SOPs for vulnerable population and special groups

I. Pregnant or nursing mothers: Pregnant or nursing women in any circumstances should not 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 fetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participant so if any Clinical trial except such trials as are designed to protect or advance the health of Pregnant or nursing women or fetuses 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 prenatal transmission of HIV infection from mother to child, trials for detecting fetal 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, GOl, I977.

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

II. Children: Before undertaking 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. Parents 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.

III. 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 behavioral 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, subordinate, employees, service personnel etc. who have reduced autonomy as research participants since the consent provided may be under duress or various other compelling reasons.