IRB Informed Consent Form (Sample)

This is a generic sample form to help you address most situations. Please adapt as appropriate for your research protocol and institution.

Project Information	
Project Title:	
Principal Investigator (PI) Name: Organization /Institute Name: Contact #:	
Other Investigators Details: Co-Investigator Name: Organization /Institute Name: Contact #:	
IRB Ref No:	Sponsor Details :

The consent document must be written and understandable to subjects. The language must be nontechnical (comparable to a newspaper or general circulation magazine), and scientific, technical, or medical terms must be plainly defined.

Informed Consent, whether oral or written, may not include language that appears to waive subjects' legal rights or appears to release the investigators or anyone else from liability for negligence.

1. PURPOSE OF THIS RESEARCH STUDY

PROCEDURES

- Describe procedures: "You will be asked to do..."
- Identify any procedures that are experimental/investigational/non-therapeutic.
- Define the expected duration of the subject's participation.
- Indicate the type and frequency of monitoring during and after the study.

2. POSSIBLE RISKS OR DISCOMFORT

These include physical injury and possibly psychological, social, or economic harm, discomfort, or inconvenience.

- Describe known or possible risks. If unknown, state so. ○ Indicate if there are special risks to women of childbearing age; if relevant, state that the study may involve risks that are currently unforeseeable, e.g., to developing fetus
- If the subject's participation will continue over time, state: "Any new information developed during the study that may affect your willingness to continue ***will communicate participation*** to you."
- If applicable, state that a particular treatment or procedure may involve currently unforeseeable risks (to the subject, embryo, or fetus, for example.)

3. POSSIBLE BENEFITS

○ Describe any benefits to the subject that may be reasonably expected. If the research does not directly benefit the participant, explain possible help to others.

4. FINANCIAL CONSIDERATIONS

- Explain any financial compensation or state: "There is no financial compensation for your participation in this research."
- Describe any additional costs to the subject that might result from participation in this study, e.g., expenditures expected in coming to the research venue, etc.
- Please indicate any financial benefits to the subjects, including the study's therapeutic or diagnostic costs.

5. AVAILABLE TREATMENT ALTERNATIVES

○ If the procedure involves an experimental treatment, indicate whether other no experimental (conventional) treatments are available and compare the relative risks (if known).

6. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- Include statements like: "This study involves (minimal risk/greater than minimal risk)." In the event that more significant than minimal risk is involved, provide the subject with the following information.
- "If you are injured directly from this research study, emergency medical care will be provided by [name] medical staff or by transporting you to your doctor or medical Centre." Indicate who will pay for this treatment.

7. CONFIDENTIALITY

○ Describe the extent to which you will maintain the confidentiality of records identifying the subject.

"Your identity in this study will be treated as confidential. The study results, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you."

In addition, list steps to protect confidentiality, such as codes for identifying data.

8. TERMINATION OF RESEARCH STUDY

Include a statement: "You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to participate. You will be provided with any significant new findings developed during

this study that may relate to or influence your willingness to continue participation. In the event, you decide to discontinue your participation in the study,

- These are the potential consequences that may result: (list)
- Please notify (name, telephone no., etc.) of your decision or follow this procedure (describe) so you can terminate your participation immediately.

In addition, your participation in the study may be terminated by the investigator or the sponsor without your Consent."

9. AVAILABLE SOURCES OF INFORMATION

- The Principal Investigator will answer any further questions you have about this study:

  Name: _____

  Phone Number: _____

- Any questions you may have about your rights as a research subject will be answered by:

  Name: _____

  Phone Number: _____

If applicable:

- In case of a research-related emergency, call:
  Day Emergency Number:
  Night Emergency Number:

10. AUTHORIZATION

I have read and understand this consent form and volunteered to participate in this research study. **I understand that I will receive a copy of this form**.

Participant Name: _____

Participant's Signature or Thump impression: _____ Date: _____

Principal Investigator Name & Signature: _____

Principle Investigator's Signature: _____ Date: _____

Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____ Date: _____