

Institutional Biosafety Committee checklist and Form

Name of the project or activity: *A phase IV, prospective, Open Label, Multi-center study of Vorasidenib in Indian adult & Paediatric participants 12 years & older with grade 2 Astrocytoma & Oligodendroglioma with a susceptible IDH1 & IDH2 mutation following surgery including biopsy, Sub-total Resection or gross total Resection.*
IBSC reference number:

Name of the principal investigator or responsible person: *RIMPA BASU ACHARI*

Designation: *SENIOR CONSULTANT*

Department: *RADIATION ONCOLOGY*

Email: *rimpa.achari@tmcokolkata.com*

Mobile number: *9051584999*

Does your R&D project/work involve any of the following activities?

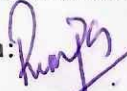
- Use, research, import, export, storage, transport, production, manipulation, genetic modification/engineering of any of the following agents: bacteria, virus, prions, fungi, parasites, plants, animals, aquatic organisms, cells, arthropods, algae

Answer: YES/ ☒ NO

If the answer to the above question is "Yes" then send an application for approval of your project or activity with the following details:

- Project protocol or activity plan
- Project start date: Proposed end date:
- Department where biological agents would be handled:
- Type of agent: bacteria, virus, prions, fungi, parasites, plants, animals, aquatic organisms, cells, arthropods, algae
- Type of activity: Use, research, import, export, storage, transport, production, manipulation, genetic modification/engineering
- Biohazard category/ risk group: 2/3/4 (Ref: Advisory Committee on Dangerous Pathogens. The Approved list of biological agents. <https://www.hse.gov.uk/pubns/misc208.pdf>)
- In case of genetically modified product sequence provided or not: Yes/No
- Infrastructure in place to deal with the bio-hazard
- Source of funding:
- Risk assessment and risk management plan
- Emergency plan for containment of accidental release or untoward incident
- Support letter from the heads of relevant departments
- Conflict of interest statement (if any)
- Covering letter
- Declaration:
 - I would follow by the rules of the Institutional Biosafety Committee (IBSC)
 - I take responsibility for risk assessment, risk management and emergency containment

I would inform the Member Secretary of the Biosafety Committee and the Biosafety Officer in case of any untoward incident or accidental release as soon as possible and latest within 48 hours of the incident

Signature of the PI or responsible person:  Date of application: 31/08/2026

Please email application before start of the project/ activity to: ibsc@tmckolkata.com For emergency contact IBSC secretariat: X 7577 or member secretary (X7751)/ biosafety officer (X7763)