***Please use this template as a general guide when developing your consent form. Customize the language, as needed, to fit your study. General comments and guidance are in blue text, and instructions are in red text. Please delete all guidance and instructions before submitting the form to the IRB. The IRB recommends that you keep the black text in the form, if applicable to your study, unless the language conflicts with what will happen in your study. Other recommendations:***

* *Use simple language (“lay language”). Avoid scientific or technical jargon.*
* *Write in a conversational tone. Use second-person pronouns (words such as “you” and “your”).*
* *Spell out all abbreviations the first time they are used, and define any medical/clinical or scientific terms.*
* *Maintain the format of the page numbering in the footer (e.g., page 2 of 3).*

**INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**TITLE:** [insert project title]

**PRINCIPAL INVESTIGATOR:** [insert the principal investigator’s name and degree/credentials]. If you so choose, you may also list the names of other investigators, below; however, if you list other investigators, the IRB recommends that you include only the names of senior key personnel, not all of the key personnel, to prevent the document from becoming outdated whenever there are study staffing changes]

**INSTITUTION:** [insert name of principal investigator’s institution (e.g., University of North Texas Health Science Center, John Peter Smith Health Network, University of North Texas at Dallas, etc.)]

**This study is funded by** [insert name of funding agency, if applicable; otherwise, delete this line]

*Key Information Section: If your project is an Expedited or Full Board project, you must include a Key Information section at the beginning of your consent form (as outlined below). Key Information sections are not required for Exempt category projects. If your project is an Exempt category project, do not include a Key Information section in your consent form (i.e., delete the Key Information language, below, and resume writing in Section I (Introduction).*

*Note: Although you may feel your project is Exempt at the time of submission, the IRB may determine otherwise upon review. If your project is determined to be Expedited or Full Board, you will be asked to include a Key Information section in this consent document.*

*Example Key Information language is included below. For additional examples/templates, please click* [*here*](https://www.unthsc.edu/north-texas-regional-irb/wp-content/uploads/sites/61/North-Texas-Regional-IRB-Example-Templates-for-Key-Information-Section-FINAL.docx)*.*

**KEY INFORMATION FOR A RESEARCH STUDY** [insert either full or abbreviated project title]

We are inviting you to take part in a research study. Your participation in this study is voluntary, and you do not have to participate.

* **WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?**

**PURPOSE:** Briefly describe purpose of the study in layperson’s terms.

**PROCEDURES:** Provide a brief overview of the study procedures.

**DURATION:** Describe the anticipated time commitment (how long the study procedures are expected to take, the expected duration of the subject’s participation, etc.)

* **WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**

This research study involves foreseeable risks and discomforts, which are summarized below:

* There is a risk of loss of confidentiality, which means that the information we collect about you could possibly be accessed by someone who is not authorized to see it. However, we will work hard to protect the information we collect about you and to keep it private.
* Provide a brief overview of the other potential risks and discomforts of the study.
* **WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

Your participation in this study [insert “may” or “may not”] directly benefit you. However, your participation in the study may help the clinical and scientific communities gain a greater understanding about [describe research topic].

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

This research project [“does” or “does not”] involve treatment. You may choose not to participate in this study.

**MAIN CONSENT FORM**

1. **INTRODUCTION**

You are invited to participate in a ***research***study. Your participation in this study is entirely voluntary. This consent form contains information to help you decide whether or not you wish to participate. Please read this consent form at your own pace. It is important that you read what is written below and ask questions about anything you do not understand. You may want to talk with your family, friends, or others to help you decide if you want to be part of this study. When you feel that your questions have been answered, you will be asked if you agree to be part of the study. If you agree, you will be asked to sign this consent form. You will be given a copy of this form to keep.

*If the subject could be a UNTHSC/JPS/UNT-Dallas student and/or employee, add (and modify as appropriate):* If you are a student or employee at the [University of North Texas Health Science Center at Fort Worth; John Peter Smith Health Network; University of North Texas at Dallas], your participation (or non-participation) will in no way affect your academic standing or employment status.

1. **STUDY PURPOSE**

The purpose of this study is to [explain the purpose in layperson’s terms].

[Insert “Approximately” or “Up to”] [insert number] of subjects will be involved in this study.

1. **ELIGIBILITY TO PARTICIPATE** *Include this section if your study involves screening procedures and/or if the study has eligibility criteria that relate to subject safety. Otherwise, delete this section.*

Describe the screening procedures. And add the following language: The information that is collected about you during the screening process [insert “will” or “will not”] be used for research purposes. Please note that you may be deemed ineligible for further participation in this study based on the information that is obtained about you during the screening process.

*If the study involves eligibility criteria that relate to subject safety (e.g., exclusion criteria that are in place to exclude enrollment of individuals from whom participation may be unsafe, etc.):* Describe the inclusion criteria and the exclusion criteria.

