



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: Initial Study Submission Form

Annexure 1 (Page 1/8)

Protocol Name 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

	Name	Designation & Qualification	Institution & Department	Signature
Principal Investigator	Dr. Anirban Mukherjee	MBBS, MD Consultant	Nuclear Medicine	
Co-Investigator	Dr. Shrey Aryan	MBBS DNB Trainee	Nuclear Medicine	
Co-Investigator	Dr. Soumendranath Ray	MBBS, DRM, DNB Consultant and Head of Department	Nuclear Medicine	
Co-Investigator	Dr. Jayanta Das	MBBS, MD Consultant	Nuclear Medicine	
Co-Investigator	Dr. Bipradas Roy	MBBS, MS, MRCS Consultant	GI-HPB Surgery	
Co-Investigator	Dr. Priya Ghosh	MBBS, MD, FRCR Consultant	Radiology	
Co-Investigator	Dr. Sayantani Sinha	MBBS, DNB Consultant	Nuclear Medicine	

Supporting Staff

Type of Review requested:

FULL REVIEW

(For additional collaborators, attach details and a letter of consent by the collaborator(s) on a separate page)

Please attach the following updated documents of study team members such as (Principal Investigator, Co-Investigator and Study Coordinator)

Curriculum Vitae (CV) ☒ Medical Registration Certificate ☒ Good Clinical Practice certificate ☒
Study Type Non-Sponsored/ (Investigator Initiated) Study ☐ Sponsored ☒

1. Sponsor Information

Full Address: TATA MEDICAL CENTER
19 MAR (E-W), NEWTOWN, RAJARHAT,
KOLKATA - 700160

Contact No:

E-Mail ID:



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International	☐	Indian ☐	
		Government	Private ☒
		Central ☐ State ☐	

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2. Total Budget ₹. 2,00,000.000

(In Words : TWO LAKH RUPEES ONLY
)

Research Funds to be deposited in:			
DJST ☐	DDF ☐	Research Society ☐	Others (Please Mention) ☒ DEPARTMENT OF NUCLEAR MEDICINE
.....details of allocation of budget in an attachment (Attached ☒)			

Type of Study			
Epidemiological ☐	Basic Sciences ☐	Animal Studies ☐	Others (please specify) ☐
Clinical	Single Center ☒		☒
	Multi-centric ☒		
	(No of centres involved=) ☐		

Clinical Trials : Medicine/Vaccines/Device/Herbal Remedies: (Tick appropriate boxes)

i. Does the Study involve use of:	Medicines ☐	Devices ☐	Vaccines ☐	Herbal Remedies ☐
	Indian system of medicine(s) ☐	N.A. ☐	Others ☐	
If other, specify:				
ii. Is it approved & marketed	India ☐	UK & Europe ☐	USA ☐	NA ☐
	Other countries, please specify:			

Tick appropriate option

iii. Does it involve a change in use, dosage, route of Administration?	☐ Yes	☒ No	☐ NA
If yes, whether CLA's/Any other Regulatory Authority's permission is obtained?	☐ Yes	☐ No	☐ NA



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If Yes, Date of permission:

Click here to enter a date.

If yes, whether DCGI's/ Any other Regulatory Authority's permission is applied for?

☐ Yes

☐ No

☐ NA

iv. Is it an Investigational New Drug (IND)?

☐ Yes

☐ No

☐ NA

If Yes, please provide IND Number:

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a) In vitro studies data

☐ Yes

☐ No

☒ NA

b) Pre-clinical Studies done

☐ Yes

☐ No

☒ NA

c) Clinical Study is : ☐ Phase I ☐ Phase II ☐ Phase III

☐

Phase IV

☐

d) To submit package insert in case test drug is already marketed in India

Attached ☐

e) Are you aware if this study/similar study is being done elsewhere?

☐ Yes

☐ No

☒ NA

If Yes, specify details:

f) Whether CLA's permission for testing IND obtained?

☐ Yes

☐ No

☒ NA

If yes, Date of permission

Click here to enter a
date.

g) For Ayurvedic or herbal formulation, a copy of the marketing / manufacturing license issued by the FDA to the company to be submitted

☐ Yes

☐ No

☒ NA

1. **Please note:** Protocol, Introduction, Review of literature, Aim(s) & Objectives, Justification for study, Methodology describing the potential risks & benefits, Outcome measures, Statistical analysis and whether it is of national significance with rationale (submit as attachment).

2. Subject selection

i. Number of subjects at this center 20 ii. Total number of subjects at all sites NA

iii. Number of subjects at sites in India NA iv. Duration of Study 1 YEAR

v. Will subjects from both sexes be recruited ☒ Yes ☐ No ☐ NA

vi. Type of Subjects Volunteers ☒ Patients ☐ NA ☐

vii. Vulnerable Subjects ☐ Yes ☐ No ☒ NA



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If Yes, please mention:	Pregnant women	☐	Elderly	☐	Mentally challenged	☐
	Foetus	☐	Illiterate	☐	Handicapped	☐
	Children	☐	Captives	☐	Terminally Ill	☐
	Elderly	☐	Seriously Ill	☐	Economic/socially backward	☐
	Dependant staff	☐	Institutionalized	☐	Students	☐
	Employees	☐	Others (specify)			

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Privacy and confidentiality			
i. Study involves	Direct Identifiers ☐	Indirect Identifiers ☐	Completely anonymised/delinked ☐
ii. Confidential handling of data by staff	☒ Yes	☐ No	☐ NA
Use of biological/hazardous materials			
a. Use of fetal tissue or abortus	☐ Yes	☐ No	☒ NA
b. Use of organs or body fluids	☐ Yes	☐ No	☒ NA
c. Use of recombinant/gene therapy	☐ Yes	☐ No	☒ NA
If Yes, has the Department of Biotechnology (DBT) approval for DNA product has been obtained?		☐ Yes	☐ No ☐ NA
d. Use of pre-existing/stored/left over samples	☐ Yes	☐ No	☒ NA
e. Collection for banking/future use	☐ Yes	☐ No	☒ NA
f. Use of ionizing radiation/radioisotopes	☒ Yes	☐ No	☐ NA
If Yes, has Bhaba Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?		☒ Yes	☐ No ☐ NA
g. Use of infectious/bio hazardous specimens	☐ Yes	☐ No	☒ NA
h. Proper disposal of material	☐ Yes	☐ No	☒ NA
2. Will any sample collected from the patients be sent abroad?		☐ Yes	☐ No ☒ NA

If Yes, specify with details of collaborators



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Biological Samples dispatched abroad				
a) Sample will be sent abroad because:	Facility not available in India	☐		
	Facility in India inaccessible	☐		
	Facility available but not being accessed	☐		
Mention reasons:				
b) Has permission from Director General of Foreign Trade (DGFT) been applied?	☐ Yes	☐ No	☐ NA	
c) Has permission from Director General of Foreign Trade (DGFT) been obtained?	☐ Yes	☐ No	☐ NA	
3. Is the protocol being submitted for clearance from the Health Ministry's Screening Committee (HMSC) for international collaboration? (required in case of studies involving collaborations with foreign laboratory/clinic/institutions)	☐ Yes	☐ No	☐ NA	
4. In case of studies involving collaborations with other Indian or foreign laboratory/clinic/institution has administrative sanction from the Dean obtained/applied for?	☐ Yes	☐ No	☐ NA	
Consent				
Written	☒	Oral	☐	
		Audio- Visual	☐	
		N.A.	☐	
Consent Form	Understandable language	☒	Statement that study involves research	☒
	Alternatives to participation	☐	Confidentiality of records	☒
	Sponsor of study	☐	Contact information	☒
	Purpose and procedures	☒	Statement that consent is voluntary	☒
	Risks and discomforts	☐	Right to withdraw	☒
	Compensation for participation	☐	Compensation for study related injury	☐
	Compensation for participation			☐
				☐
				☐
				☐
Benefits				
Benefits , if any, on future commercialization	Yes	☐	NA	☒
Consent for future use of biological material	Yes	☐	NA	☒
If written content will not be obtained mention the reasons:				
Whether applied for waiver of consent?	Yes	☐	No	☐
Consent obtained by	PI/ Co- I	☒	Nurse/ Counsellor	☒
		☐	Research Staff	☐
		☐	Other	☐

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12. Will advertising be done for recruitment of subjects?

(posters, flyers, brochures, websites – if so, kindly attach a copy)

☐ Yes ☐ No ☒ NA

13. Risks & Benefits :

☐ Is the risk reasonable compared to the anticipated benefits to Subjects/ community/ country?

☒ Yes ☐ No ☐ NA

☐ Is there physical/social/psychological risk/discomfort?

☒ Yes ☐ No ☐ NA

Minimal or, no risk

☒

If YES,

More than Minimal Risk

☐

High risk

☐

Subject Direct ☒ Indirect

☐

☐ Is there a benefit

Benefit to Society

☒

14. Data & Safety Monitoring :

i. Is There a data & safety monitoring committee/Board (DSMB)?

☐ Yes ☐ No ☒ NA

ii. Is there a plan for reporting adverse events?

☐ Yes ☐ No ☒ NA

☐ Sponsor

☐ Ethics Committee

☐ DSMB

If yes, reporting is done to :

iii. Is there a plan for interim analysis of data?

☐ Yes ☒ No ☐ NA

iv. Are there plans for storage and maintenance of all trial Database?

☒ Yes ☐ No ☐ NA

If Yes, for how long?

