# **INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM FOR CLINICAL STUDIES**

**Protocol Title**:

Application No.:

**Sponsor:** If applicable

**Principal Investigator:** Name, Telephone number, E-mail

1. **What should you know about this study?**
2. You are being asked to join a research study.
3. This consent form explains the research study and your participation in the study.
4. Please read it carefully and take as much time as you need.
5. Please ask questions at any time about anything you do not understand.
6. Your participation is voluntary. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
7. During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
8. Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
9. For clinical trials: A description of this clinical trial will be available at …………………You can search the Web site at any time.
10. If you have clinical tests done as part of this research study, a statement will be added to your medical record that you are in this research study. Results from any clinical tests will be included in your medical record. Persons other than the investigators and care providers will not have access to this information.
11. **Why is this research being done?**

This research is being done to.... (Provide objectives in simple language)

1. **What will happen if you join this study?**

If you agree to be in this study, we will ask you to do the following things:

(Provide methods /interventions/ procedures in simple language)

**How long will you be in the study?**

You will be in this study for (Duration of the participation of the subject)

**How many people will be in this study?** (Sample size)

1. **What are the risks or discomforts of the study?**

(Provide all the potential risks and discomforts associated with research study design in simple language)

1. **Are there risks related to pregnancy?** (If the subject is a female)
2. **Are there any benefits to you being in the study?**

(Provide specific benefits to the subjects -if any- in simple language)

1. **What are your options if you do not want to be in the study?**

You do not have to join this study. If you do not join, your care will not be affected.

1. **Will it cost you anything to be in this study?**

Yes **** No ****

1. **Will you be paid if you join this study?**

Yes **** No ****

1. **Can you leave the study early?**

YES, if you wish you do not have to continue in this study

1. **What are some of the reasons for early discontinuation of the study?**

(Provide specific reasons -if any- in simple language)

1. **How will your privacy be protected?**
2. ALL information about you will be protected.
3. The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form.
4. Depending upon the methodology, the investigator may also collect other information including your name, address, date of birth, and health information.
5. Only people on the research team will know your identity and that you are a participant in the research study.
6. You may cancel your permission to use your information at any time by notifying the Principal Investigator of this study in writing. The Principal Investigator’s name, address, phone and fax information are on page one of this consent form. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.
7. **Will the study require any of your other healthcare providers to share your health information with the researchers of this study?**

Yes **** No ****

1. **If the answer is YES to the above, will it affect the confidentiality of your information and provision of care for you**

Yes **** No ****

(If yes, provide specific explanations in simple language)

1. **What happens to Data, Tissue, Blood and Specimens that are collected in the study (and transported elsewhere-if applicable)?**

Biological samples and tissues are used in this study

Yes **** No ****

Biological samples and tissues are transported elsewhere for further analysis

Yes **** No ****

This study cannot be undertaken without your permission to use the biological samples collected from you. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

* You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
* The investigators of this research may study your data and the tissue, blood or other specimens collected from you.
* If data, tissue, blood, or other specimens are in a form that identifies you, the investigator may use them for future research only with your consent.
* If data, tissue, blood or other specimens are in a form that does not identify you, they may be shared with other academic medical centres for further analysis
* You will not own any product or idea created by the researchers working on this study.
* You will not receive any financial benefit from the creation, use or sale of such a product or idea.

1. **Assent Statement** (if it is an older child but not attained adulthood by age, explain the study and methods in a manner understandable to the child and obtain assent)
2. **What other things should you know about this research study?**

1. **What do you do if you have questions about the study?**

Call the principal investigator. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the University Ethics Committee at 662 2002.