



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

Annexure 10

AX 10/SOP 20/V7

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"/> |



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

| | | | |
|---|--------------------------|--------------------------|--------------------------|
| 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: