2.1 Principles for research involving human participants

A number of principles should guide research that involves human participants. For a general statement of the principles, applicants should consult the Declaration of Helsinki. These principles include, but are not limited to, the following, which will be used by ethics committees to assess research proposals:

2.1.1 Informed consent

The ethical foundation of informed consent is respect for persons. Researchers thus should make themselves familiar with the provisions of the Code of Health and Disability Consumers' Rights.

Informed consent is required from participants involved in human research especially if the research constitutes a health care procedure. If informed consent cannot be obtained in writing, the circumstances under which consent was obtained should be recorded. If the participants

themselves cannot provide informed consent, justification must be provided for using these participants within the research. Ethics committees will be required to consider if the circumstances are appropriate for the waiving of informed consent. In cases where deception is used in research, justification must be provided as well as a method of debriefing participants.

Some of the basic criteria of informed consent to participate in a health research are:

(a) the participants must be competent to understand the relevant issues prior to giving to their specific consent;

(b) information about the proposed research must be comprehensively, properly and appropriately given, including any likely outcomes of participation in the research;

(c) the participants' consent must be voluntary and not unduly influenced by financial reward (see **2.1.5 Payments for Participation in Research**), or by duress in any manner and the involvement of dependent or vulnerable groups must be appropriate with measures in place to ensure they are not exploited;

(d) participants must be able to withdraw from the research at any time without the waiver of any rights and without giving reasons; and

(e) in the case of those who are unable to give their own consent, for example the mentally incapacitated, the unconscious patient or children, proxy consent should be sought from a person with appropriate legal authority[1].