INSTITUTIONAL ETICAL COMMITTEE
DR. B BOROOAH CANCER INSTITUTE, GUWAHATI

AX1-V2/SOP-03/V2
PROJECT SUBMISSION FORM FOR REVIEW BY IEC

A. Grouping of Project

Project No.	(Will be allotted by IEC office)
Title:	
PI:	

Please complete the questionnaire for submitting the research proposal to IEC, BBCI, Guwahati for review and approval.

Study Group

(Please select the option Y/N as applicable)

	Group		Detail	Yes	No
			Controlled trial		
1.	A1	a	Is this a randomized controlled trial?	**Y**	**N**
2.	A1	b	Is this a non-randomized controlled trial?	**Y**	**N**
3.	A1	c	Is this a controlled trial that seeks new indication for establishing drug, process or a procedure?	**Y**	**N**
			Uncontrolled trial		
4.	A2	a	Is this a prospective trial testing new intervention, drug, or device on patients?	**Y**	**N**
5.	A2	b	Is this a prospective trial designed to test new (unproven) indication for established drug, process, procedure or device on patients?	**Y**	**N**
6.	A2	c	Is this a pilot trial on new intervention, drug, and device on patients?	**Y**	**N**
7.	A2	d	Is this a survey, QoL, psychosocial studies?	**Y**	**N**
			Trial/study involve transfer of data/ material from BBCI Guwahati		
8.	A3	a	Is this a multi-center trial/study?	**Y**	**N**
9.	A3	b	If multicentric, is BBCI Guwahati the co-coordinating center?	**Y**	**N**

	Group		Detail	Yes	No
10.	A3	c	Does this trial/study involve transfer of patients' data to another site (including industry)?	**Y**	**N**
11.	A3	d	Does this trial/study involve transfer of patients' blood, serum, DNA, tissue to another site?	**Y**	**N**
			Intramural Funding		
12.	A4	a	Are you seeking intramural funding?	**Y**	**N**
13.	A4	b	Does this trial/study use additional resources of BBCI Guwahati beyond the usual patients' work-up (e.g. IHC, molecular profiling, MRI etc. which is not a routine part of work-up)?	**Y**	**N**
			Extramural Grants		
14.	A5	a	Are you submitting application for extra-mural grant for this trial/study?	**Y**	**N**
15.	A5	b	Is this trial/study partly or wholly supported by grants from sponsored industry?	**Y**	**N**
16.	A5	c	Is this a phase IV/ marketing trial/study undertaken on behalf of the industry?	**Y**	**N**
			Modification in approved trial/study		
17.	A6		Are you seeking modification/s in the BBCI Guwahati - IEC approved trial/study?	**Y**	**N**
			Patient to bear the cost of trial/study		
18.	A7	a	Are patients going to bear the cost of experimental intervention or drug therapy?	**Y**	**N**
19.	A7	b	Will patient/participant undergo additional blood sample collection, biopsy, endoscopy, procedure etc.?	**Y**	**N**
20.	A7	c	Will patient/participant bear the cost of complications arising from experimental treatment?	**Y**	**N**
21.	A7	d	For the trial/study purpose, will the patient spend Rs. 5000/- or more above the usual expenses (for any reason such as drug therapy, additional investigation, prolonged stay or repeated travel)?	**Y**	**N**
			Community or screening trial/studies		
22.	A8	a	Will this trial/study be undertaken in the community?	**Y**	**N**
23.	A8	b	Will this trial/study involve screening in the community?	**Y**	**N**

	Group		Detail	Yes	No
			Trial/study involving Vulnerable Population		
24.	A9		Does this trial/study involve children, pregnant or nursing women, economically or socially disadvantaged group, mentally challenged/mentally differently abled group, participants with reduced autonomy, persons who are terminally ill, have incurable disease, mental illness or any other vulnerable group.	**Y**	**N**
			Trial/study involving genomics & proteomics		
25.	A10		Does this trial/study involve conducting genomics or proteomics studies on patients' specimens?	**Y**	**N**
			Trial/study with conflict of interest		
26.	A11		Will this trial/study involve development of a device, drug or test that would lead to profits or patent?	**Y**	**N**
			Trials involving standard treatment/procedures/ and Feasibility studies		
27.	A12		Is this a prospective follow-up study (documentation of parameters only) of patients being offered standard treatment at BBCI Guwahati?	**Y**	**N**
28.	A13		Is this a phase II-IV trial/study restricted to standard intervention/ treatments published in EBM booklet?	**Y**	**N**
29.	A14		Is this a feasibility study for introduction of new treatment, practices/procedures recently shown in major national/ international studies, to be beneficial / superior and need to be started at BBCI Guwahati?	**Y**	**N**
30.	A15		Is this a review of procedures/practices routinely followed at BBCI Guwahati?	**Y**	**N**
31.	A16	i)	Is this a retrospective analysis of charts and audit of procedures / tests / treatments?	**Y**	**N**
		ii)	Is this a prospective analysis of charts and audit of procedures / tests / treatments?	**Y**	**N**
32.	A17	i)	Is this a retrospective review of biological material/ specimen (may involve some additional staining techniques)?	**Y**	**N**
		ii)	Is this a prospective review of biological material/ specimen (may involve some additional staining techniques)?	**Y**	**N**
33.	A18	i)	Is this a retrospective review of radiology reports and their clinical correlation?	**Y**	**N**
		ii)	Is this a prospective review of radiology reports and their clinical correlation?	**Y**	**N**
34.	A19	i)	Is this a retrospective review of laboratory reports and their clinical correlation?	**Y**	**N**
		ii)	Is this a prospective review of laboratory reports and their clinical correlation?	**Y**	**N**
			Procedure / demonstration at workshops etc.		
35.	A20		Are you demonstrating an experimental procedure which is	**Y**	**N**

	Group	Detail	Yes	No
		'not an established standard of care' at a workshop, or a public meeting?		
36.	A21	Are you performing a procedure at a workshop conducted at BBCI Guwahati by non- BBCI Guwahati staff member? (Please check other requirements also)	**Y**	**N**
Signature of PI				
Date of submission				

B. Project Fact Sheet

B1	Project No. ***(To be filled by IEC Secretariat)***	
B2	Date of receipt by IEC	
B3	Project Title:	
B4	Key Words title (2-4 options)	
B5	Principal Investigator: Co-Principal Investigator: Co-Investigators:	
B6	Number of ongoing studies in which PI is involved? (as PI only)	
B7	Contact number Principal Investigator	
B8	Site/sites where study is to be conducted i.e. BBCI / Any other (Please specify): If Sites other than BBCI, (i.e., TMH, ACTREC, HBCHRC Vizag, MPMMCC/HBCH Varanasi, HBCH, Sangrur etc.,) then, please attach local IEC approval.	☐ Yes ☐ No ☐ NA
B9	Tick the type of study (multiple options if applicable)	☐ Investigator Initiated study ☐ Pharmaceutical sponsored Study ☐ Thesis * If * thesis specify the name of the student_____ ☐ Investigator Initiated study + Thesis
B10	Funding Agency /* Sponsor	
B11	Total estimated budget in Rs.	
B12	Duration of the Project (months)	
B13	Total number of participants to be accrued in	

	study (including BBCI Guwahati, if multi-institutional study)	
B14	Number of participants from BBCI Guwahati to be accrued	
B15	a) If this is a retrospective study, mention time frame from which data is collected b) The total number of participants whose data is being analyzed	
B16	Will biological products/data be sent out of the country? (Yes/No) If yes, attach the copy of regulatory clearance obtained [DCGI/ ICMR /Health Ministry Screening Committee (HMSC)]	Yes/No
	Signature of PI	
	Date of submission	

* Sponsor means a person who takes responsibility for and initiates clinical research. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation/research unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-Investigator means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

Investigators Declaration:

1.	This research project (including collection of blood or tissue samples for research) will not be started until the final approval of the IEC has been obtained.
2.	We agree to undertake research proposal involving human participants in accordance with the New Drugs and Clinical Trial Rules, ICH-GCP and ICMR ethical guidelines. We will not modify the research protocol, consent, etc. without prior approval by the IEC.
3.	We agree to obtain a properly informed and understood consent from all trial participants before their inclusion in the trial by using the informed consent form that is approved by the IEC. Participants will receive an 'information sheet' which will detail the project design in simple understandable layperson's language.
4.	We agree to report within a week all serious adverse events (SAEs) associated with the trial in the SAE form to the IEC. In the event of a death of the trial participant, the Secretary, IEC and DSMU, will be informed within 24 hours.
5.	We agree to submit status report at least annually, of the trial in the appropriate form. A final report will be submitted at the end of the trial.

6.	Full details on funding and a proposed budget are included with the trial proposal. The proposed budget is presented on the specific budget sheet of this form.
7.	We understand that the IEC is concerned about transparent financial transactions during the trial. A report on how the trial funds were utilized will be presented to the IEC along with the final project report at the end of the trial.
8.	We understand that IEC will review and score those aspects of the budget proposal limited to, study merit, participants' rights, safety, and well-being.
9.	We agree to remit service charges and Estimated Professional charges to BBCI, Guwahati as per the existing norms of BBCI, Guwahati for clinical services. (This will not apply to intramural projects and those projects co-sponsored by CRI/ACTREC/ DAE and projects funded by ICMR/ DBT /DST/WHO/IAEA).
10.	We agree that the grant money will be spent in accordance with the budget proposal only. The funds will not be used for any other purposes without prior approval from the IEC. Thirty percent of the surplus grant if left over at the end of the study will be credited to BBCI Guwahati. The remaining 70% of the surplus grant money may be used for conducting intramural research, improving teaching facilities in the department, providing financial assistance to investigators for conferences, etc. after obtaining permission from the IEC.
11.	For all research proposals that are sponsored by a pharmaceutical or biomedical company, we the investigators will ensure that the Sponsor Company will underwrite all expenses such that neither the hospital nor the study participants are made to bear the expenses while participating in the trial. We will also ensure that in the event of complications arising directly due to the trial or litigation, the cost of management or legal fees will be borne by the Sponsor Company totally.
12.	We will declare any financial gain from the commercial sponsor and any conflict of interest in the drug or product by way of consultations, shareholding, etc. as detailed in the Conflict of Interest Policy of BBCI Guwahati.
13.	We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the Institutional Ethics Committee of BBCI Guwahati approved protocol.
14.	All data and biological specimen collected during the research project, including those supported by commercial sponsors (e.g. pharmaceutical company), will remain the property of BBCI Guwahati or as per the Clinical Trial Agreement.
15.	The salaries for the staff employed for the research project will be as shown in the budget sheet and at par with the prevailing, BBCI Guwahati salary scales.
16.	The study documents will be made available to members of the IEC at any time for random verification and monitoring. We will ensure that the study documents are archived for 15 years post study close out or until the sponsor confirms that the records are no longer required; whichever is earlier.
17.	We promise to ensure that there is no falsification of data when compared to the source documents. We agree to clarify any doubts or discrepancies that may arise during the data monitoring evaluation.
18.	All the findings and conclusions of the proposed project such as review of case records, analysis of forms of treatment, investigations, etc. will be first presented to the staff members of BBCI Guwahati before they are released or presented

	elsewhere.
19.	We will not issue any press release before the data and conclusions have been peer-reviewed by the BBCI Guwahati staff or published in a peer-reviewed journal.
20.	All serious injuries arising from the trial will be the responsibility of the Investigators. The investigators agree to cover any expenses for injury and/or compensation arising from the study as per the national regulations/institutional policies.
21.	We will constantly inform the IEC of BBCI Guwahati about amendments in the study protocol, data collection forms, informed consent forms, budget expenses, salaries, other trial documents, etc. as and when they occur. No changes in the study protocol or conduct of the study will be carried out without prior approval of the IEC of BBCI Guwahati.
22.	We realize that the IEC is particular that all aspects of the study are in accordance with the New Drugs and Clinical Trial Rules, ICH-GCP and ICMR ethical guidelines, 2017. We will comply with all policies and guidelines of the BBCI Guwahati and affiliating/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.
23.	We understand that serious protocol violations and/or non-compliance during the trial by the investigators may result in withdrawal of project approval by the IEC of BBCI Guwahati.
24.	We agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical investigators participating in clinical trials.

