AX1-V2/SOP-07/V2

Form A

Continuing Review Application

SECTION A

1) BBCI Guwahati Study No:
2) CTRI No (if applicable):
3) Date of Registration:
4) Protocol title:
5) Principal Investigator:
6) Names of Co-Investigator:
7) Phone No:
8) Email Id:
9) Institute:
10) Source of funding: Please tick
    - ☐ Intramural
    - ☐ Extramural – Please specify_____
    - ☐ Pharma – Please specify_____
    - ☐ Others- Please specify_____
    - ☐ Not applicable
11) Account No (If Applicable):
12) Date of IEC approval:
13) Date of lapse of IEC approval (for the full duration of the study):
14) Mention overall duration of study (in years/months) approved by IEC at the time of study approval:
15) Start Date of study:
16) If the start date is > 6 months from the IEC approval date kindly provide the reasons for the same

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

18) CRA approval valid till date:

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

20) Study was initially reviewed by expedited review (Please tick) – ☐ Yes ☐ No

21) Is the study expected to extend beyond the projected duration: ☐ Yes ☐ No

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

23) Are you applying for extension for the same: ☐ Yes ☐ No

24) If yes- period of extension requested? _____

25) 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)

☐ Ongoing (Kindly select one option from below)

☐ Active Enrollment

☐ Accrual completed

☐ Target accrual reached- ☐ Yes ☐ No ☐ NA

If No – provide reasons_____

☐ Follow-up

☐ Analysis

☐ Not started/Not initiated (If 'Not started' state Reason)

_____

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 BBCI, Guwahati (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 BBCI Guwahati case number/Sub Id)
   m) Withdrawn by PI: Reason and state at which phase of the study – before /during/after completion of intervention (Specify BBCI Guwahati case number/Sub Id)
   n) Deaths: State at which phase of the study – before /during/after completion of intervention (Specify BBCI Guwahati 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

BBCI Case No/Sub Id	SAE Event	Report type	Arm	Date submitted to DSMU

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

BBCI 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 re-consented 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. The study will be then monitored by DSMU, BBCI Guwahati)

13) Has the study been monitored?

☐ Yes ☐ No ☐ NA

(If 'YES', submit the monitoring report only in case of pharma-sponsored)

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 _____

20) Total Budget utilized for patient reimbursement_____ (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: _____

SIGNATURE:

Principal Investigator:

Date**:**

AX1-V2/SOP-07/V2

Form B

Continuing Review Application Form / Annual Status Report Form

(Basic Human study)

BBCI Project No:
PROTOCOL TITLE:
Principal Investigator: **Co- Investigator (s):** **Phone no:** **Email Id:** **Institute**: Dr. B Borooah Cancer Institute **Date of BBCI Guwahati IEC approval: _____ Approval valid up to: _____** **Mention overall duration of study (in years/months) approved by IEC at the time of study approval:** **Start Date of study:** If the start date is > 6 months from the IEC approval date kindly provide the reasons for the same **Duration of study:** **Period of Report of the current CRA:_____/_____/_____ to _____/_____/_____** **Funding Source :** **Account no :**

1) Project Status

□ Ongoing

- Active accrual on going
- Accrual completed /Follow-up
- Analysis on going

□ Not started/Not initiated

If 'Not started' state reasons

2) Provide the date of last status review report submitted to BBCI Guwahati - IEC for this project : _ _ /_ _/_ _ _ _ □ NA

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

☐ Yes ☐ No

If '**YES**', Were these Protocol Amendments approved by BBCI Guwahati- 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 BBCI-IEC in a tabular column with details of amendment no. with date, date of submission to BBCI-IEC and date of approval by BBCI-IEC.

4) Have there been any Informed Consent document amendments since the last status report?

☐ Yes ☐ No ☐ NA

If '**Yes**', were these informed consent document amendments approved by BBCI Guwahati - 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 BBCI-IEC in the tabular column with details of amendment no. with date, date of submission to BBCI-IEC and date of approval by BBCI-IEC.

5) Summary of Protocol participants:

- Total patients/samples to be recruited at BBCI Guwahati (IEC ceiling)_____
- Total number of samples screened since protocol began: _____
- Total Screen failures since protocol began: _____
- Total participants accrued / samples collected since protocol began_____
- New participants accrued /samples collected since protocol began: _____
- Date of accrual of last participant / Samples: _____
- Number of active participants/Sample (analysis going on) _____
- Number of samples analyzed: ___
- Any other: _____

6) Is the recruitment on schedule?

☐ Yes ☐ No ☐ NA

(If '**NO**', please attach a sheet giving reasons 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 BBCI-IEC?

☐ Yes **(Kindly attach a sheet explaining the changes)**

☐ No

☐ NA

8) Were any samples not suitable for analysis during the last one year (only the report period.)**?**

☐ Yes (Kindly attach a sheet stating reasons)

☐ No

☐ NA

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

☐ Yes (Kindly attach a sheet with details)

☐ No

☐ NA

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

☐ Yes (Kindly attach a sheet with details)

☐ No

☐ NA

11) Were there any protocol deviations/violations in the study?

☐ Yes (Kindly attach a sheet with details)

☐ No

☐ NA

12) Is interim data analysis report available?

☐ Yes (If '**YES**', kindly submit as an attachment)

☐ No

☐ NA

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

☐ Yes (Kindly attach a sheet enclosing the details)

☐ No

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

☐ Yes ☐ No ☐ NA

14) Has any information appeared in the literature, OR evolved from this OR similar research that might affect the BBCI-IEC evaluation of the risk/benefit analysis of human subjects involved in this protocol?

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

☐ No

☐ NA

15) Was the study Monitored by Data Safety and Monitoring Unit (DSMU)?

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

☐ No

☐ NA

If Yes, When was study last monitored?
Date of monitoring _____

Monitored by _____

Number of subjects monitored _____

16) Is the DSMU report available?

☐ Yes (If '**YES**', submit as an attachment)

☐ No

☐ NA

17) Did the Data safety and monitoring team have any adverse comments regarding the study?

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

☐ No

☐ NA

18) <u>Scientific and Technical Progress</u>

a) Progress made against the Approved Objectives, Targets & Timelines during the Reporting Period.(Attach a separate sheet of detailed work progress report till date, including tables/figures and experimental data generated last one year and future objectives)

b) Summary and Conclusions of the Progress made so far (minimum 100 words, maximum 200 words) **c) Details of New Leads Obtained, if any:**
19) Is the project likely to finish in the stipulated time? If no please mention reason for not being able to complete the work in stipulated time, what percent of work is pending and the period of extension (months/year(s)) is required to complete the project. How many prior extensions sought? (in numbers)
20) 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 ☐ NA
21). Details regarding the budget: (kindly attach account statement sheet duly signed by Accounts Officer) Total budget proposed for the project: Rs. _____ Total budget sanctioned for the project: Rs. _____ Total amount utilized for the Project: Rs _____ **If extramural funding was sought, name the funding source and amount.** Funding Source: _____ Amount : Rs. _____

SIGNATURES:
Principal Investigator:
Date: