



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

Annexure 8

AX 08/SOP 20/V 7

Checklist-Requirements for Research involving economically/socially backward/illiterate 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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are convincing scientific and ethical justification given?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes: Are adequate safeguard in place to minimize these risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do the anticipated benefits justify requiring the subjects to undertake the risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is inclusion of vulnerable population warranted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Can the research question be answered by using a non-vulnerable population?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are provisions made to obtain the consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are special needs of counseling and confidentiality accounted for in the research design?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there any special problems such as confidentiality and reporting that might arise in this research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Signature of Principal Investigator: Date:

IEC Office use only

Comments

Primary Reviewer Signature & Date: