Title: Vulnerable Population

SOP Code: SOP/09/V1.2

Effective date : 04/03/2016

Table of Contents

The Declaration of Helsinki states that 'Medical research involving a underprivileged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of that population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.'

1. Purpose

The purpose of this SOP is to describe how the IEC will ensure that the rights and interests of vulnerable population are safeguarded. The EC will ensure that individuals or communities included for research are selected in such a way that the burdens and benefits of the research are equally distributed.

2. Scope

This SOP applies to the process by which the EC will protect the rights and interests of vulnerable population. Additional protection will be ensured depending upon the risk of harm and the likelihood of benefit.

3. Responsibility

It is the responsibility of the EC members to identify study proposals including vulnerable population and ensure that these are considered for full board. The EC will ensure that measures for safeguarding rights and interests of vulnerable participants are mentioned in the face sheet, study proposal, Participant /Assent Information Sheet/ and informed consent/assent form. They have the responsibility to ensure that the vulnerable population is not exploited and they will guide the investigators to design protocols and describe the process of informed consent in such a manner that this will be done.

4. Flow chart

No.	Activity	Responsibility
1	Receive the submitted documents ↓	IEC Secretariat
2	Determine protocols including vulnerable population ↓	IEC members and Chairperson
3	Review of protocol by appropriate reviewes and assess whether their inclusion is justified ↓	IEC members and Chairperson
4	Ensure measures for protecting rights and interests of vulnerable population are described in the face sheet ↓	IEC members and Chairperson
5	Review the Participant /Assent Information Sheet/ and Informed Consent/Assent form	IEC members and Chairperson

5. Detailed instructions

5.1 Determine protocols including vulnerable population

Project proposals presented before the Ethics Committee Meeting which includes vulnerable population: It is the responsibility of the EC to see whether the inclusion of

vulnerable populations in the study is justifiable or the population is just being exploited to generate clinical data. In such cases, appropriate reviewers will assess the risk and ensure measures for protecting their rights. Review of risk assessment will be documented in IEC minutes.

5.2 Vulnerable groups: Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed.

a. Research on genetics should not lead to **racial inequalities**;
b. Persons who are **economically or socially disadvantaged** should not be used to benefit those who are better off than them;
c. Rights and welfare of **mentally challenged and mentally differently able persons** who are incapable of giving informed consent or those with behavioural disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented;
d. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have **reduced autonomy** as research participants, since the consent provided may be under duress or various other compelling reasons.
e. Persons who are terminally ill, have incurable disease and mental illness.

5.2.1 Consideration issues and protection of specific vulnerable groups:

i. ***Children*** **:**

Before undertaking research/trial in children the investigator must ensure that –

a. Children will not be involved in research that could be carried out equally well with adults;
b. The purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;
c. A parent or legal guardian of each child has given proxy consent;
d. The assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;
e. Research should be conducted in settings in which the child and parent can obtain adequate Medical and psychological support;
f. Interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;
g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;
h. Interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;

i. The risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

ii. Pregnant or nursing women:

Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation.
As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

a. The justification of participation of these women in clinical trials would be that they **should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits.**
Example of such trials are,

- To test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child,
- Trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc.
- Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

b. **Research related to termination of pregnancy:** Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

c. **Research related to pre-natal diagnostic techniques :** In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

iii. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure providing information to the subject and his understanding of such consent, shall be maintained by the investigator for record.

6. Glossary

Vulnerability

- The Council for International Organizations of Medical Sciences **(CIOMS)** defines **vulnerability** as “Substantial incapacity to protect one’s own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means

of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group."

- **Vulnerable (research) participants:** Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. (WHO)

7. References

1. Ethical Guidelines for Biomedical Research on Human Participants , ICMR , 2006
2. E6 Good Clinical Practice: Consolidated Guidance, April 1996, ICH –GCP
3. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants , 2011
4. Training curriculum for ethics in clinical research - www.fhi.org
5. SOPs Ethics Committee for Research on Human
6. Order from Director General of Health Services (DGHS), Ministry of Health and Family Welfare, Office of Drugs Controller General (India), Gazette of Indian New Delhi, dated 31st July 2015 No.489.

8. **ANNEX**

ANNEX 1 Document history AF/EC/01/09/V1.2

ANNEX 1 AF/EC/01/09/V1.2

Document history

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.1	24th September 2014	Flow Chart improved on Page 3
Dr. Ragini Kulkarni	Version 1.2	4th March 2016	Inclusion of the paragraph under 5.2.1, bullet iii - regarding AV consent in case of vulnerable participants