If you have any questions, concerns, suggestions please email to: iecbbci2021@gmail.com

Study Team Undertaking with Duties & Delegation:

Project Title-

Sr. No.	**CC No.** if available	**Investigator Name**	**Email**	**Status** (PI, Co-PI, CI,)	***Role & responsibility**	**Conflict of Interest Yes/No. (If Yes, Please specify)**	**Sign & date**
1.							
2.							
3.							

*Choose from the following list.

A.	Concept	**K.**	Data collection and monitoring of data

B.	Design	**L.**	Interpretation of Data
C.	Screening of Patients	**M.**	Statistical analysis and interpretation
D.	Selecting, recruitment & Consenting of Patients	**N.**	Maintaining patients file and master file of project
E.	Laboratory Investigations	**O.**	Drafting final report
F.	Laboratory report Interpretation	**P.**	Publication
G.	Treatment Decision	**Q.**	Assigning duties to the study team
H.	Patient Evaluation	**R.**	Communication with IEC
I.	AE and SAE management, evaluation and reporting	**S.**	Any others, please specify
J.	Examination of patients on follow-up	**T.**	

Note: Investigators may clarify any of the points in this undertaking with the IEC secretariat.

Financial Disclosure Form for Researchers

Project entitled: …… ……
Name of PI:

1. Employment or Leadership Position

Check yes if you or your immediate family member currently holds any full-time or part-time employment or service as an officer or board member for an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

2. Consultant or Advisory Role

Check yes if you or your immediate family member holds or has held any consultant or advisory arrangements with an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

3. Stock Ownership

Check yes if you or your immediate family member currently holds any ownership interest in any company (publicly traded or privately held) that has an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

4. Honoraria

Check yes if you or your immediate family member has been paid directly any honoraria (reasonable payments for specific speeches, seminar presentations, or appearances)

from an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

5. Research Funding

Check yes if you or your immediate family member currently conducts any clinical research project(s) funded, in whole or in part, or has received any post study awards by an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

6. Patent or Royalty interests

Check yes if you or your immediate family member has received any patent or royalty from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

7. Other Remuneration

Check yes if you or your immediate family member has received any trips, travel, gifts, or other in-kind payments at any point from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐ No If yes, amount received in last 12 months in Rs. _____

I hereby agree to recuse myself from any deliberations and actions involved in the approval or re-approval of a protocol for which I have a real or apparent conflict of interest, and from discussions of these matters unless my presence for discussions is requested by the IEC Chair.

☐ I hereby declare that I have no conflict of interest in my project.

☐ I have the above conflict/s of interest:

_____ _____

Signature of PI **Date**

Consent of Head of the PI's Department		
Date: I have reviewed the project entitled "…… ……..." submitted by ……, Principal Investigator from my Department. I endorse the project and have 'no objection' for submission for consideration by Institutional Ethics Committee. I concur with the participants / investigators included in the study. I have reviewed the financial and non-financial disclosure : ☐ Yes ☐ No PI has conflict of interest: ☐ Yes ☐ No		
Signature & date	Name	Department

Consent from Disease Management Group (DMG) / Working Group / Scientific Committee	
Date: The project entitled "_____" submitted by_____ (Principal Investigator's name) has been discussed in _____ (DMG/ Working group name/ Scientific Committee) and is accepted to be submitted for Institutional Ethics Committee review. The investigators / participants included in the study are acceptable to the members. I have reviewed the financial and non-financial disclosure: ☐ Yes ☐ No PI has conflict of interest: ☐ Yes ☐ No	
DMG / Scientific Committee discussion :	
Signature & date	Name (Convener or senior member of DMG / Working group / Chairman of Scientific Committee):

