

REGIONAL HEALTH RESEARCH AND DEVELOPMENT COMMITTEE-XI
Department of Science and Technology

PROJECT TITLE:

PROPONENT/S:

A. CHECKLIST FOR INFORMED CONSENT

YES NO N/A

- | | | | |
|---|-----|-----|-----|
| 1. Demonstrates that potential benefit outweigh potential harm through literature reviews and preview trials | | | |
| 2. Informed consent form (in English and Filipino or in a language understandable to the study participants) | [] | [] | [] |
| 3. Contains the following of an informed consent. | | | |
| a. The study is investigative in nature | [] | [] | [] |
| b. The number of study participants in the trial | [] | [] | [] |
| c. The purpose / objective of the study | [] | [] | [] |
| d. The trial procedures to be done, including all invasive procedures | [] | [] | [] |
| e. The expected duration of a subject's involvement and number of follow-up visits | [] | [] | [] |
| f. Potential or direct benefits (if any) from participation | [] | [] | [] |
| g. Alternative procedures (s) or course(s) of treatment that may be available | [] | [] | [] |
| h. The risks, discomforts and inconveniences associated with the study, or when applicable, to an embryo, fetus or nursing infant | [] | [] | [] |
| i. The provision for management of adverse reaction | [] | [] | [] |
| j. The study participant's responsibilities | [] | [] | [] |
| k. A statement that participation is voluntary | [] | [] | [] |
| l. A statement giving study participants the option to Withdraw | [] | [] | [] |
| m. That a study participant shall be given information that may be relevant to his/her willingness to continue participation | [] | [] | [] |
| n. A statement guaranteeing confidentiality | [] | [] | [] |
| o. Circumstances/reasons under which the subject's participation may be terminated | [] | [] | [] |
| p. A statement on reimbursement of trial-related expenses of participants (if applicable) | [] | [] | [] |
| q. A statement on reimbursement of trial-related expenses of participants (if applicable) | [] | [] | [] |
| r. A statement guaranteeing medical care/indemnification for adverse events not subjects to previous waiver | [] | [] | [] |
| s. Whom to contact in case of questions on adverse event (telephone number of contacts included) | [] | [] | [] |

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|---|-------------|
| 4. Provision for management of adverse reactions | [] [] [] |
| 5. Interim analysis and provisional or mandatory cessation guidelines in case harmful effects are demonstrated during the study. | [] [] [] |
| 6. Full disclosure of potential sources of conflict of interest involving any of the authors or the granting agency. | [] [] [] |
| 7. Full disclosure of publication rights | [] [] [] |
| 8. Amount and method of reimbursement of trial-related expenses of the study participants. | [] [] [] |
| 9. Non-materials compensation to participant such as health education or other creative benefits, where no clear, direct benefit from the project will be received by the participants. | [] [] [] |
| 10. Guarantee of medical care/indemnification of study participants in case of trial-related injuries, which shall not be subject to previous waiver | [] [] [] |
| 11. A description of who may solicit consent and how and when it will be done | [] [] [] |
| 12. A description of who may give consent (especially in studies involving minors and those who are not legally competent to give consent) | [] [] [] |

NOTE:

The study participant or representative shall be given a copy of the signed and dated written informed consent form.

Ethical considerations in the study should be stated so that the Ethics Review Committee will be able to assess if the investigators have given attention to appropriate ethics part of the research.

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B. COMMENTS:

- | | |
|--------------------------|--|
| <input type="checkbox"/> | Approval / Favorable opinion |
| <input type="checkbox"/> | Modifications required prior to approval |
| <input type="checkbox"/> | Disapproval / Negative opinion |
| | Reason/s for disapproval |

RHRDC - ETHICS Chair
 Signature over printed name
 Date: _____

C. FINAL ACTION:

<input type="checkbox"/>
<input type="checkbox"/>

Approved

Disapproved

DR. ALVIN S. CONCHA
Chair-Ethics and Review Committee
RHRDC-XI

MR. ELVI TAMAYO
Member
Ethics and Review Committee
RHRDC-XI

DR. BERNADETTE DEL ROSARIO
Member
Ethics and Review Committee
RHRDC-XI

PROF. JOSE MA. ERNESTO Y. TOMACRUZ
Member
Ethics and Review Committee
RHRDC-XI