**GUIDELINES FOR DRAFTING AN INFORMED CONSENT FORM**

1. All studies involving human subjects should have a properly drafted consent form. No study should be done on human subjects without obtaining informed consent and sufficiently before the start of the study, at an appropriate time, and not at a time when he/she is under stress such as surgical procedure, and is unable to understand the study. Ensure the subject does not have impaired judgment.
2. Consent may be written or verbal or telephonic. In case of unwritten consent, it should be signed by the person taking the consent.
3. In case of a minor, consent from guardian / parents is needed.
4. In case of a mentally or physically incapacitated subject or children, consent should be obtained from parents/guardian or immediate relative such as, wife or husband (having no conflict of interest), father or mother, brother or sister etc.
5. In case of community studies, community leaders, elders, local political leaders, religious leaders (in certain cases), and governmental officials should be taken into confidence, and a written consent should be obtained.
6. In case of doing a study in other locations such as other hospitals and clinics, permission from appropriate authority or physicians should also be obtained.
7. The consent form should be in English, Urdu or other local language if needed. These should be identical in such a way that the translation of one into other is similar. The language should be easy which can be understood by study subjects (uneducated or primary passed). Use of technical terms should be avoided.
8. A properly drafted consent form should contain the following important points.
   1. Information sheet. There should be one paragraph or page giving information about the nature of study, its purpose and need, possible benefits of the study, and procedures to be carried out on the study subjects.
   2. Possible risks and benefits to the study subjects
   3. Availability of alternate treatment in case of therapeutic trials
   4. Voluntary participation without any compulsion, moral or otherwise and without any financial incentive or coercion. However, financial assistance or reimbursement for time and traveling may/should be provided to study subjects; which should commensurate with the time spent, and should not be too high.
   5. Right to withdraw from the study at any time without affecting their rights and treatment.
   6. Confidentiality
   7. If any specimen is to be stored, its time of storage and permission to use it in further research.
   8. Name and contact number of the investigator in case the study subject wants further clarification or information about study.
   9. Authorization from study subjects with their signature, thumb impression, signature of witness etc.





**CONSENT FORM**

***For MINIMAL RISK Medical Human Subject Research***

(e.g., for blood draws, data collection, leftover specimens, interviews, surveys etc.)

* Instructional text appears in red  ***and should be removed prior to submission to the ERC***.
* Red text in parentheses ( ) should be replaced by information for your study, e.g., (your ***name*** here)

**CONTACT INFORMATION:**

Name of Principal Investigator -----------------------------------------------------------------------

Address and phone number -------------------------------------------------------------------------

-----------------------------------------------------------------------------------------------------------------

-----------------------------------------------------------------------------------------------------------------

**DESCRIPTION:** You are invited to participate in a research study on

* (describe project in non-technical language; include types of questions that will be asked, if applicable;
* (Explain purpose of the research).
* (Describe procedures, questions, survey, mention video/audio recording (if applicable), and what will become of tapes after use, e.g., shown at scientific meetings; describe the final disposition of the material, data, recording).

**RISKS AND BENEFITS:**

* The risks associated with this study are (describe foreseeable risks or discomfort to subjects; if none, state as such)**.**
* The benefits which may reasonably be expected to result from this study are

(describe any benefits; if none, state as such).

* Your decision whether or not to participate in this study will not affect your employment/medical care.

**TIME INVOLVEMENT:** Your participation in this experiment will take approximately

(amount of time).

**PAYMENTS:** You will receive (describe reimbursement; where there is none, state as such) as payment for your participation.

**PARTICIPANT’S RIGHTS:** If you have read this form and have decided to participate in this project, please understand that

* Your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
* You have the right to refuse to answer particular questions.
* If you agree, your identity will be made known; otherwise your privacy will be maintained all published and written data resulting from the study.

**EXPERIMENTAL SUBJECTS BILL OF RIGHTS:** As a research participant kindly check that whether your following rights have been fulfilled:

* Be informed of the nature and purpose of the experiment;
* be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
* Be given a description of any attendant discomforts and risks reasonably to be expected;
* Be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
* Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
* Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
* Be given an opportunity to ask questions concerning the experiment or the procedures involved;
* Be instructed that consent to participate in the medical experiment may be withdrawn at any time and you may discontinue participation without prejudice;
* Be given a copy of the signed and dated consent form; and
* Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

The extra copy of this consent form is for you to keep.

Signature of Adult Participant Date

When consent is obtained from legally authorized representative LAR (e.g., parent(s), guardian), include these signature lines for representatives and a description of their authority to act for the participant:

Signature of Parent, Guardian Date

**Person Obtaining Consent**

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject’s Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

Signature of Person Obtaining Consent Date

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a **short form** foreign language consent.

Signature of witness Date

(e.g., staff, translator/interpreter, family member, or other person who speaks both English

and the participant’s language)

* Translated short form must be signed and dated by both the participant (and their LAR) and the witness.
* The English consent form (summary form) must be signed by the witness and the POC. The non-English speaking participant does not sign the English consent.