AX1-V6.1/SOP 07/V6.1

Form A
Continuing Review Application
SECTION A

1) TMC Study No:
2) CTRI No (if applicable):
3) Date of CTRI Registration:
4) Protocol title:
5) Principal Investigator:
6) Phone No:
7) Email Id:
8) Institute:
9) Source of funding: Please tick

☐ Intramural

☐ Extramural – Please specify and provide relevant documents (CTA/Approved MoU/sanction letters from funding agencies) _____

☐ Pharma – Please specify_____

☐ Others- Please specify_____Please specify and provide relevant documents (CTA/Approved MoU/sanction letters from funding agencies)

☐ Not applicable

10) Account No (If Applicable):
11) Date of IEC approval:
12) Date of Validity of IEC approval (for the full duration of the study):
13) Mention overall duration of study (in years/months) approved by IEC at the time of study approval:
14) Start Date of study:
15) If the start date is > 6 months from the IEC approval date kindly provide the reasons for the same

16) Date of approval of last CRA (if applicable):

17) CRA approval valid till date :

18) Period of report of the current CRA : _____/___/_____ to _____/__/_____

19) Study was initially reviewed by expedited review (Please tick) – □ Yes □ No

20) Is the study expected to extend beyond the projected duration: □ Yes □ No

21) If Yes- provide reasons for not being able to complete the work in stipulated time

22) Are you applying for extension for the same: □ Yes □ No

23) If yes- period of extension requested? _____

24) How many prior extensions sought? (in number) _____

Section B

If the study pertains to retrospective case series / paraffin blocks / MRI or other radiological studies, etc. Please provide information on the status/progress of the study so far with regards to the final accrual/objective. Please mark what is not relevant as not applicable.

1) No of study arms (If Applicable):

2) Project Status (In case of studies on blocks/samples/retrospective case series please give the following information with respect to amount of work completed)

- Active enrollment ongoing
- Active accrual and intervention ongoing
- Accrual completed and intervention ongoing
- Accrual completed and follow-up ongoing
- Case review/sample review ongoing (audit studies)
- Data Analysis ongoing
- Publication activities ongoing
- Not started/Not initiated

If 'Not started' state reasons

The research is permanently closed to the enrollment of new subjects (Tick)

□ Yes □ No □ NA

All subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; (Please tick)

□ Yes □ No □ NA

The remaining research activities are limited to data analysis (Please tick)

□ Yes □ No □ NA

3) Provide the date of last status review report submitted to IEC for this project _____(State NA if this is the first status report)

4) Summary of Protocol participants: (If the study does not deal with patient accrual, please provide a summary of the progress on the study so far)
    a) Target accrual of trial (entire study) including healthy volunteers, patients and biomedical samples/blocks) _____
    b) Total patients/samples to be recruited at TMC (IEC ceiling)_____
    c) Screened: _____
    d) Screen failures: _____
    e) Total participants/samples accrued since protocol began _____(should be equal to sum of i to n)
    f) Date of accrual of first subject/sample:
    g) New participants accrued since last review _____
    h) Date of accrual of last participant: _____
    i) Active on intervention- (exclude subjects who have completed intervention)05
    j) No of participants who have completed intervention and are on follow-up:02
    k) Patients lost to follow up: (includes subjects who have completed intervention)
    l) Consent Withdrawn: _Reason and state at which phase of the study – before /during/after completion of intervention (Specify TMC case number/Sub Id)
    m) Withdrawn by PI: Reason and state at which phase of the study – before /during/after completion of intervention (Specify TMC case number/Sub Id)
    n) Deaths: State at which phase of the study – before /during/after completion of intervention (Specify TMC case number/Sub Id)

Sub id	**Phase- Before /during/after completion of intervention**	**Whether notified to IEC- Yes/No** **If No- provide reasons**

o) Any other: _____

p) Any Impaired participants

- None_____
- Physically _____
- Cognitively _____
- Both _____

5) a) Have any SAEs been noted since the last status report?