C. Project Submission Overview

C.1	**Title**	
C.2	**Principal Investigator**	
C.3	**Introduction/ background** Give the background, including human or animal research relevant to the design of the proposed study. When new techniques or procedure are to be used, provide a description of preliminary work. When an investigation drug is to be used, animal data and phase I or II data on the drug should be included. A summary of how the study may help in the future should be included in the protocol.	
C.4	**Aims/ Objectives** Clearly state the aims or objectives of the study. Whenever possible this should be in the form of a hypothesis.	
C.5	**Design of the Study (see study design enclosed)**	
C.5.1	**Treatment studies /Interventional Studies**	
	➢ Randomized controlled trial • Double-blind randomized trial • Single-blind randomized trial • Partial-Blind randomized trial • Open labeled ➢ Adaptive clinical trial ➢ Nonrandomized trial (quasi-experiment) ➢ Interrupted time series design Any other (please specify)	
C.5.2	Pre-clinical: Phase-I, Phase-II, Phase-III, Phase-IV, NA	
C.5.3	Pharmacokinetics Pharmacodynamics	☐ Yes ☐ No ☐ NA ☐ Yes ☐ No ☐ NA
C.5.4	Feasibility Study Pilot Pivotal	☐ Yes ☐ No ☐ NA ☐ Yes ☐ No ☐ NA ☐ Yes ☐ No ☐ NA
C.5.5	Observational studies	
	➢ Prospective cohort ➢ Retrospective cohort	

	➢ Time series study ➢ Case-control study ➢ Nested case-control study ➢ Cross-sectional study ➢ Community survey (a type of cross-sectional study) ➢ Longitudinal study ➢ Epidemiological study ➢ Survey (others) ➢ Others (please specify)	
C.6	**Study Population**	
C.6.1	**Eligibility** (Explain inclusion and exclusion criteria; To be stated clearly in the summary) (Explain inclusion of Normal / Healthy volunteer, Student, Staff of the institute in the study) **Specify Age**	
C.6.2	Does it involve vulnerable participants? **Individuals may be considered to be vulnerable if they are:** • Socially, economically or politically disadvantaged and therefore susceptible to being exploited • Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled. • Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions. • Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.	☐ Yes ☐ No (If yes, tick the appropriate boxes) ☐ Minors (up to 18 years) ☐ Pregnant women ☐ Elderly ☐ Seriously/terminally ill ☐ Neonates ☐ Mentally challenged ☐ Handicapped ☐ Economically/socially disadvantaged ☐ Institutional employees / students
C.7	**Study methodology** Explain, in sequence, the conduct of study and all data collection procedures. Describe the involvement of human participants including initial evaluation procedures and screening tests, phases, medical/surgical procedures and sequence of the study.	

	Separate standard and experimental aspects of the study as much as possible. Give brief account of procedures for treatment, dose adjustments, etc. Describe the randomization procedure, if applicable. Specify if procedure involves banking of biological samples. Define stop points and criteria for withdrawing participants from the study.	
C.7.1	How many participants/samples will be screened? How many participants/samples are likely to be accrued?	
C.7.2	**Power estimates** Describe power calculations, if the study involves statistical comparisons between two or more groups. Mention evidence to support that adequate number of participants can be enrolled during the study period by the investigators.	
C.7.3	**Variables to be estimated** (e.g. response, survival, toxicity, age, etc.) Enumerate the variables, outcomes and end points that will be measured. Try to separate variables as response and explanatory variables. Describe the type and frequency of tests, admissions, outpatient visits, etc. used to obtain these variables.	
C.7.4	**Analysis of the variables** Describe how the variables obtained during the study will be statistically analyzed. e.g. Univariate comparison or Cox- proportional hazards model, etc.	
C.8	**Adverse Events**	
C.8.1	Have you defined adverse events in your study, and what rules would be used for stopping the study due to adverse events? (Please note that SAEs have to be reported to IEC as per national regulations and SOPs.)	
C.8.2	Describe all possible risks and discomfort to participants due to use of intervention and /or data collection methods proposed risks, discomfort, side effects of drug et. Describe expected degree and frequency of such c.	
C.8.3	Describe benefits to the participant/s in this study. Also describe the benefits, if any, to the society.	

C.8.4	Describe benefit/risk assessment	
C.8.5	If the procedures in the trial are invasive or potentially harmful, describe what arrangements have been made for treatment of the complications arising from the trial?	
C.8.6	If some procedures in this trial are emotionally upsetting describe what arrangements have been made for psychological counseling?	
C.8.7	Who will bear the cost of treating the complications arising from this trial?	
C.8.8	a) Have you made provision for insuring trial participants for any accidental unforeseen trial related injury? b) Does this study require institutional insurance coverage?	☐ Yes ☐ No**, Specify** ☐ Yes ☐ No
C.9	**Informed Consent**	
C.9.1	Describe the participant recruitment strategy adopted	• OPD basis [ ] • EMR data base [ ] • Referrals [ ] • Advertisements [ ] • Any other- Please specify
C.9.2	Describe	
	(i) How, where, when and by whom the Informed Consent /assent will be obtained?	
	(ii) How much time the participant/s will be given to consider participation and decide?	
	(iii) Describe additional plans/needs for informed consent/assent in case the study involves special population such as minors, pregnant mothers, neonates, etc.	
	(iv) Describe how you will assess that information is correctly understood by the participant.	
C.9.3	In what way will you ensure the confidentiality and privacy of the participants?	
C.10	Are you seeking waiver of consent? If Yes, specify reasons	☐ Yes ☐ No

C.11	**Drug/Sponsor details**	
C.11.1	Does your study involve testing of drug/s, device/s and/or biologics? If yes- 1) Please attach copy of DCGI permission/DCGI Application 2) If marketed drug, please attach copy of package insert/product insert.	☐ Yes ☐ No
C.11.2	Are drugs already approved by the regulatory authorities and available in the market or are the new ones?	Already approved [ ] New one [ ] NA [ ]
C.11.3	Does your study involve modified or new claims, namely, indications, dosage forms (including sustained release dosage form) and route of administration of already approved drugs and combination of two or more drugs?	☐ Yes ☐ No
C.11.4	Who has prepared and /or is manufacturing the drug/s, device/s and biologics under investigation?	
C.11.5	Who holds the patent or IND/IDE of the drug/s, device/s and biologics under investigation?	
C12	**Permissions /Agreements**	
C12.1	Does your study require permission from	
	1. Director, BBCI, Guwahati?	☐ Yes ☐ No
	2. Health Ministry's Screening Committee (HMSC)?	☐ Yes ☐ No
	3. Drugs Controller General India (DCGI)?	☐ Yes ☐ No Please Specify
	4. Others? If yes, please Specify:	☐ Yes ☐ No
C12.2	Does your study require you to send human biological material/data outside India?	☐ Yes ☐ No ☐ NA
C12.3	If yes, have you obtained/sought permission	
	1. from the Director, BBCI, Guwahati	☐ Yes ☐ No ☐ NA
	2. from Health Ministry's Screening Committee (HMSC)	☐ Yes ☐ No ☐ NA
	3. from DCGI	☐ Yes ☐ No ☐ NA
	4. Others, please specify	☐ Yes ☐ No ☐ NA
C.12.4	Has BBCI, Guwahati and the collaborating institution/sponsor signed CTA/MoU/MTA/	☐ Yes ☐ No ☐ NA

	other agreement for that? If yes, attach a copy of CTA/MoU/MTA/other agreement	
C.12.5	If the study is to be conducted fully or partially outside the BBCI, Guwahati please describe the need for permission from institution(s), health center(s), local government/administrative bodies, etc.	
C.12.6	Have you made provision for insuring yourself, and BBCI, Guwahati against any legal action that may arise out of this project?	
C.13	**Trial Monitoring , Data Management and access**	
C.13.1	Does your study have provisions for monitoring the data to ensure the safety of participants?	☐ Yes ☐ No ☐ NA
C.13.2	Who will be responsible for monitoring and ensuring the safety of participants?	
C.13.3	i. Who will be maintaining the trial records and where? ii. For how long will the data be stored? iii. Give details of where they will be stored and who will have access to the trial/study master file and other trial/study documents.	
C.14	**Post research access**	
C.14.1	Post research access will be provided to the participants? If yes, describe briefly arrangements made for post research access.	☐ Yes ☐ No ☐ NA
C.14.2	What are the reasonable possibilities of the availability of the investigational drug(s)/ device(s) and biologics for the study participant/s, after the study completion, if found to be effective?	
C.15	**Results**	
C.15.1	How are the results of the study intended to be reported and disseminated?	Please tick in the box ☐ Peer reviewed scientific journals ☐ Other publication ☐ Conference presentation ☐ Internal report ☐ Submission to regulatory authorities

		☐ Access to raw data and right to publish freely by all the investigators in study or by independent steering committee on behalf of all investigators. ☐ Other……Please specify…….	
C.16	**Name of PI:**	**Signature:**	**Date:**

D. Budget Sheet for the Proposed Study

1	Title of the Project:			
2	Principal Investigator			
3	Designation and address of the PI			
4.	Source of funding			
	Intramural			
	Extramural			
	a) Government (please specify)	☐ Central	☐ State	☐ Local
	b) Private Foundation: (please specify)	☐ Indian	☐ Foreign	
	c) Industry: (please specify)	☐ Private	☐ Public	☐ Other
	d) Other:			
	Pharma sponsored	☐ Indian	☐ Foreign	
	Address, phone, fax. E-mail of sponsor with the name of the contact person			
	No funding required			
5.	Total Budget for the entire project in Rs.			
6.	Duration of the Project in months			
7.	Proposed date of starting the project			
8.	Direct payments to investigators, if any			
9.	Any other benefits to the investigators			
10	**Name of PI:**	**Signature:**		**Date:**

Detailed Budget for the Proposed Study*

1	**Source of funding**	**Please specify:**			
	Items	1st Year	2nd Year	3rd Year	Total
2	**Salaries-personnel (Numbers)**				
	Doctor / Post-Doc (Research Fellow)				
	Research Nurse				
	Data operator				
	Any other specify				
	Equipment and Hardware- kindly specify				
	-				
	-				
	-				
	-				
4	**Drugs and Consumables**				
	-				
	-				
	-				
	-				
5	**Clinical Investigations**				
	-				
	-				
	-				
6	**Hospitalization**				
	-				
	-				

	-				
7	**Travel expenditure for investigators**				
	-				
	-				
8	**Travel expenditure for trial participant and one attendant**				
9	**Honorarium to doctors/technicians**				
10	**Insurance**				
	i. for investigators				
	ii. any unforeseen, accidental trial related injury				
11.	**Any other expenditures**				
12.	**Miscellaneous**				
13.	**Service Charge (as per current BBCI Guwahati norms for pharma sponsored studies)** (TMC,CRI, DAE, ICMR, DBT, DST, IAEA, WHO, IARC etc. funded project are exempted)				
14.	**Estimated** Professional charges for clinical services (**as per current terms for pharma sponsored studies)**				
15	Grand Total				
	Name of PI:	**Signature:**			**Date:**

Note:

- PI should devise incremental budget whenever necessary.
- Please provide the complete break-up of item nos. 3, 4 & 5 on separate sheet.
- Please specify year-wise total in grand total column

Project No.	
Trial Register No.	
Project Title (To be filled by PI)	..
Revised Title if any (To be filled by IEC)	
Principal Investigator	..

Institutional Ethics Committee Approval

Project No._____

The members of the Institutional Ethics Committee met on …… at Dr. B Borooah Cancer Institute, Guwahati and reviewed the above named project with all the documents submitted. The Institutional Ethics Committee after careful deliberations has granted final approval to the project. The above mentioned project/ study may now be undertaken at Dr. B Borooah Cancer Institute, Guwahati in accordance with the study protocol submitted by the investigators, subject to fulfilling local and other institutional regulations.

Member Secretary ……..…….	Chairperson…..……..
Name: ……..…	Name:……..
Date…….	Date…….

Instructions:

- This form must be printed and not handwritten.
- Fill the form completely (If there are any questions/queries, please contact the IEC office.
- Make sure to include the e-mail address and contact numbers of the PI, Co-investigators.
- Please submit the documents as per the checklist (AX2-V2/SOP03/V2) to ensure all requirements for submission are fulfilled for timely review by IEC. Submit the submission form (Part A, B, C, D) along with the supporting documents to the IEC office.

AX2-V2/SOP-03/V2

CHECKLIST OF DOCUMENTS

Item No.	Mandatory Documents	Yes	No	NA
1.	IEC processing fee **(applicable for pharma sponsored trials)**			
2.	Project Submission Form **(both hard and soft copies)** duly signed by the Principal Investigator			
	A. Grouping of Project			
	B. Project Fact Sheet Investigators Declaration Conflict of Interest Consent of Head of the PI's Department Consent from Working Group/ Scientific Committee			
	C. Project Submission Overview			
	D. Budget Sheet for the Proposed Study Detailed Budget for the Proposed Study			
3.	Study Protocol			
4.	Lay summary			
5.	Participant Information Sheet & Informed consent forms (ICFs) in English & Assamese (and if required any other language)			
6.	Back translations of ICFs (not mandatory for Hindi & Assamese)			
7.	Application for waiver of consent			
8.	Case Record Form			
9.	Questionnaire			
10.	Investigator Brochure			
11.	Package insert/label			
12.	Insurance policy			
13.	DCGI approval letter/ DCGI submission letter			
14.	NOC from DCGI /ICMR/HMSC			
15.	Appendix VII (Schedule Y) Undertaking By The Investigator			
16.	Clinical Trial Agreement (CTA)/Memorandum of Understanding(MOU)/Material Transfer Agreement(MTA) if applicable			
17.	Brief resume of Principal Investigators and Co-investigators (1 Page each)			
18.	Copy of Good Clinical Practice training certificate for all investigators			
19.	Medical Council Registration of Principal Investigators and Co-investigators			
20.	Copy of Valid Good Clinical Practice training certificate for all investigators			
20.	Any Other			

AX3-V2/SOP-03/V2

Institutional Ethics Committee
Document Receipt Form

BBCI Study Number: **Submitted date:**	
Type of Submission:	**Initial Review:**
Protocol Title:	
Principal Investigator:	
Mode of submission: ☐ Post ☐ E-submission ☐ In Person	
Type of document:	

Checklist to assess the projects before they are submitted to IEC review

Item No	Mandatory Documents	Yes	No	NA
1.	IEC processing fee **(applicable for pharma sponsored trials)**			
2.	Cover letter enlisting documents enclosed.			
3.	Project Submission Form (both hard and soft copies) duly signed by the Principal Investigator			
4.	**A.** Grouping of Project			
5.	**B.** Project Fact Sheet Investigators Declaration Conflict of Interest Consent of Head of the PI's Department Consent from Working Group			
6.	**C.** Project Submission Overview			
7.	**D.** Budget Sheet for the Proposed Study Detailed Budget for the Proposed Study			
8.	Study Protocol			
9.	Lay Summary			
10.	Participant Information Sheet & Informed consent forms (ICFs) in English & Assamese (and if required any other language)			
11.	Back translations of ICFs (not mandatory for Assamese)			

Item No	Mandatory Documents	Yes	No	NA
12.	Application for waiver of consent			
13.	Case Record Form			
14.	Questionnaire			
15.	Investigator Brochure			
16.	Package insert/label			
17.	Insurance policy			
18.	Drugs Controller General, India (DCGI) submission letter			
19.	Drugs Controller General, India (DCGI) approval			
20.	HMSC approval			
21.	Appendix VII (Schedule Y) Undertaking By The Investigator			
22.	Clinical Trial Agreement (CTA) **if applicable**			
23.	Memorandum of Understanding (MoU) **if applicable**			
24.	Material Transfer Agreement (MTA) **if applicable**			
25.	Brief resume of Principal Investigators and Co-investigators (1 Page each)			
26.	GCP Training certificate			
27.	Medical Council Registration of Principal Investigators and Co-investigators			

Documents submitted:

☐ Complete

☐ Incomplete will submit on……...

Comments:

Receiver Name, Sign & Date

(IEC Secretariat)