



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

Annexure 8

AX 08/SOP 20/V 7.1

Checklist-Requirements for Research involving economically/socially backward patients

Principal Investigator (Name, Designation & Affiliation):

IEC No. of the Project:

Study Title:

.....

	Yes	No	NA
Does the research pose greater than minimal risk to patients?	☐	☐	☐
If yes: Are convincing scientific and ethical justification given?	☐	☐	☐
If yes: Are adequate safeguard in place to minimize these risks?	☐	☐	☐
Do the anticipated benefits justify requiring the subjects to undertake the risks?	☐	☐	☐
Is inclusion of vulnerable population warranted?	☐	☐	☐
Can the research question be answered by using a non-vulnerable population?	☐	☐	☐
Will efforts be made to ensure that participants are free from coercion, exploitation, and /or unrealistic promises?	☐	☐	☐
Are provisions made to obtain the consent?	☐	☐	☐
Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?	☐	☐	☐
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	☐	☐	☐
Are special needs of counseling and confidentiality accounted for in the research design?	☐	☐	☐
Are there any special problems such as confidentiality and reporting that might arise in this research?	☐	☐	☐

Signature of Principal Investigator: Date:

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Comments	
Primary Reviewer Signature & Date:	