

TMC/IRB/SOP-04 Standard Operating Procedure (SOP) for Initial Study Submission

Annexure 2: Undertaking by the investigator as per Schedule III, Table 4 of NDCT (Third Amendment) Rules, 2022

Protocol Name: MRI- guided Focal Boost in Prostate Cancer Radiation Therapy

1. **Full name, Address and Title of the Principal Investigator/** (Investigator(s) when there is no Principal Investigator)
Dr. Indranil Mallick
Senior Consultant, Radiation Oncology,
Tata Medical Center
14 Major Arterial Road (E-W), Rajarhat, NewTown,
Kolkata-700160
2. **Name and Address of the medical college, hospital or other facility** where the clinical Trial will be conducted:
Education, training & experience that qualify the Investigator for the clinical trial [Attach details including Curriculum Vitae, Good Clinical Practice Certificate & Medical Council Registration Certificate and/or any other statement(s) of qualification(s)].
Tata Medical Center
14 Major Arterial Road (E-W), Rajarhat, NewTown,
Kolkata-700160
3. **Name and Address of all clinical laboratory facilities** to be associated with the study.
NA
4. **Name and Address of the Ethics Committee that is responsible for approval and continuing review of the study.**
Institutional Review Board
Tata Medical Center
14 Major Arterial Road (EW)
Newtown, Rajarhat,
Kolkata – 700 160, India
5. **Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s).**
Dr. Moses Arun Singh S
Dr. Ishwar Gopinath
6. **Protocol Title and Study number** (if any) of the **clinical trial** to be conducted by the Investigator.
MRI- guided Focal Boost in Prostate Cancer Radiation Therapy

7. Commitments

- I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study.

Prepared by : Dr Indranil Mallick
Reviewed by: Prof Partha Pratim Majumder
Reviewed by: Dr Pattatheyl Arun
IRB Member Secretary
TMC-IRB Chairperson
Head of the Institution

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- I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
- ❖ I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/favourable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature
 - ❖ I agree to personally conduct and/or supervise the clinical trial at my site.
 - ❖ I agree to inform all Subjects that the drugs are being used for investigation purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met
 - ❖ I agree to report to the Sponsor all adverse experiences that occur in the course of the study in accordance with the regulatory and GCP guidelines.
 - ❖ I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
 - ❖ I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
 - ❖ I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
 - ❖ I agree to promptly report to the IRB/EC all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
 - ❖ I agree to inform all serious adverse events to the Sponsor as well as the IRB/EC within 24hrs of their occurrence.
 - ❖ I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
 - ❖ I have/do not have any conflicts of Interest (COI) in the study i.e. Financial/Personal or others.
 - ❖ I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8 Signature of the Investigator with Date

Name of the Investigator: Dr. Indranil Mallick

Prepared by : Dr Indranil Mallick
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IRB Member Secretary
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