PHARMACY, MEDICINES & POISONS BOARD

Form CT 9

Confidential

PHARMACY ACT [CHAPTER 35A:03]

CONSENT OF PERSON WHO WILL PARTICIPATE IN A CLINICAL TRIAL

(To be completed in triplicate)

I *(state full names)*
……
……

born on the ....

of *(state address)*
.....……
……
do hereby confirm that I have freely consented to participating in the clinical trial to be conducted by

.....……
……

at *(state name of institution or place where the trial is to be conducted).*……

for the purposes of
.....……
……
……..

Date …… ……
Signature of person

……
……..
Witness

Guardian's signature, if necessary

CHECK LIST OF INFORMED CONSENT PROCESS

Informed consent shall include the following elements:-

1. Statement that the study involves research.

2. Explanation of the purposes of the research.

3. Expected duration of the subject's participation in the research.

4. Description of the procedures to be followed.

5. Identification of any procedures that are experimental.

6. Description any reasonably foreseeable risks or discomfort to the subject.

7. Description of any benefits to the subject or to others that may reasonably be expected from the research.

8. Disclosure of appropriate alternate procedures or courses of treatment, if any, that might be advantageous to the subject.

9. Statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained, and if applicable, a statement of the possibility that the food and drug administration may inspect the records.

10. For research involving more that minimal risk, an explanation as to whether any compensation is available if injury occurs, and if so, what they consist of, or where further information can be obtained.

11. Explanation of whom to contact for answers to pertinent questions about the research, research subject's rights, and whom to contact in the event of a research- related injury to the subject.

12. Statement that participation is voluntary, thatrefusa1 to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

13. Statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue, will be provided to the subject.

14. The last sentence should explicitly read "I voluntary agree".

15. The consent form should be translated into the local language.

Regulatory, ethical and scientific review are done through:-

- scientific analysis.
- ethical analysis and reasoning
- Regulatory analysis and reasoning

Ethical reasoning and analysis include the following factors:-

- Identifying a problem that appears to be morally questionable or troubling.
- Accurately understanding the facts and circumstances pertaining to the problem.
- Identifying common and shared values (including the three principles namely:- beneficence, respect and justice according to *Belmont* report) that pertain to the problem.
- Identifying and using tried and true moral arguments.
- Making a considered moral judgment (finding an ethical solution) by relating the moral values, arguments, and pertinent examples to the problem in question.

Regulatory analysis and reasoning will be in accordance with sections 42-44 of the Pharmacy Act (1988)