AX1-V2/SOP-4a/V2

Dr. B Borooah Cancer Institute

Tata Memorial Centre

Study Assessment Form

Protocol Number :	Date (DD/MM/YY):
Protocol Title :	
Principal Investigator:	
Department :	
Application ☐ New ☐ Revised	
Total No. of Participants:	
Funding Agency:	
Duration of the Study:	
Lead discussant Name	
Type of the Study :	**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) comment:_____ ☐ Pre-clinical ☐ Phase-I, ☐ Phase-II, ☐ Phase-III, ☐ Phase-IV, ☐ NA

	Feasibility Study:- ☐ Pilot ☐ Pivotal ☐ Pharmacokinetics ☐ Pharmacodynamics **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) _____
Research involves – ☐ Less than minimal risk ☐ Minimal risk ☐ Minor increase over minimal risk or Low risk ☐ More than minimal risk or High risk	
Review Type	☐ Full board ☐ Expedited
Justification for expedited review	Comment:
CTRI Registration	☐ Applicable ☐ Not Applicable
Academic clinical trial to be notified to DCGI as per New Drugs and Clinical Trial Rules [i.e. clinical trials looking at any new indication or new route of administration or new dose or new dosage form and the data generated is not intended for	☐ Yes ☐ No ☐ N/A

submission to licensing authority for marketing purposes.]	
Does this study require institutional insurance coverage	☐ Yes ☐ No ☐ N/A
Does this study require permission from regulatory authorities?	☐ Yes ☐ No ☐ N/A If Yes- ☐ DCGI ☐ ICMR ☐ other govt. Departments/Agencies
Are human biological material/data sent abroad?	☐ Yes ☐ No ☐ N/A Comment: If yes, permission required ☐ Health Ministry's Screening Committee(HMSC) ☐ Others, please specify
Description of the study in brief: (Study objectives/study hypothesis etc) –	

Mark and comment on whatever items applicable to the study

Section A- To be filled by scientific lead discussants		
1	Need for human participants	☐ Yes ☐ No ☐ N/A Comment:
2	Objectives of the study	☐ Clear ☐ Unclear What should be improved?
3	Background information and data	☐ Sufficient ☐ Insufficient Comment:
4	Availability of similar study / results	☐ Yes ☐ No ☐ N/A

		Comment:
5	Relevance of the work in the context of contemporary Translation or clinical cancer research: * Does this study address an important research question or is it a predominantly service proposal?* If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?	☐ Yes ☐ No ☐ N/A Comment: (please specify)
6	Methodology:	☐ Clear ☐ Unclear What should be improved?
7	Classify Risk/Benefit	☐ Less than minimal risk/ High Benefit ☐ Less than minimal risk/ Low benefit ☐ Minimal risk/ High Benefit ☐ Minimal risk/ Low benefit ☐ High Risk/High Benefit ☐ High Risk/Low Benefit
8	Risk and benefit considerations a) Are both risks and anticipated benefits accurately identified, evaluated, and described? b) Have the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions? c) Are the risks to subjects reasonable in relation to the importance of the knowledge from the study? d) Are the risks (physical, psychological, legal, economic, and social) to subjects minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk? e) Are the risks minimized, whenever appropriate, by using procedures already	 ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A ☐ Yes ☐ No ☐ N/A

	being performed on the subjects for diagnostic or treatment purposes? f) Does the study define risk management plan?	☐ Yes ☐ No ☐ N/A
9	Inclusion Criteria	☐ Appropriate ☐ Inappropriate Comment:
10	Exclusion Criteria	☐ Appropriate ☐ Inappropriate Comment:
11	Discontinuation and withdrawal criteria	☐ Appropriate ☐ Inappropriate Comment:
12	Does the 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 ☐ N/A
13	Study/Data collection proforma	☐ Appropriate ☐ Inappropriate Comment:
14	Involvement of vulnerable participants	☐ Yes ☐ No ☐ N/A Comment: • Children (up to 18 years); • Women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare. • Terminally ill or are in search of new interventions having exhausted all therapies • Suffering from stigmatizing or rare diseases. • Economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/gay/bisexual and transgender (LGBT), etc.); • Have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defense services personnel, healthcare workers, institutionalized individuals, under trials and prisoners). • 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. • Tribally and marginalized communities; • Refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster • Situations • Afflicted with mental illness and cognitively impaired individuals, differently abled mentally and physically disabled; Comments on addressing vulnerability issues:
15	Sufficient number of participants?	☐ Yes ☐ No ☐ N/A Comment:
16	Control Arms (placebo, if any)	☐ Yes ☐ No ☐ N/A Comment:
17	Are qualifications and experience of the participating investigators appropriate?	☐ Yes ☐ No ☐ N/A Comment:
18	Is the duty delegations as per investigator's expertise and study design?	☐ Yes ☐ No ☐ N/A Comment:
19	Disclosure or declaration of potential conflicts of interest	☐ Yes ☐ No ☐ N/A Comment:
20	Facilities and infrastructure of BBCI Guwahati for conduct of the research	☐ Appropriate ☐ Inappropriate Comment:
21	Is community consultation required	☐ Yes ☐ No ☐ N/A Comment:
22	Involvement of local researchers and institution in the protocol design, analysis and publication of results	☐ Yes ☐ No ☐ N/A Comment:

23	Contribution to development of local capacity for research and treatment	☐ Yes ☐ No ☐ N/A Comment:
24	Benefit to local communities	☐ Yes ☐ No ☐ N/A Comment:
Section B- To be filled by both scientific and non-scientific lead discussants		
25	Has the PI applied for waiver of consent?	☐ Yes ☐ No ☐ N/A Comment:
26	Has the criteria for waiver of informed consent documentation been met?	☐ Yes ☐ No ☐ N/A Comment:
27	Is the waiver of consent granted?	☐ Yes ☐ No ☐ N/A **Specify reasons for granting waiver of consent** ☐ Research involves 'not more than minimal risk ☐ There is no direct contact between the researcher and participant ☐ Rights of the participants are not violated ☐ Confidentiality of data and privacy of research participant are protected If No, **Specify reasons for not granting waiver of consent**
28	Does the study involve consenting of participants	☐ Yes ☐ No ☐ N/A Comment:
29	Are procedures for obtaining informed consent appropriate?	☐ Yes ☐ No ☐ N/A Comment:
30	Contents of the informed consent document	☐ Clear ☐ Unclear Comment:
31	Language of the informed consent document	☐ Clear ☐ Unclear Comment:
32	Does the informed consent document address all the essential elements of	☐ Yes ☐ No ☐ N/A

	consenting as per the regulations/guidelines?	Comment:
33	Contact persons for participants mentioned?	☐ Yes ☐ No ☐ N/A Comment:
34	Privacy & Confidentiality ensured?	☐ Yes ☐ No ☐ N/A Comment:
35	Inducement for participation	☐ Unlikely ☐ Likely Comment:
36	Does the ICF provide explanations of the research to the participant with an accurate assessment of its risks and anticipated benefits?	☐ Yes ☐ No ☐ N/A Comment:
37	Provision for Medical / Psychosocial Support	☐ Appropriate ☐ Inappropriate Comment:
38	Provision for treatment of study-related injuries	☐ Appropriate ☐ Inappropriate Comment:
39	Provision for Compensation	☐ Appropriate ☐ Inappropriate Comment:
40	Provision for post-trial access	☐ Appropriate ☐ Inappropriate Comment:
41	Provision for payments	☐ Appropriate ☐ Inappropriate Comment:
42	Provisions for monitoring the data to ensure the safety of participants	☐ Yes ☐ No ☐ N/A Comment:
43	Voluntary, Non-Coercive Recruitment of Participants	☐ Yes ☐ No ☐ N/A Comment:

Assessment Report

Project number:		
Project title:		
DECISION :	☐ Approved ☐ Revisions with minor modifications ☐ Revisions with major modifications for resubmission ☐ Not approved ☐ Deferred	
Findings/ Modifications required :		
Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators? ☐ Yes ☐ No ☐ N/A		
Signature :		Date**:**

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Assessment Report
Assessment of Resubmitted Protocol

Protocol Number :	**Date (DD/MM/YY):**
Protocol Title :	
Principal Investigator:	

Has the PI done the revisions/ modifications or provided justification (as applicable) according to the IEC recommendations:

☐ **Yes** ☐ **No** ☐ **Partial**

Findings/ Modifications required –

DECISION :

☐ **Approved**

☐ **Revisions with minor modifications**

☐ **Revisions with major modifications for resubmission**

☐ **Not approved**

☐ **Deferred**

Is there any conflict of interest (scientific, service or financial) between you and that of the Investigators? ☐ **Yes** ☐ **No**

Signature :		**Date:**