Annexure 3

AX 03/ SOP 20/ V7.1

Checklist- Research Involving Cognitively Impaired Participants

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

IEC No. of the Project: ……..

Study Title: ……

……

- 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 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 participants in which there is Anticipated Direct Benefit to the subject** (All items must be "Yes")		
	One of the following is true (Check the box that is true) ☐ The risk to the participants is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. ☐ More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants well – being.	☐ Yes	☐ No
	The risk is justified by the anticipated benefit to the participants.	☐ Yes	☐ No
	The relation of anticipated benefit to the risk is at least as favourable to the participants as that presented by available alternative approaches.	☐ Yes	☐ No
	The proposed plan for the assessment of the capacity to consent is adequate.	☐ Yes	☐ No
	Assent is required of: (One of the following must be **"Yes")** One of the following is true (**Check box that is true)** ☐ All participants ☐ All participants capable of being consulted. ☐ None of the participants	☐ Yes	☐ No

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	Participants will be withdrawn if they appear to be unduly distressed.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

Signature of Principal Investigator: …….. **Date:** ……

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Comments	
Primary Reviewer Signature & Date:	