**DIRECTIONS**

**SHORT FORM CONSENT**

*This document is an example. There are various ways to set up this document. This is just one example for you to use.*

A short form consent is used when the participant or legally authorized representative is verbally presented the elements of informed consent.

**IRB REQUIRED DOCUMENTS**

* The oral summary with the elements of informed consent that will be used by the research team.
	+ Provide the document to the IRB in English and in the participant’s preferred language.
* The short form consent that will be used by the research team.
	+ Provide the document to the IRB in English and in the participant’s preferred language.

**DIRECTIONS**

* Read the short form consent and oral summary. Adapt the text according to your research.
	+ Adapt **ORANGE TEXT** to fit your research.
	+ Choose the appropriate statement in **GREEN TEXT** that applies to your research. Delete the other statement not being used.
	+ Choose the appropriate **BLUE TEXT** option. Delete the other option not being used.
	+ Deletethe **RED TEXT** from the consent form.
* Format the document to un-bold the text in color and change the font color to black.

**PROCEDURES**

* Presentation
	+ Key information must be presented first.
	+ All the elements of informed consent must be verbally presented to the participant or legally authorized representative.
* Participant or Legally Authorized Representative
	+ Allow the participant or legally authorized representative to ask questions about the research during and after the verbal presentation.
	+ If the participant or legally authorized representative agrees to participate in the research, the individual will sign the short form consent.
		1. Documents are provided in the participant’s preferred language.
	+ A signed copy of the short form consent and oral summary are provided to the participants.
		1. Documents are provided in the participant’s preferred language.
* Witness
	+ The person who will observe the verbal presentation given to the participant or legally authorized representative.
	+ The witness will sign the short form consent and oral summary.
	+ The witness must understand both English and the participant’s preferred language.
	+ The witness must not be a part of the research team or involved in the research.
* Individual Obtaining Consent
	+ The person who verbally presents the summary of the elements of informed consent.
		1. The research team may use a translator to obtain consent. A second individual is still required to serve as the witness.
	+ The individual obtaining consent will sign the oral summary.

**SHORT FORM CONSENT**

**{Title of your study}**

You are being asked to participate in a research study. Your participation is completely voluntary. You can skip any parts of the research you are not comfortable with and stop at any point. You will not be penalized or lose benefits if you refuse to participate or decide to stop at any point during the study.

Before you agree, the researcher must tell you about:

* the purposes, procedures, and duration of the research
* any foreseeable risks or discomforts
* any benefits to the research
* any incentive or compensation
* protecting your privacy and confidentiality
* how your data will be used in the future

**{OPTIONAL: Use the following additional elements of consent if they apply to your research. Delete the elements of consent that do not apply to your research. These elements are typically used in non-invasive and invasive research.}**

* **any procedures which are experimental**
* **any compensation or medical treatments if you are injured**
* **any alternative procedures or treatments**
* **the possibility of unforeseeable risks**
* **any circumstances that will stop you from participating**
* **any consequences to you if you decide to stop participating**
* **any additional costs to you**
* **any new findings which may occur during the research and may affect your willingness to participate**
* **how many people will be in the research study**
* **disclosing the research results to you**
* **genomic sequencing in your biospecimens**
* **your biospecimens will be used for commercial profit.**

**{Leave the following statements if this research is a clinical trial and will be registered on ClinicalTrials.gov. 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.}**

**If you agree to participate, you will sign this document. The research team will give you a signed copy of this document and a oral summary of the research.**

If you have any questions or concerns, please contact **{TTU PI Name}** from the Department **{Department’s Name}** at Texas Tech University. Their contact information is **{PI’s telephone number XXX-XXX-XXXX}** or **{PI’s email address}**. If you have questions about your rights as a research participant, contact the Human Research Protection Program, Office of Research and Innovation, Texas Tech University, Lubbock, Texas 79409. You can contact them at 806-742-2064 or email at hrpp@ttu.edu.

Signing this document means that the research study, including the above information, has been described to you verbally, and that you voluntarily agree to participate.

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Signature of **{CHOOSE ONE OPTION: Participant or Legal Authorized Representative}** Date

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Printed name of **{CHOOSE ONE OPTION: Participant or Legal Authorized Representative}**

**{OPTIONAL: If the Legal Authorized Representative signs the short form consent then include the line for the participant’s name.}**

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**Printed name of Participant**

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Signature of Witness Date

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Printed name of Witness

**ORAL SUMMARY**

Hello,

Thank you for your interest in participating in this research. For the next few minutes, I am going to tell you about this research project and what your participation would involve. If you have any questions or concerns, please stop me.

The study is called, “**{Title of your study**.**}**” This study will help us learn how **{briefly describe the purpose of your study.}**

You will be asked to **{describe what their participation entails in this study.}** We are asking for **{amount of time}** of your time. The study will take place in the **{Building Name}** building located on the **{Texas Tech University campus or site}**. The study will be conducted in **{number of}** visits.

**\*\*Note this is only an example and may change according to your research. \*\***

* **First Visit: {Provide a detailed explanation of the procedure.}**

**{Provide a detail of risks and or discomforts the participant may experience.}**

**{Amount of time this procedure will take.}**

* **Second Visit: {Provide a detailed explanation of the procedure.}**

**{Provide a detail of risks and or discomforts the participant may experience.}**

**{Amount of time this procedure will take.}**

* **Third Visit: {Provide a detailed explanation of the procedure.}**

**{Provide a detail of risks and or discomforts the participant may experience.}**

**{Amount of time this procedure will take.}**

Your participation is completely voluntary. You can skip parts of the research you are not comfortable with and stop at any point. You will not be penalized or lose benefits if you refuse to participate or decide to stop at any point during the study.

**{There are no foreseeable risks OR Some risks include (Enter risks)}** with this research. **{There are no direct benefits OR You will receive (Enter benefit)}** for your participation. We appreciate your time and effort with this research study.

**{If you are providing an incentive/compensation to the participant provide the following: a description of the incentive/compensation; any restrictions or requirements for participant compensation, if it is a drawing the odds of winning, and the time frame of when the participant will receive the incentive/compensation.}**

Your name will not be linked to any material in reports, publications or presentations. No one other than the researchers associated with this project will have access to the raw data. All related documentation will be stored in the researcher’s locked office **{and/or}** on a password protected computer.

**Identifiers might be removed from the {CHOOSE ONE OPTION: identifiable private information OR identifiable biospecimens} and after such removal the {CHOOSE ONE OPTION: information or biospecimens} could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.**

**or**

**Your {CHOOSE ONE OPTION: information OR biospecimens} collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.**

The study is being run by **{TTU PI’s Name and Co-Investigator’s Name}** from the Department **Department’s Name** at Texas Tech University. If you have questions, you can call **{him/her}** at **{XXX-XXX-XXXX}**. Texas Tech University also has an Institutional Review Board that protects the rights of people who participate in research. You can contact them at 806-742-2064 or hrpp@ttu.edu. This contact information will be in the short form document that you will take home.

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Signature of Individual Obtaining Consent Date

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Printed name of Individual Obtaining Consent

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Signature of Witness Date

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Printed name of Witness

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Name of Participant

**CONSENT PROCESS STEPS**

**{Individual obtaining consent will verbally present the elements of informed consent that are outlined in the summary.}**

**{After the individual obtaining consent has finished verbally presenting the information.}**

**{Individual Obtaining Consent}** Do you have any questions about this research or your participation?

**{Individual Obtaining Consent}** If you would like to participate please sign and date the short form consent.

**{Individual Obtaining Consent}** I am now going to have the witness sign and date the short form consent.

**{Individual Obtaining Consent}** The witness and I are now going to sign and date the oral summary.

**{Individual Obtaining Consent}** Here is a signed copy of the short form consent and oral summary for your records.