of Research Study: [insert title of research study here]

## Investigator: [insert name of principal investigator]

## Key Information:

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research. More detailed information is listed later on in this form.

[Complete the table with a brief summary of the following key elements; Detailed information can be provided in later sections of this form]

|  |  |
| --- | --- |
| **Why you are invited to take part in this study:** |  |
| **Purpose of this study:** |  |
| **Voluntary Participation:** | Your decision to be in this study is voluntary. |
| **Right to Withdraw from Study:** | If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.  |
| **Length of Study Participation:** |  |
| **Study Procedures:** | The main procedures in the study include: |
| **Risks of Study Participation:** |  |
| **Benefit of Study Participation:** |  |
| **Costs of Participation:** |  |
| **Confidentiality of your information:** |  |

## Detailed Information: The following is more detailed information about this study in addition to the information listed above.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team. Include a telephone number and email address.]

This research has been reviewed and approved by the Texas A&M Institutional Review Board (IRB). You may talk to them at at 1-979-458-4067, toll free at 1-855-795-8636, or by email at irb@tamu.edu., if

1. You cannot reach the research team.
2. Your questions, concerns, or complaints are not being answered by the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research participant.
5. You want to get information or provide input about this research.

## How many people will be in the research?

We expect about \_\_\_\_\_ people to participate in this research at our site. Approximately \_\_\_\_\_ people will participate in the entire study nationally [or internationally].

## What happens if I say yes, I want to be in this research?

[Tell the subject what to expect using lay language and simple terms. Include the following items, if applicable:]

* The drugs, biologics or supplements that will be given to the subject
* All devices that will be used
* All hospitalizations, outpatient clinic visits and telephone or written follow-up
* The length and duration of visits and procedures
* If blood will be drawn, indicate the amount [in English units and units familiar to subjects, e.g., teaspoons or tablespoons] and frequency
* Explain who the subjects will interact with
* Location where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* What is being performed solely as part of the research study
* What is being performed as part of standard care; identify what procedures are part of regular medical or dental care that will be done even if the subject does not take part in the research
* How often procedures will be performed
* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* If photographs, audio or video taping will be used.
* If specimens will be collected.
* Whether the research will (if known) or 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

[Include for a clinical trial that involves randomization. Otherwise delete this section.] The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being given each treatment. [For double-blinded research add] Neither you nor the study doctor will know which treatment you are getting. [For single blinded research add] You will not be told which treatment you are getting, however your study doctor will know.

## What are my responsibilities if I take part in this research?

[Delete this section if the research is not a clinical trial.]

[Include this section if you need to educate the research subject about potential health and safety implications of a research intervention.]

If you take part in the research, it is important for your safety that you:

* Follow the directions of the study doctor and research staff.
* Tell your other health care providers that you are in a research study.
* Tell your study doctor and staff about all medications you are taking (prescription and over the counter) and all of your health issues.
* Call the study doctor or staff at \_\_\_\_\_\_ if you have any questions.

## What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research.

[If appropriate, discuss what might happen if there are risks to dropping out of the study early; Otherwise delete].

If you decide to stop, we may ask you if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

## Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[Include for research where this is a meaningful possibility.] The doctor (or other person) in charge of the research study or the sponsor can take you out of the study even if you do not ask to leave. This may happen if [Describe reasons why the subject may be withdrawn.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What are the risks of being in this study? (Detailed Risks)

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.

* Physical risks
* Psychological risks
* Privacy/confidentiality risks
* Legal risks
* Social risks
* Economic risks
* Group or community risks
* For research involving genetic testing, subjects must be informed of any risks associated with the genetic information that may result such as reduced access to or retention of benefits or entitlements (e.g., insurance, educational opportunities, employment, etc.); stigmatization; psychological distress in response to information; or detection of biological relationships within a family.]

Choose from the following Example language as applicable, add additional risk language as needed and delete the rest:

For breach of confidentiality: [The only risk/One of the risks] of being in this study is that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected.

For some studies with investigational drugs: This is the first time the experimental drugs are being used together. For this reason, we do not know all the possible side effects, and we do not know how frequently they might occur or how serious they might be.

For studies with venipuncture: The risks of having blood drawn include slight pain when the needle is inserted. You may develop a harmless black and blue mark, and your arm may be sore. Occasionally, some people feel dizzy or lightheaded when blood is drawn. They may become sweaty, feel cold or tingly, and may faint or throw up. Risks that are possible but unlikely include infection, nerve damage, and puncturing an artery instead of a vein.

For studies with ECG: The risks include skin irritation and a rash from wearing or removing the patches that stick to your skin or from the gel that is used with them.

For studies with CT scans: CT scans give detailed images of the inside of your body. The amount of radiation a person receives during a CT scan is moderate (more than you would receive from a dental or chest X-ray and about the same as the dose we get from normal background radiation over four or five years). We know that radiation is harmful, but the risk to your health is hard to measure. If you have had many X-rays or scans or if you might be pregnant, you should ask the study doctor about this risk.

For studies with genetic testing: Because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except those with fewer than 15 employees, to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

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

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.

[Include for research that involves known risks to an embryo or fetus] The procedures in this research may harm a pregnancy or unborn child in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. You should not become pregnant or father a baby while on this research study.

[Include for research that involves pregnant women or women of child-bearing potential and procedures whose risk profile in pregnancy is not well known.] If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include when reproductive risks when appropriate] If you are a woman who is able to have children, you must have a negative pregnancy test before you start the study and you must agree to use an effective birth control. Describe acceptable birth control methods.

If you become pregnant during the study, you should tell the study doctors. You will [explain what will be done if a woman becomes pregnant while in the study and whether or not it is expected that the baby’s health, in addition to the mother’s health, will need to be followed for a period of time as well.]

[For male subjects, if there is a risk to his partner, this must also be discussed along with the precautions that he and his partner must take.]

[Include for Department of Defense (DoD) research where DoD-affiliated personnel are subjects and if the HSR includes a risk to their fitness for duty (e.g. health, availability to perform job, data breach).] This research project may impact your fitness for duty. Please seek command or Component guidance before participating.

[Include for Department of Defense (DoD) research, if applicable.] This research includes the potential risk of the loss of clearance, credentials, or other privileged access or duty.

## ***What are the costs of being in the research?***

[Include for research that will NOT result in any costs to the participants. Otherwise delete.] Taking part in this research study will not lead to any costs to you.

[Include for research that may result in additional costs to the participants. Otherwise delete.] Taking part in this research study may lead to added costs to you. [Describe what these costs are.]

[Include for a clinical trial. Otherwise delete.]You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. You remain responsible for all deductibles, co-pays, and balances under your insurance. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. A member of the study team can talk to you about what procedures would be considered standard care and the coverage of those costs.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the TAMU HRPP/IRB and other representatives of this organization. [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research is FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities as required by law.]

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include for NIH-funded studies or those receiving a Certificate of Confidentiality by request from NIH. Otherwise delete.]This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information or documents that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained. A separate repository protocol may be required by the IRB]

[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, Date/Time (AM or PM) of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, the TAMU HRPP, the US Office for the Protection of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) may be granted direct access to your records to conduct and oversee the research. By signing this document you are authorizing this access.

[Include for FDA-regulated controlled drug and device trials (except Phase I drug trials) and FDA-regulated pediatric post-market surveillance trials of devices. Otherwise delete.] 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.

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your health related records and information. These are described in the HIPAA Authorization.

[Include for research involving prisoners. Otherwise delete.]If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

## Funded/Supported By: [List all monetary and/or non-monetary support for this research. If none, state Texas A&M University or applicable agency.] This research is funded/supported by \_\_\_\_\_\_\_\_\_\_.

## Financial Interest Disclosure:

[Include if there is a financial interest to disclose. Otherwise delete.] The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

## What else do I need to know?

[Include for research involving more than minimal risk. Otherwise delete.]

[Include if study is not funded, PI-inititated, or federally funded.] If you become ill or get injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

Texas A&M University has no program to pay for medical care for research-related injury. This does not keep you from seeking to be paid back for care required because of a bad outcome.

[Include if study has an industry sponsored contract that will cover subject injury] If you have an injury or illness from the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the injury/illness is directly related to the research and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

[Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[When participants are paid by check by TAMU, insert:] The financial office at Texas A&M University may be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

[Include if biologic specimens obtained could be part of or lead to the development of a commercial product. Otherwise delete.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens.] Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will/will not contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

[Include for Department of Defense (USDOD) research that targets military personnel where participants will be paid. Otherwise delete.]Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

[Include for research studies using a drug, biological product, device, or vaccine designed to treat, diagnose, cure or prevent COVID-19. Otherwise delete.] Due to the coronavirus public health emergency, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the order applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this “Countermeasures Injury Compensation Program” please go to https://www.hrsa.gov/cicp/about/index.html or call 855-266-2427.

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.

**Signature Block for Capable Adult**

|  |
| --- |
| **Your signature documents your permission to take part in this research.** |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |
| Printed name of person obtaining consent |

[Add the following if a witness is required to observe the consent process. e.g., short form of consent documentation or participants unable to read].

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

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

Signature of witness to consent process Date

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

Printed name of person witnessing consent process

**Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature documents your permission for the named subject to take part in this research. |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

**[Add the following block if you will document assent of the subject.]**

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

[Add the following if a witness will observe the consent process. e.g., short form of consent documentation or participants unable to read.]

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

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

Signature of witness to consent process Date

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

Printed name of person witnessing consent process

**Signature Block for Parent permission to enroll Child**

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s participation in the research. Contact legal counsel if any questions arise.

Your signature documents your permission for the named child to take part in this research.

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

Printed name of child

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

Printed name of parent [ ] or individual legally authorized [ ] Date

to consent for the child to participate

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

Signature of parent [ ] or individual legally authorized [ ] Date

to consent for the child to participate

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

Printed name of parent [ ] or individual legally authorized [ ] Date

to consent for the child to participate

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

Signature of parent [ ] or individual legally authorized [ ] Date

to consent for the child to participate

If signature of second parent not obtained, indicate why: (select one)

[ ] The IRB determined that the permission of one parent is sufficient.

[ ] Second parent is: [ ] deceased [ ] unknown [ ] incompetent [ ] not reasonably available

[ ] Only one parent has legal responsibility for the care and custody of the child

[Add the following block if you will obtain assent of children]

Assent:

 [ ] Obtained signature on separate assent document

 [ ] Obtained verbally without a signature

 [ ] Not obtained because the child is not capable of providing assent

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

Signature of person obtaining consent Date

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

Printed name of person obtaining consent