



## INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

### Annexure 10

#### AX 10/SOP 20/V7.1

### Checklist-Requirements for Research involving institutionalized/Refugees/Migrants/Homeless

Principal Investigator (Name, Designation & Affiliation): .....

IEC No. of the Project: .....

Study Title: .....

.....

	Yes	No	NA
Does the project involve recruiting			
<input type="checkbox"/> Institutionalized			
<input type="checkbox"/> Refugees			
<input type="checkbox"/> Migrants			
<input type="checkbox"/> Homeless			
Does the research pose greater than minimal risk to these 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"/>



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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:** .....

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<b>Comments</b>	
<b>Primary Reviewer Signature &amp; Date:</b>	