SOP: 13

PROCEDURE FOR REVIEWING THE RESEARCH PROPOSALS INVOLVING VULNERABLE POPULATION

PURPOSE

To review the research proposals submitted by the investigators which involves vulnerable population both scientifically and ethically

SCOPE

Applicable to IGIDS.

RESPONSIBILITY

All members of IEC and investigators are responsible for implementing this SOP.

PROCEDURE

1. The term vulnerable research participants refers to individuals whose willingness to volunteer in a research trial may be duly influenced; they include infants, children and adolescents, pregnant and lactating women, students and employees, mentally challenged patients, critically ill patients etc.
2. Vulnerable groups can become participants only if the study is designed to protect or advance the health of this population and for which the non-vulnerable group would not be suitable participants
3. In case of trials involving children, the assent of the child should be obtained (Children aged 7-18 years); in addition, consent should be obtained from parents/guardian.
4. Rights and welfare of people who are unable to provide informed consent must be protected. Informed consent should be obtained from legally authorized representatives in the presence of impartial witness and also with adequate explanation of risks and benefits.
5. Expert opinion of additional members would be obtained if necessary.

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