□ Yes □ No □ NA

If 'Yes', attach in format below

TMC Case No/Sub Id	SAE Event	Report type	Arm	Date submitted to IEC

b) In case of multicentre trials state whether reports of offsite SAEs have been submitted to the IEC –

□ Yes □ No □ NA

6) Have any Deviations/Violations/Waivers been noted since the last status report?

□ Yes □ No □ NA

If 'Yes', attach in format below

TMC Case No/Sub Id	Type of Deviation	Study Arm	Date of submission

7) Have any unanticipated problems involving risks to participants or others (including but not limited to adverse events) been noted?

□ Yes □ No □ NA

If Yes please provide a summary-

8) Were there any Complaints about the research?

□ Yes □ No

If Yes please provide a summary-

If this is your first CRA kindly mention about the changes which has been done in the period after final approval till the submission of this CRA.

9) Have there been any Protocol amendments since last status report?

□ Yes □ No □ NA

If 'YES', please provide in format below

Amendment No. Version Dated	Date of submission	Date of IEC Approval

1) Were any changes initiated in approved research without IEC approval to eliminate apparent immediate hazards to the participants:

□ Yes □ No □ NA

If yes please provide in format below

Date Reported to the IEC.	Description of change	Date of IEC Approval

2) Have any Informed Consent documents been amended since the last status report? □ Yes □ No □ NA

If 'YES', fill in format below

Amendment No. Version Dated	Date of submission	Date of IEC Approval

3) If the amendments were approved by IEC then please state whether all the patients were reconsented on the amended ICF on the next scheduled visit

□ Yes □ No □ NA

Amendment No. Version Dated	Date of submission	Date of Approval

4) Is the recruitment on schedule?

□ Yes □ No □ NA

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

5) Have there been any changes in the participant population, recruitment or selection criteria since the last status report was submitted to IEC?

□ Yes □ No □ NA

(If 'YES', Kindly attach a sheet explaining the changes)

10) Have any participating investigators been added or deleted since the last status report was submitted to IEC?

□ Yes □ No □ NA

(If 'YES', Kindly attach a sheet with details regarding the changes)

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

□ Yes □ No □ NA

(If 'YES', kindly give details in the attached sheet)

If 'YES', kindly confirm if MOU/CTA has been submitted to the IEC: □ Yes □ No□ NA

12) Does the protocol have an inbuilt monitoring plan?

□ Yes □ No □ NA

(Kindly mark the above as 'No' in case of an Investigator initiated study wherein there is no external DSMB to monitor the data generated.

13) Has the study been monitored?

□ Yes □ No □ NA

If YES, Kindly select the following

External/Sponsor Monitoring- □

IEC Monitoring-□

Sponsor Audits- □

(If 'YES', submit the monitoring report)

Date of monitoring _____

Monitored by _____

Number of subjects monitored _____

14) Is the Data Safety and Monitoring Board report available?

□ Yes □ No □ NA

(If 'YES', submit as an attachment)

15) Did the monitoring team have any adverse comments regarding the study?

□ Yes □ No □ NA

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

16) Is the report on interim data analysis available?

□ Yes □ No □ NA

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

17) 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 □ No □ NA

(If 'YES' kindly attach a sheet providing the details)

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

□ Yes □ No □ NA

(If, 'YES', kindly attach a sheet enclosing the details)

If 'YES' then has this been intimated to the TRAC office?

□ Yes □ No □ NA

Please provide summary of current risk-potential benefit assessment based on study results if any?

19) Details regarding the budget- : (kindly attach consolidated account summary duly signed by Accounts Officer)

Total budget proposed for the project _____

Total budget sanctioned for the project _____

Total budget utilized for the project (entire budget utilized) _____

If funds unutilized, to state the reason: _____

20) Total Budget utilized for patient reimbursement (entire budget)_____ (kindly attach details of reimbursement to participants e.g. investigations/scans/travel as per IEC approved budget)

21) 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 □ No □ NA

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

22) Any other information: _____

SIGNATURES:

Principal Investigator:

Date: