Institutional Review Board
Malabar Cancer Centre (IRB, MCC)

Title: Protection of Vulnerable Population in Clinical Research

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Approved By

Chairperson Member Secretary
(Institutional Ethics Committee)

SOP 15/VER1 ***Pages: 1 to 5***

15.1. PURPOSE:

The purpose of this SOP is to describe the policies and procedures for reviewing research involving vulnerable population such as children, prisoners, fetuses/neonates, pregnant women and individual with consent capacity impairment.

15.2. SCOPE:

This guideline is applicable to all members IRB-Institutional Ethics Committee (IEC) of Malabar Cancer Centre, involved in review of clinical trials proposals that include the vulnerable population.

15.3. INTRODUCTION:

The IRB-Institutional Ethics Committee (IEC) of Malabar Cancer Centre takes special consideration in protecting the welfare gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, pregnant women, and individuals with consent capacity impairment.
The IRB-IEC carefully considers group characteristics, such as economic, social, physical, and environmental conditions, to ensure that the research incorporates additional safeguards measures for vulnerable subjects.

The IRB-IEC may require additional safeguard measures to protect potentially vulnerable population. For instance, the IRB-IEC may require that the investigator submit each signed informed consent form to the IRB-IEC, that someone from the IRB-IEC oversee the consent process, or that a waiting period be established between initial contact and enrollment to allow time to allow the subject time for family discussion and query resolution, family discussion and questions.

IRB-IEC expects to follow the principals laid down in the ICMR-Ethical Guidelines for Biomedical Research on Human Participant.

15.4. RESPONSIBILITY:

It is the responsibility of the Chairperson and Member-Secretary of IRB-IEC to implement, amend and give training to other members of IRB of this SOP.

15.5. PROTOCOL REVIEW PROCESS: DETAILED INSTRUCTION

15.5.1. For Pregnant Women, Foetuse:

- Research involving pregnant women and fetuses should involve the least possible risk. The IRB-IEC will document specific findings to minimize the potential for risk or harm to the fetus, and additional attention must be given to the conditions for obtaining informed consent.

- The IRB-IEC will ensure that women are not encouraged to discontinue nursing for the sake of participation in research except in the cases where breast-feeding is harmful to the infant. IEC will also ensure that compensation in terms of supplying supplementary food such a milk formula will be considered in such circumstances.
- In the event of research related to pre-natal diagnostic techniques, IRB-IEC will ensure that such research is limited to detect foetal abnormalities or senetic disorders and not for sex determination.

15.5.2. Research involving Prisoners:

- Prisoners may have a limited ability to make truly voluntary and un-coerced decisions about whether or not to participate as research subject.

15.5.3. Children involved as subjects/ participants in Research:

- IRB-IEC requires special protections for research involving children. Under the regulations, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable conducted.

The proposed clinical research must fall within one of the four following categories:

(i) Clinical Trial not involving Minimal Risk.
(ii) Clinical trial involving greater than minimal risk, but presenting the prospect of direct benefits to the individual subjects.
(iii) Clinical trial involving greater than minimal risk, yield knowledge that can be generalized about subject's disorder or condition.

- Clinical trial not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children.

- Each category has specific conditions that must be included in their organization Standard Operating Procedures (SOPs) if the institution is involved in human research where children are in the subject population.

- **Parental/Legally acceptable representative Permission**:

  - The IRB-IEC require that adequate provisions are made for solicit the permission of each child's parents or guardian/legally acceptable representative.

  - Where parental permission is to be obtained, the IRB-IEC will determine whether permission of one parent is sufficient or whether permission must be obtained from both parents in order for the research to be conducted.

- **Assent of the Child**:

  (a) Provisions must also be made in the protocol to obtain the child's assent when the child is capable of giving assent.
  (b) IRB-IEC may determine that the assent of the child is not necessary if and only if all three of the following conditions are satisfied:
  (i) The research offers the child the possibility of direct benefit.
  (ii) The benefit is important to the health or well being of the child.
  (iii) The benefit is available only in the context of the research.

- IRB-IEC will take great care in approving research where the child is suffering from a life-threatening illness with little real chance of therapeutic benefit from the research.

- IRB-IEC will respect the child's refusal to participate in the research and will be cautious in allowing parents/ legally accepted representatives to overrule.

- IRB-IEC requires assent form is tailored for the child, with respect to his or her level of understanding. For young children, especially, the assent form should be designed as per the guidelines provided in the annexure of SOP 03/VER1 (*ANX3-VER1/SOP03/VER1*).

15.5.4. Clinical trial involving Decisionally Impaired Subjects:

- IRB-IEC will consider selection issues, privacy and confidentiality, coercion and undue influence, and risk-benefit analysis. Additional safeguards must be considered by the IRB-IEC to protect these subjects.

References:

1. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) Retrieved from *http://www.cdsco.nic.in/html/Schedule-Y 20 (Amended 20Version- 2005)*
2. WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) Retrieved from - *www.who.int/tdr/publications/publications*
3. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) (1996) Retrieved form - *http://www.ich.org/LOB/media/MEDIA482.pdf*
4. ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) Retrieved from - *http://www.icmr.nic.in/ethical guidelines.pdf*

GLOSSARY

Children: A young human being below the age of full physical development or below the legal age of majority.

Foetus : Means the product of conception from implantation until delivery.

Neonate : Means a newborn.

Pregnancy: This encompasses the period from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Decisionally-impaired Individuals: Decisionally-impaired individuals are those who have a diminished capacity for judgment and reasoning due to psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals, who may be considered decisionally impaired, with limited decision-making ability, are individuals under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps.