**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 studied?

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

## What happens if I say “Yes, I want to be in this research”?

[Tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* A 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
* The length and duration of study visits, activities, and procedures
* With whom the participant will interact
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* How often study activities and procedures will be performed
* What is being performed as part of the research study
* When applicable indicate that the participants will be asked for permission to be contacted for future research.
* When applicable describe if audio or video recording any research activities. Include if agreement to be recorded is required for participation or if it is optional.

## What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time and it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research***,*** [Describe the adverse consequences.] If you decide to leave the research, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the perticipant, if any.]

[Describe what will happen to data collected to the point of withdrawal. Describe whether participants will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a participant may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

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

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the participants may be withdrawn, if appropriate.]

[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.

## Is there any way being in this study could be bad for me (Detailed Risks)?

[Delete this section if there are no additional risks or discomforts besides what was included in Key Information.]

[The risks of procedures may be presented in a table form.]

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

* Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks
* Group or community risks]

[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 Department of Defense (USDOD) 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).. Otherwise delete.] 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 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 and other 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 institution. [Add to this list other organizations that may have access to the participants records such as the US Department of Defense 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 will be retained after the study for future research, explain where the data will be stored, who will have access to the data, and how long the data will be retained.]

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

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

OR

Your information that is 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 participant.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[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 that is more than minimal risk. Otherwise delete.]If you need medical care because of taking part in this research study, please seek medical treatment through the treatment center of your choice. Contact the investigator to inform [her/him] about any related injury or illness. Generally, this care will be billed to you or your insurance. Texas A&M University has no program to pay for medical care for research-related injury. [For industry sponsored research describe any reimbursement available for treatment due to research related injury or illness, as stated in the contract.]

[For studies taking place in a school, this paragraph must be included:] Parents please be aware that under the Protection of Pupils Right Act 20 U.S.C. Section 1232 (c)(1)(A), you have the right to review a copy of the questions asked of or materials that will be used with your students. If you would like to do so, you should contact [Principal Investigator] to obtain a copy of the questions or materials.

[Include if participants will be paid. Otherwise delete.] If you agree to take part in this research study, 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 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.

[When applicable indicate when and how the participant will be informed of the results of the research.]

[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.

## Optional Elements:

[Include for any optional elements of the research. If audio or video recordinging is required to be in this study please make it clear in the procedures section of this document. Otherwise delete.] The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

|  |  |  |
| --- | --- | --- |
| I agree | I disagree |  |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team or TAMU Compliance. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study. (A separate protocol may be required by the IRB for the storage of identifiable data for research purposes). |

**[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