



INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital

Established in 1986

IEC-I Re-registration No. ECR/229/Inst./MH/2013/RR-16, IEC-II registration No. ECR/417/Inst./MH/2013 Issued under rule 122DD of Drugs & Cosmetic rule 1945.

Recognized by:

**The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER),
Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP)
for its compliance with international and local standards in ethical review.**

Annexure 3

AX 03/ SOP 20/V5

Checklist- Research Involving Cognitively Impaired Adults

- The purpose of this checklist is to provide support for IEC members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.
 1. For review using the expedited procedure this checklist is to be completed by the **Designated Reviewer** to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
 2. For review using the convened IEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject (All items must be "Yes")		
<input type="checkbox"/> Yes	<input type="checkbox"/> No	One of the following is true (Check the box that is true) <ul style="list-style-type: none"> <input type="checkbox"/> The risk to the participants is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. <input type="checkbox"/> More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants well – being.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The risk is justified by the anticipated benefit to the participants.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The relation of anticipated benefit to the risk is at least as favourable to the participants as that presented by available alternative approaches.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The proposed plan for the assessment of the capacity to consent is adequate.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Assent is required of: (One of the following must be "Yes") One of the following is true (Check box that is true) <ul style="list-style-type: none"> <input type="checkbox"/> All participants

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		<input type="checkbox"/> All participants capable of being consulted. <input type="checkbox"/> None of the participants
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The consent document includes a signature line for a legally authorized representative.

2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")

<input type="checkbox"/> Yes	<input type="checkbox"/> No	The proposed plan for the assessment of the capacity to consent is adequate.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The objectives of the trial cannot be met by means of study of participants who can give consent personally.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The foreseeable risks to the participants are low.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The negative impact on the participants well-being is minimized and low.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The trial is not prohibited by law.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Participants have a disease or condition for which the procedures in the research are intended.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Participants will be particularly closely monitored.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Participants will be withdrawn if they appear to be unduly distressed.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The proposed plan for the assessment of the capacity to consent is adequate.
<input type="checkbox"/> Yes	<input type="checkbox"/> No	Assent is required of (One of the following must be "Yes") One of the following is true (Check box that is true) <input type="checkbox"/> All participants <input type="checkbox"/> All participants capable of being consulted. <input type="checkbox"/> None of the participants
<input type="checkbox"/> Yes	<input type="checkbox"/> No	The consent document includes a signature line for a legally authorized representative.

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Signature of Principal Investigator: _____ Date _____

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Comments:	
Primary Reviewer Signature & Date	