



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

Annexure 6

AX 06/SOP 20/V7

Checklist-Requirements for Research involving terminally ill 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 terminally ill 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 safeguards in place to minimize these risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are appropriate studies that have been conducted on animals and adults justified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If No: Is the lack of appropriate studies conducted on animals and adults justified?	<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 the 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 to 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 participant's 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:	