**Guidelines for the Preparation of the Informed Consent Form (ICF)**

**(FOR RESEARCHER’S USE ONLY)**

While submitting your project to the CNU ERC, ensure that you have included an ICF that is prepared as per the guidelines for ICMR Ethical Guidelines 2006, ICH-Good Clinical Practice, Declaration of Helsinki and PHREB National Ethical Guidelines.

Note to investigators regarding the process of obtaining informed and understood consent:

1. ICF in English and dialect spoken and understood by research participants
2. Font style: Arial Narrow; Size: 12
3. All the consent forms must have version no., date, page no. in the footer
4. Separate forms should be prepared when minors (children) are study participants; assent form for the mature minors (7-18 years old) and consent form for the parents (refer to Form 5).
5. The ICF and PIS describes minimal requirements. Feel free to add other information if you wish to, if necessary.
6. The prospective participant should be given a Participant Information Sheet (PIS) first.
7. The participant should then be encouraged to read the PIS and think it over, preferably for a period of 24 hours. Following which, the participant should be served a questionnaire to ensure that he/she is aware of his/her own rights as a participant in the study. The ICF should be served to the participant only after ensuring that the participant is now prepared for informed decision making.
8. The lead researchers are urged by the CNU ERC to use the simple non-technical words or should add the glossary and follow the sample template of PIS and ICF.
9. Use of alternative wording or different formats may slow down the review process. The PIS should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.
10. The researcher should explain all the details to the participant in a language she/he understands.
11. The ICF must have the name and contact no. of the lead researcher or of any other co- investigator in case of an emergency, or even to seek answers to their queries.
12. A copy of the signed ICF must be given to prospective participants. A receipt of a copy of ICF by the subject should be documented by the investigator in the source documents.
13. Please tailor your ICF to suit the needs of the research population.
14. If your form is more than one page, there should be a line at the bottom of each page for the subject’s initials, except for the last page where the signature is obtained.
15. Please make provision on the form of signature/thumb impression if the participant is unable to provide signature/ written consent by virtue of medical reason/ disability.

**PARTICIPANT INFORMATION SHEET (PIS)**

| Project Title: |
| --- |
| Investigator/s: |
| Sponsor: |

Purpose and conduct of study

* Why is the study being done? What has been done previously?
* How will the present study be conducted?
* What is the nature and extent of involvement of research participants?

Risks and Inconveniences

* Will there be discomforts? Are these described clearly?
* Will there be risks? Are these explained fully?
* Are there other effects the participants need to know in order to make a decision?

Possible benefit for the participants

* What benefits can the participants expect?

Compensation

* Will there be reimbursement of travel or meal expenses? Compensation for loss of income?
* Are there other financial considerations?

Provision for injury or related illness

* Will the participants be given free treatment in case of injury or illness incurred as a result of participating in the study?

Contact person

* Who is the person knowledgeable about the research and rights of the participants? How can he/she be contacted?

Voluntariness of Participation

* Is the participant free of any coercion in participating? Is there assurance that the participant can withdraw anytime without affecting his/her normal activities, grades, etc?
* Is there provision for obtaining the informed consent from the legal representative in case of minors, the mentally handicapped or the incapacitated?

Confidentiality

* Is there a statement that describes the measures that will be taken to keep and ensure the confidentiality of the participant’s records?

**INFORMED CONSENT FORM (ICF)**

| Study Title: |
| --- |
| Subject’s Initials: |
| Date of birth/Age |

1. I confirm that I have read and understood the information sheet dated \_\_\_\_\_\_\_\_ for the above study and have the opportunity to ask questions;
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected;
3. I understand that the sponsor of the research study, others working on the sponsor’s behalf, CNU ERC and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access;
4. However, I understand that my identity will not be revealed in any information released to third parties or published;
5. I agree not to restrict the use of any data or results that arise from this study provided such as use is only for scientific purpose(s); and
6. I agree to take part in the above study.

I have read the above information and agreed to participate in this study. I have received a copy of this form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of signature of the participant or Date

Legal Acceptable Representative

Address:

Occupation:

Phone no:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Impartial Witness’ signature and date: Date

Address:

Phone no:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and signature of Primary Investigator Date

Address:

Phone no: