Institutional Review Board
Informed Consent Document for Research

Principal Investigator: **Revision Date:**
Study Title:
Institution/Hospital:

This informed consent document applies to
(Example: adults, child 12-17 years, parent, legal representative, healthy volunteer, etc.)

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. [INSERT ONLY IF APPLICABLE: You may choose not to participate and receive alternative treatments without affecting your healthcare/services or other rights]. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

1. **Purpose of the study:**

   The purpose of the study is

   You are being asked to participate in a research study because

2. **Procedures to be followed and approximate duration of the study:**

3. **Expected costs:**

4. **Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:**

5. **Unforeseeable risks:**

   [INSERT ONLY IF APPLICABLE: Because this treatment is investigational, meaning non-FDA approved, there may be unknown or unforeseeable risks associated with participation.]

6. **Compensation in case of study-related injury:**

7. **Good effects that might result from this study:**

   a) The benefits to science and humankind that <u>might</u> result from this study.
   b) The benefits you might get from being in this study.

8. **Alternative treatments available:**

9. **Compensation for participation:**

10. **Circumstances under which the Principal Investigator may withdraw you from study participation:**

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11. What happens if you choose to withdraw from study participation?

12. Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact **(INSERT NAME OF RESEARCHER)** at **(INSERT RESEARCHER'S PHONE NUMBER)** or my Faculty Advisor**, (INSERT NAME OF FACULTY ADVISOR)** at **(INSERT FACULTY ADVISOR'S NUMBER)**.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (**INSERT NUMBER AND CONTACT INFORMATION**).

13. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. *[Insert a description of how records and data/specimens will be stored and maintained and who will have access. Describe any study specific issues that may increase the risk of breach of confidentiality.]* ***See the description and examples in the IRB application.***

14. Privacy:

[INSERT STUDY SPECIFIC "Privacy Information Template Language", which can be located at:

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____