INSTITUTIONAL ETHICS COMMITTEE
BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY, LUCKNOW

Continuing Review Application Form/Annual status Report form
(For Interventional Study, 6 copies required)

IEC code No.: **Study/Protocol No. (For drug/device trials/any other):**
Protocol title:
PI : **Institute:** **Date of IEC approval :** **Start Date of study:** **Duration of study:**

1. Project Status

[ ] Ongoing

[ ] Completed

[ ] Accrual completed

[ ] Follow-up

[ ] Suspended

[ ] Terminated

[ ] Closed

[ ] Not started/Not initiated

If 'Not started' state reasons:

2. Provide the date of last status review report submitted to IEC for this project

3. Have there been any amendments since the last status report?

[ ] YES

[ ] NO

If 'Yes', Were these Protocol amendment approved by IEC

- YES, if 'YES', please provide date of approval_____
- No

Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

4. **Have there been any Participant Information Document (PID) amendments since the last status report?**

   [ ] YES

   [ ] NO

   If 'Yes', Were these PID amendment approved by IEC

   - YES, if 'YES', please provide date of approval_____
   - No

Note: Kindly attach a sheet with the list of amendments to be approved / approved by the IEC in a tabular column with details of amendment no. with date, date of submission to IEC and date of approval by IEC.

5. **Summary of protocol Participants:**

- Accrual ceiling set by IEC_____
- New participants accrued since last review_____
- Total participants accrued since protocol began_____
- Number of active patients_____
- Number of patients who have completed the study_____
- Impaired participants:
  - None_____
  - Physically_____
  - Cognitively_____
  - Both_____

6. **Is the recruitment on schedule?**

   [ ] YES

   [ ] NO

   (If 'NO', please attaché a sheet giving reason and your plans to improve accrual)

7. **Have there been any changes in the participant population, recruitment or selection criteria since the last status report was submitted to IEC review?**

   [ ] YES (If 'YES', kindly attach a sheet explaining the changes)

[ ] NO

8. **Have any participants withdrawn from this study during the last one year?**

   [ ] YES (If 'YES', kindly attach a sheet stating reasons for drop-outs)

   [ ] NO

9. **Have any participating Investigators been added or deleted since last status report was submitted to IEC?**

   [ ] YES (If 'YES', kindly attach a sheet with details regarding the changes)

   [ ] NO

10. **Have any new collaborating sites (institutions) been added or deleted since the last status report was submitted to IEC?**

    [ ] YES (If 'YES', kindly attach a sheet with details)

    [ ] NO

11. **Does the Protocol have an inbuilt monitoring plan?**

    [ ] YES

    [ ] NO

12. **Is interim data analysis report available?**

    [ ] YES (If 'YES', kindly submit as an attachment)

    [ ] NO

13. **Has any information appeared in the literature, or evolved from this or similar research that might affect the IEC evaluation of the Risk/Benefit analysis of human subjects involved in this protocol?**

    [ ] YES (If 'YES', kindly attach a sheet with details)

    [ ] NO

14. **Have any unexpected complications, AEs or SAE been noted since last status report?**

    [ ] YES

    [ ] NO

    (If 'YES', please attach a sheet giving complete details regarding number of SAEs occurred, whether reports of SAEs have been submitted to IEC, type of adverse events in a tabular format.)

15. **When was study last monitored?**

    Date of monitoring_____

    Monitored by_____

    Number of subjects monitored_____

16. **Is report of the data safety and monitoring board report available?**

    [ ] YES (If 'YES', submit as an attachment)

[ ] NO

17. Did the monitoring team have any adverse comments regarding the study?

[ ] YES (If 'YES', please attach a copy of their comments)

[ ] NO

18. Has there been any presentation/publication related to the data generated in this trial?

[ ] YES (If 'YES', kindly attach a sheet with details)

[ ] NO

19. Have any investigators developed an equity or consultative relationship with a source related to this protocol which might be considered as conflict of interest?

[ ] YES (If 'YES', kindly append a statement of disclosure for the same)

[ ] NO

_____

Signature of PI

Name_____ **Date**_____