*If the study does not have eligibility criteria that relate to subject safety, please add the following statement:* You are being asked to participate in this study because (add a brief list of inclusion criteria).

1. **STUDY PROCEDURES**

If you decide to participate in this study, you will be asked to [explain ALL of the procedures that the subjects will be asked to undergo as part of this study; identify and describe any procedures that are experimental].

*For any of the additional procedures outlined in this section below, please delete if not applicable to your study.*

*If the study involves a survey, questionnaire, interview, and/or focus group:*

Describe the type/nature of the questions or topics that will be discussed.

*If the study involves collection of data from a subject’s medical records:*

 Specify the name of the facility (hospital, etc.) from which the medical records will be obtained.

Describe the data items that will be collected from the subject’s medical records and used for research purposes.

*If the subjects will be recorded (audio, video, screen capture, etc.):*

Inform the subjects that they will be recorded and provide information about the recordings (e.g., the type of recording, how and where the recording will be stored, how long the recording will be maintained, when the recording will be destroyed, measures that will be in place to secure the data, etc.).

*If blood will be drawn:*

Describe how the blood will be drawn (e.g., from a vein in your arm, from a finger-stick, etc.), the number of times blood will be drawn, the amount of blood that will be drawn each time, and the total amount of blood that will be drawn from each subject*.* Use common measurements such as teaspoons or tablespoons.

*If the study involves obtaining biospecimens (blood, tissues, etc.), add the following information:*

The research [insert “will” or “might” or “will not”] include whole genome sequencing. *If the study will or might include whole genome sequencing*: Explain what “whole genome sequencing” means in layperson’s terms.

Your biospecimens (even if identifiers are removed) may be used for commercial profit, and you [insert “will” or” will not”] share in this commercial profit.

*If the study involves obtaining information that may be clinically relevant (e.g., information obtained from blood draws, ultrasounds), add the following statement:*

The researchers may learn clinically-relevant information about your health as part of this research. Your individual results [insert “will” or “will not”] be shared with you. Describe how, and under what conditions, the information will be shared, if applicable.

1. **EXPECTED TIME OR DURATION OF PARTICIPATION**

Describe the total expected duration of the subject’s participation in the study, including the estimated amount of time needed to complete each component of the research, when relevant. (For example: You will be asked to participate in two interviews. The first interview is expected to last approximately 2-3 hours. The second interview will take place approximately one month after the first interview. The second interview is expected to last 1-2 hours.) Describe the total number of study visits and/or other relevant study-related contacts (phone calls, emails, etc.), when applicable.

1. **RISKS AND DISCOMFORTS OF THE STUDY**

There is a certain amount of risk that is involved with participating in a research study. Every precaution will be taken by the research team to minimize these risks and ensure your safety. Please remember that if you feel uncomfortable about any of these risks, discuss your concerns with the research team. You do not have to enroll in this study. If decide to enroll in this study, you are free to withdraw from the study at any time.

This study involves informational risks (such as breach of confidentiality). Describe all other reasonably foreseeable risks and discomforts associated with study (physical, informational, emotional, legal, etc.). Describe the side effects of drugs, supplements, and other relevant items.

In addition to the potential risks (described above), the research procedures may involve risks to you that are currently unforeseeable at this time.

*If applicable, add:* If you are or become pregnant during this study, there may be risks to the embryo or fetus that are currently unforeseeable.

Significant new findings that are developed during the course of the research that may relate to your willingness to continue participation will be provided to you.

1. **BENEFITS**

You [insert “are not expected to directly benefit from participation in the study” or “may”] directly benefit from this study. [Describe the direct benefits to the subject, if applicable.]

The investigators hope that the information that is gained in this study will benefit [describe others who will benefit (e.g., society, scientists by helping them advance knowledge about a certain topic, etc.].

1. **CONTACTS**

If you have any questions about the research, concerns about your participation in this study, and/or if you have a research-related injury, please contact [insert name of principal investigator and PI’s contact information, including phone number; Note: If you want to include any additional contact information (e.g., for another investigators), you may do so]. If you have questions about your rights as a research subject, you should contact the North Texas Regional Institutional Review Board by phone at (817) 735-0409.

1. **ALTERNATIVES**

*Include one of the following items (select the one that is true for your study):*

There are no alternative treatments or interventions involved in this study, other than what has been described. Therefore, the only alternative is that you may choose not to participate in this study.

OR

Describe the appropriate, alternative procedures or courses of treatment that might be advantageous to the subject.

1. **CONFIDENTIALITY**

All of your records will be kept as confidential as possible under current local, state and federal laws. You will not be identified in the analysis or presentation of the data in subsequent publications and presentations at local, national and/or international academic conferences.

Include a brief description of the security measures that will be in place to protect the research data (e.g., electronic research data will be securely managed and stored on password-protected computers; paper documents will be stored in locked file cabinets in the principal investigator’s office, etc.).

*If the project involves biospecimens, then:*

Describe how and where the biospecimens will be securely stored; describe how the samples will be labeled (e.g., with your unique ID number, which does not contain any of your direct identifiers such as your name or date of birth); state whether or not any of the subject’s identifiable information will be associated with their biospecimens (e.g., via a master list that links identifiable information (such as the subject’s name, date of birth, medical record number, etc.) to their unique ID number, etc.).

*If the study involves the collection of identifiable private information or identifiable biospecimens, include one of the following statements (select the statement that is correct for your study):*

Identifiers might be removed from the identifiable [insert “private information” or “identifiable biospecimens” (or insert both phrases)], and after such removal, the de-identified [insert “information” or “biospecimens” (or insert both words)] could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

OR

Your [insert “information” or “biospecimens” (or insert both words)] that are collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Authorized representatives from the following organizations may need to review your research information as part of their responsibilities to protect research participants:

* University of North Texas Health Science Center Office of Research Compliance
* North Texas Regional Institutional Review Board
* Other federal regulatory agencies, as required
* List any other relevant institutions, hospitals, etc.

*If the study is a clinical trial which is either on, or will need to be added to Clinical Trials.gov, add the following language:*

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

*If the study is covered by an NIH Certificate of Confidentiality (COC), add the following language:*

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose or use information that may identify you, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of federal agencies. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The protection offered by the Certificate does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject’s threat of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities, and will do so without disclosing your participation in this study. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

1. **COMPENSATION FOR INJURY** *(delete this section if not applicable to your study)*

We at [insert the name of your institution (e.g., the University of North Texas Health Science Center at Fort Worth, John Peter Smith Health Network, University of North Texas at Dallas, etc.)] have not set aside any funds for financial compensation for costs of medical treatment if you get injured as a result of your participation in this research.

If required, medical care will be made available to you in the case of such injury, but you (or your private insurer, Medicare, Medicaid or other governmental health care program) will be responsible for the expense of any medical care that is needed, including hospitalization.

You should know that by signing this form you are neither waiving any of your legal rights against or releasing the principal investigator, the [insert name of your institution (e.g., University of North Texas Health Science Center at Fort Worth, University of North Texas at Dallas, etc.)], or any of their respective agents from liability for negligence with respect to the conduct of this study. If you are injured and feel that your injury justifies a legal remedy, you have the right to do so.

1. **COSTS AND PAYMENTS OF THE STUDY** *(delete this section if not applicable to your study)*

*If applicable:* Provide information about any payments that will be made to the subjects.

*If applicable:* Describe any costs to the subjects that may result from participation in the research.

1. **LEAVING THE STUDY**

You may refuse to participate or stop participating in this study at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled.

*If there will be a way for the subject to withdraw from the study, add the following:*

If you want to withdraw from the study, you may do so by [describe the procedures for withdrawing from the study (e.g., by notifying a member of the research team in whatever form is most convenient (e.g. verbally, written, email).

*If there will NOT be a way for the subject to withdraw from the study (e.g., due to the nature of the project, such an anonymous survey), then:*

Include information about this topic in the consent form. For example: Due to the nature of this project (anonymous survey), there will be no way for you to withdraw from the study once you have turned in your survey.

*If the investigator may terminate the subject’s involvement in the study, add the following:*

Your participation in the study may also be terminated by the investigator at any time, for any reason, without regard to your consent. For example, your participation may be terminated if [describe any foreseeable circumstances and/or reasons that the subject’s participation may be terminated (e.g., if you miss too many study visits, etc.]

Research information that was collected about you prior to your withdrawal or termination [insert “may” or “will not”] be retained and used for research purposes. Describe any other relevant information that the subjects need to know about withdrawing from the study (e.g., return of equipment, safety concerns related to early withdrawal, etc.)

1. **CONSENT**

**I voluntarily agree to participate in this study. All of the study procedures have been described to me, and all of the risks have been explained. I have been given an opportunity to ask questions, and all of my questions have been answered to my satisfaction. I will receive a copy of this informed consent form.**

|  |  |
| --- | --- |
|  |  |
| **Printed Name of Participant** |  |
|  |  |
| **Signature of Participant** | **Date** |
|  |  |
| **Printed Name of Person Obtaining Consent** |  |
|  |  |
| **Signature of Person Obtaining Consent** | **Date** |

*Delete the following sections if they are not applicable to your study.*

**AUTHORIZED REPRESENTATIVE:**

|  |
| --- |
|  |
| **Printed Name of Authorized Representative** |
|  |  |
| **Signature of Authorized Representative** | **Date** |

**WITNESS:** If this form is being read to the subject because the subject cannot read the form, a witness must be present and is required to print their name and sign here.

|  |
| --- |
| **Printed Name of Witness to Oral Presentation** |

|  |  |
| --- | --- |
| **Signature of Witness to Oral Presentation** | **Date Time** |