

## Annexure 8 AX 08/SOP 20/V6



Checklist - Requirements for Research Involving economically/socially backward/illiterate patients

### INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No. ....

Principal Investigator

Proj. No.-

Study

Title: \_\_\_\_\_

\_\_\_\_\_

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	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"/>

Comments-

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Name & Sign of Primary reviewer :

Date: