



**Tata Medical Center
Institutional Review Board**

Supersedes Document Dated :
10/01/2022
SOP : TMC-IRB
Version No.: V12.1
Effective Date :
18/01/2024

TMC/ IRB/ SOP-4: Undertaking by the investigator (As per Schedule III, Table 4 of NDCT Rules, 2019)

Annexure 2 (Page 1/3)

Protocol Name: Study Title: Comparative Evaluation of FAPI PET-CT, CECT, and Diagnostic Laparoscopy for Detection of Peritoneal Metastases in Newly Diagnosed Gastric Carcinoma: Impact on PCI Scoring and Treatment Strategy

Protocol No.:

1. Full name of Principal Investigator: Dr. Anirban Mukherjee

Address: Department of Nuclear Medicine, Phase 1, Tata Medical Center, Kolkata

Title of the Principal Investigator: Associate Consultant, Nuclear Medicine

2. Name and address of the medical college, hospital or other facility where the clinical Trial will be conducted:

Tata Medical Center, Kolkata

Education, training & experience that qualify the Investigator for the clinical trial (Attach details including Medical Council Registration number, and / or any other statement(s) of qualification(s).

3. Name and address of all clinical laboratory facilities to be used in the study. – Department of Nuclear Medicine, Tata Medical Center, Kolkata

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, Kolkata

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. Shrey Aryan

Dr. Soumendranath Ray

Dr. Jayanta Das

Dr. Bipradas Roy

Dr. Priya Ghosh

Dr. Sayantani Sinha

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator: : Comparative Evaluation of FAPI PET-CT, CECT, and Diagnostic Laparoscopy for Detection of Peritoneal Metastases in Newly Diagnosed Gastric Carcinoma: Impact on PCI Scoring and Treatment Strategy

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This Document is Electronically Signed

Prepared by : Dr Tanuj Chawla/ Dr Indranil Mallick
IRB Secretariat

Reviewed by: Prof Siddhartha Roy
TMC-IRB Chairperson

Approved by: Dr Pattatheyl Arun
Head of the Institution



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7. Commitments:

- (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
- (ii) 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.
- (iii) I agree to personally conduct and/or supervise the clinical trial at my site.
- (iv) I agree to inform all Subjects that the drugs are being used for investigational 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.
- (v) 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.

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- (vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
- (vii) 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.
- (viii) 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.
- (ix) 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.
- (x) I agree to inform all serious adverse events to the Sponsor as well as the IRB/EC within 24hrs of their occurrence.
- (xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
- (xii) I have/do not have any conflicts of Interest (COI) in the study i.e. Financial/Personal or others.
- (xiii) 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 Investigators:

Dr. Shrey Aryan

08/06/26
Date:


Signature of the Investigator:

Dr. Soumendranath Ray

8.6.26
Date:


Signature of the Investigator:

Dr. Jayanta Das

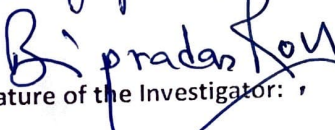
8.6.26
Date:


Signature of the Investigator:

Dr. Bipradas Roy

Date:

8.6.26


Signature of the Investigator:



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Dr. Priya Ghosh

Date: 8/6/28 Signature of the Investigator:

P. Ghosh

Dr. Sayantani Sinha

Date: 8/6/28 Signature of the Investigator:

S. Sinha



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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 Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

I agree to inform all unexpected serious adverse events to the Sponsor, Licensing Authority as well as the Ethics Committee and copy to the Head of the Institution within one day of their occurrence.

I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials

I agree to declare conflict of interest, if any during the discussion and decision taking in the EC Meetings.

Name of the Principal Investigator: Dr. Anirban Mukherjee

Signature of the Principal Investigator:

Date: 08.06.2024

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IRB Secretariat

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Head of the Institution