**TO THE RESEARCHERS:**

* **This is a consent template to be used any time consent forms are signed or when data may be identifiable.**
* **Insert your information as it pertains to your study in the place of the red font.**
* **You will notice some verbiage in black font; this stays as part of your form and aids us in being compliant with federal regulations**
* **PLEASE DO NOT COPY AND PASTE FROM YOUR APPLICATION TO HERE SINCE LANGUAGE HERE MUST BE IN MUCH SIMPLER TERMS.**
* **It helps to write as if you are having a conversation with a potential participant who is not familiar with technical or scientific terms.**
* **The Project Description that is under the title of your study is meant to provide enough information for the potential participant so that they can decide whether or not they want to be in your study.**
* **The IRB Application has content that if you check “yes” must be on this consent form (Section XII).**
* **All researchers are strongly encouraged to refer to the following federal regulations (46.116 and 46.117) regarding additional information about informed consent:**
* **The final reading level for the Informed Consent should be below 9th grade (use the Flesch-Kincaid Grade level on** [**https://readabilityformulas.com/freetests/six-readability-formulas.php**](https://readabilityformulas.com/freetests/six-readability-formulas.php) **to check the readability). See IRB handbook (https://www.uttyler.edu/research/compliance/files/irb/handbook-irb.pdf)**
  + **Tips to achieve 8th grade reading level**
  + [**https://www.wheatmark.com/5-easy-tips-to-lower-your-flesch-kincaid-readability-score/**](https://www.wheatmark.com/5-easy-tips-to-lower-your-flesch-kincaid-readability-score/)
  + [**https://readabilityformulas.com/articles/how-can-i-simplify-my-writing.php**](https://readabilityformulas.com/articles/how-can-i-simplify-my-writing.php)
  + [**https://readable.com/blog/7-strategies-to-simplify-your-writing-and-improve-readability/**](https://readable.com/blog/7-strategies-to-simplify-your-writing-and-improve-readability/)

**Note; Inclusion of the Title can bump the reading level significantly! When checking reading level it is OK to not include the title when assessing the reading level.**

[**CFR 46.116 and 46.117 Informed Consent**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)

**WHEN YOU COMPLETE YOUR CONSENT FORM, PLEASE REMOVE THIS EXPLANATORY SECTION AND CONVERT REMAINDER OF YOUR TEXT TO BLACK, 12-14 FONT.**

**THE UNIVERSITY OF TEXAS AT TYLER**

**Informed Consent to Participate in Research**

**Institutional Review Board #**

**Approval Date:**

**Title of Research Study**:

**Project Description:**  I am a (explain your title and role) at The University of Texas at Tyler, and I want to (see/explore/etc.) (explain in very *simple*  terms what you want to know as a result of this study). (Explain why this research would be important for people meeting inclusion criteria for this study or similar populations).

**If you agree to participate in this study, we would ask you to do the following things:**

Explain in *bulleted* format and in extremely simple terms (5th-8th grade level) what the participant would have to do in the order they would occur. Be sure to include locations of data collection, time frames of frequency, duration, etc.

**Potential Risks:** Any risks on the IRB application must be reflected here, but in simpler terms. For those who sign consent forms or there are any identifiable data, include this statement:With any research study there is always a risk of a breach of confidentiality. Then explain how those breaches are minimized or eliminated.

When you feel there are no risks, put this statement:We know of no known risks other than those encountered in normal everyday life.

**Potential Benefits:** Any benefits on the IRB application must be reflected here, but in simpler terms. This statement is NOT to say how the study benefits the participant, but how the findings of your research may help society in general, or contribute to science.

**Understanding of Participants:**

1. I have been given a chance to ask any questions about this research study. The researcher has answered my questions. I understand any and all possible risks.
2. If I sign this consent form I know it means that:

* I am taking part in this study because I want to. I chose to take part in this study after having been told about the study and how it will affect me.
* I know that I am free to not be in this study. If I choose to not take part in the study, then nothing will happen to me as a result of my choice.
* I know that I have been told that if I choose to be in the study, then I can stop at any time. I know that if I do stop being a part of the study, then nothing will happen to me.
* I know the information that is obtained from me during this study may be shared with other researchers, but if so, my name and any other identifying information will not be with this information. I know the researchers may keep this information for a minimum of three years or until I inform them that I no longer give permission to share it. I know that it is unknown as to how long other researchers will keep my information.

1. I have been promised that that my name or other identifying information will not be in any reports (presentations, publications) about this study unless I give my permission. The UT Tyler Institutional Review Board (the group that makes sure that research is done correctly and that procedures are in place to protect the safety of research participants) may look at the research documents. This is a part of their monitoring procedure and will be kept confidential.
2. If I have any questions concerning my participation in this project, I will contact the principal researcher: (enter researcher contact information)
3. If I have any questions concerning my rights as a research subject, I will contact the Human Research Protections Program at (903) 877-7632 or at irb@uthct.edu.
4. Research results from this study may be shared with other researchers for future research but any identifying information will be removed by the principal researcher of this study before information is shared.

**CONSENT/PERMISSION FOR PARTICIPATION IN THIS RESEARCH STUDY**

I have read and understood what has been explained to me. I give my permission totake part in this study as it is explained to me. I give the study researcher permission to register me in this study. I have received a signed copy of this consent form.

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Signature of Participant Date

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

Printed Name of Participant

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

Witness to Signature

1. I have discussed this project with the participant, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks. I believe the participant understood this explanation.

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Researcher/Principal Investigator Date Time (CST)