

Annexure 6 AX 06/SOP 20/V6.1



Checklist - Requirements for Research involving terminally ill patients

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

Principal Investigator Name: _____

Proj. No of IEC.- _____

Study Title: _____

RISK DETERMINATION	BENEFIT ASSEMENT	IEC ACTION
<input type="checkbox"/> Minimal	<input type="checkbox"/> With direct benefit <input type="checkbox"/> Without direct benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	<input type="checkbox"/> Potential benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	<input type="checkbox"/> No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	<input type="checkbox"/> Approved case by case (with special safeguards) <input type="checkbox"/> Not Approved
<input type="checkbox"/> Less than minimal risk	<input type="checkbox"/> With direct benefit <input type="checkbox"/> Without direct benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	<input type="checkbox"/> Potential benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	<input type="checkbox"/> No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	<input type="checkbox"/> Approved case by case (with special safeguards) <input type="checkbox"/> Not Approved
<input type="checkbox"/> Minor increase over	<input type="checkbox"/> With direct benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved

minimal risk or Low risk	<input type="checkbox"/> Without direct benefit	
	<input type="checkbox"/> Potential benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	<input type="checkbox"/> No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	<input type="checkbox"/> Approved case by case (with special safeguards) <input type="checkbox"/> Not Approved
<input type="checkbox"/> More than minimal risk or High Risk	<input type="checkbox"/> With direct benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	<input type="checkbox"/> Without direct benefit	
	<input type="checkbox"/> Potential benefit	<input type="checkbox"/> Approved <input type="checkbox"/> Not Approved
	<input type="checkbox"/> No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	<input type="checkbox"/> Approved case by case (with special safeguards) <input type="checkbox"/> Not Approved

Minimal risk- Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely

	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"/>
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 inclusion of vulnerable population warranted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No	NA
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 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"/>

Comments-

Name & Sign of Primary Reviewer :

Date: