CTSI Consent Executive Summary

***Note to the Investigator:*** *Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the participants' future reference.*

***DIRECTIONS FOR USE OF THIS TEMPLATE:***

* ***This template is required for studies that go through the Clinical & Translational Science Institute (CTSI), but any study may use this document to accompany their full consent document.***
* *You are encouraged to try to keep this document as short and simple as possible (e.g. one page or less). Detailed descriptions should be reserved for the full consent document.*
* ***Do not adjust the bottom margin or use the footer.*** *Do not delete the watermark fields in the footer.*
* *Replace bracketed items in the header, such as “[Title of Study]” with the requested information.*
* *Read guidelines for each section, complete as applicable for your project and then delete the template guidelines.*
* *Example text may be used if needed. Instructions in red font should be replaced or deleted.*
* *Phrases such as “I understand…” or “You understand…” are not appropriate and should not be included in the document.*
* *The document should be written at an appropriate grade level for the group of participants. Most word processors include the ability to assess the reading level.*

**STUDY SHORT TITLE:**

**RESEARCHER (PI):**

**SPONSOR/SUPPORTER:**

Include the following statement verbatim:

We are inviting you to take part in a research study. *Please read the entire consent form in addition to this summary, ask questions, and take time to understand the study before you make any decision.*

These sections should provide very brief and direct information about the study. Example text is provided; revise as needed.

**Why me?** We have selected you because you…

**What are the study goals?** To learn how…

**What if I don’t want to take part?** Taking part is up to you. There is no pressure to take part, and no standard treatment or care will be withheld if you don’t take part.

**What is experimental in this study?** The parts of the study that are experimental are…

**Is there a sugar pill or fake treatment?**

**Are there risks?** Yes, there are risks. Risks are listed in detail in the “Risks” section of the consent form. Please read the Risks section and all sections carefully.

Revise if there *is* direct benefit to the participants.

**Are there any benefits?** There is no direct benefit to you to take part in this study. What we learn from this study may help other people in the future.

**Are there costs?**

**What about time, inconvenience, or travel?**

**Will I be paid for my time?**

***If you decide to participate, please keep a copy of this summary and the consent form.***