

APPENDIX 1: GUIDELINES FOR THE CONTENT OF RESEARCH PROTOCOLS
– CARPHA’S Research Ethics Committee

The following information should be included in research protocols:

1. **TITLE OF THE PROPOSED RESEARCH**
2. **DATE** (and Version - if there has been a previous submission)
3. **NAME AND ADDRESS (Postal and E-mail) or ALL THE INVESTIGATORS, COLLABORATORS, AND/OR SUPERVISORS** (starting with the principal investigator).
Indicate if which parts of the protocols each investigator will be responsible for, who will actually carry out if any procedure on participants, and where appropriate, what training they have had.
4. **SITE/S OF RESEARCH** (Attention should be paid to the facilities available for participants’ comfort, and availability of emergency procedures in the event of an unanticipated occurrence).
5. **NUMBERS OF RESEARCH PARTICIPANTS TO BE ENROLLED**
6. **PROPOSED DURATION OF THE STUDY**
7. **A SUMMARY OF THE PROPOSED STUDY** — not more than 300 words and should include:
 - I. *The hypothesis and scientific basis or justification for the study*
 - II. *The usefulness and significance of the study*
 - III. *An outline of the study design*
 - IV. *An indication of steps taken to ensure and maintain confidentiality*
 - V. *An assessment of the benefits to participants (and/or groups in the community or the entire community) and the risks*
8. **THE PROJECT PROPOSAL** (must be submitted in the template provided) — to include:
 - A. An introduction and background information on the research topic
 - B. A clear statement of the objectives of the research proposal

- C. The justification for the research (*This should include review of the current knowledge from the literature on the topic, with an explanation why this project is necessary, and how it will contribute to the overall knowledge in this area*)
- D. Materials and methods
- These include:
- Details of procedures to be performed (*e. g. volume of blood, the frequency, timing, and possible site of the blood-taking; any drug administration, physiological measures, etc.*)
 - Which procedures may cause pain and/or discomfort for research participants
 - Choice of participants, inclusion exclusion criteria, number of participants (and a justification for that number), any controls, etc.
 - A statement that participants were selected only because of the specific problem under investigation, and not because of their easy availability, diminished autonomy, or any social bias.
- E. The name, address, telephone and fax numbers, as well as email address of a contact person outside of the research process
- F. A statement confirming that reasonable time will be given for the participant to consider his/her involvement
- G. Procedures for obtaining informed consent, including statements that the researcher/s will read the informed consent form to the participant or his/her legal guardian and will provide that person with a copy of the form, that questions from the person will be invited, and that all efforts will be made to ensure that s/he understands its content before the seeking of consent
- H. A copy of the informed consent form and recruitment posters (see details below)
- I. Methods to protect the confidentiality of participants, and methods to ensure that a participant who opts out of a research endeavour is well protected as far as health care delivery is concerned and not disadvantaged in any way.
- J. Methods for data collection, analysis and secure storage
- K. Assumptions made
- L. Relevant references (i.e. literature citation)

9. **THE INFORMED CONSENT FORM** should include the following:

- a. Statements in language written for comprehension by the lay person outlining the purpose of the research, what will be done in the research study, and indicating that this has been explained orally and in writing to the participant (or the participant's parent or legal guardian — if a child or mentally challenged individual) who understands what will be done. These will be countersigned by the participant or his/her legally authorized representative;
- b. Explicit statements about risk or discomfort to the participant, with an assessment of the degree of risk, and viable alternatives;
- c. A statement that the participant's involvement is voluntary, and that refusal to participate or (if after having agreed to participate) withdrawal from the study at any time will not affect the participant's access to or the type of care to which s/he is entitled;
- d. The name, address, telephone and fax numbers, as well as email address of a contact person for any queries;
- e. A statement confirming that reasonable time will be given for the participant to consider her/his involvement;
- f. Statements that the participant or her/his legal guardian has read the informed consent document, or that it has been read to her/him, and that s/he understands its contents; that a copy will be given to the participant; and that the signature of the participant or the legal guardian indicates that s/he has freely agreed to participate;
- g. The signature of a witness to the consent procedure who is **not** connected to the research undertaking (i.e. a relative, caretaker, friend)