2 YEARS

Compensation

15. Is there compensation for participation?

☐ Yes ☒ No ☐ NA

If yes, ☐ Monetary In kind _____ ☐ Specify amount / kind _____

16. Is there compensation for injury?

☐ Yes ☒ No ☐ NA

If Yes, ☐ Sponsor

☐ Insurance Company

☐ Investigator

☐ Others, (Please Mention)

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17. Do you have any conflict of interest in the present study?

☐ Yes ☒ No ☐ NA

☐ Financial

☐ Non- Financial



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If yes, Specify:

18. Number of protocols handled by the PI at present including current status of ongoing studies approved by TMC-IRB or CARE carried out by the Principal Investigator.

(Information to be given: Whether study is initiated, no. of approved subjects, no. of subjects enrolled, no. of active subjects, no. of subjects who have completed the study and total duration of the study. Describe briefly in a separate sheet, if required).

ONE

19. Current brief curriculum vitae (signed & dated copy) of the study team members – principal investigator, co-investigator and study coordinator

Information required:-

- ☐ age,
- ☐ designation and department,
- ☐ educational qualification,
- ☐ Previous research experience in last five years.

(To be enclosed along with the form)

(Information about GCP training of PI and co-investigator)

20. GCP training certificates of principal investigator, co-Investigators

(To be enclosed along with the form)

21. Is the trial registered with Clinical Trial Registry of India (CTRI)/any other WHO platform registry?

☐ Yes

☒ No

☐ NA

Registration number :

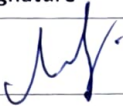
If not registered, state the reason:

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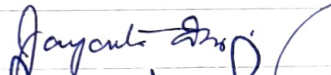
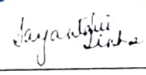
Statement of Compliance:

We, hereby, declare that, the information given above is true and that we will comply with the guidelines mentioned in the NDCT (Third Amendment) Rules, 2022 (Drugs and Cosmetic Act 1940), Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017), Indian GCP Guidelines (2001) and the International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (1996) while conducting the research study.

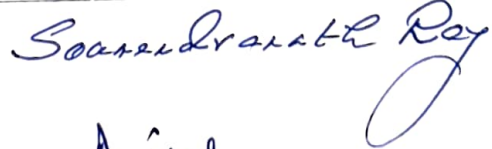
Name and Signatures of Principal investigator with Date

Name	Signature	Date
Dr. Anirban Mukherjee		08.06.26

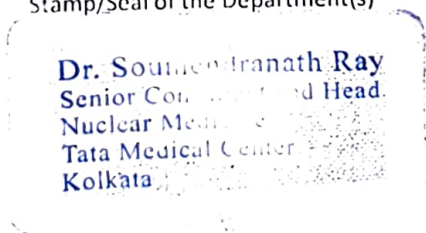
Name and Signatures of Co-investigator(s) with Date

Name	Signature	Date
Dr. Shrey Aryan		08/06/26.
Dr. Soumendranath Ray		8.6.26
Dr. Jayanta Das		8.6.26.
Dr. Bipradas Roy		
Dr. Priya Ghosh		8.6.26
Dr. Sayantani Sinha		8/6/26

Name and Signatures of Head of Department(s) with Date

Name	Signature	Date
Dr. Soumendranath Ray		8.6.26
Dr. Amrit Pipara		8.06.26.
Dr. Saugata Sen		8.6.26

Stamp/Seal of the Department(s)



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Undertaking by the investigator (As per Schedule III, Table 4 of NDCT (Third Amendment) Rules, 2022)

Protocol No:

Protocol Name: 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

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: 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
7. Commitments:

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- a. 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.
- b. 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.
- c. I agree to personally conduct and/or supervise the clinical trial at my site.
- d. 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.
- e. 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.
- f. I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
- g. 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.


08.06.24



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- h. 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. 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.
- j. I agree to inform all serious adverse events to the Sponsor as well as the IRB/EC within 24hrs of their occurrence.
- k. I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
- l. I have/do not have any conflicts of Interest (COI) in the study i.e. Financial/Personal or others.
- m. 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	8/06/26 Date:	 Signature of the Investigator:
Dr. Priya Ghosh	8.6.26 Date:	 Signature of the Investigator:
Dr. Sayantani Sinha	8/6/26 Date:	 Signature of the Investigator:

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Annexure 3:

Check List of Documents for Protocol Submission to the TMC-IRB to be filled in by the study team

S/N	Document	Yes	No	Date by which it will be submitted, if pending	NA
1)	Project submission application duly filled	☒	☐		☐
2)	Letter to Member Secretary/Chairperson	☒	☐		☐
3)	Summary of protocol (in not more than 500 words)	☒	☐		☐
4)	Protocol	☒	☐		☐
5)	Amendments to protocol	☐	☐		☐
6)	Informed consent document in English	☒	☐		☐
7)	Informed consent document in Regional languages (Total No. : TWO)	☒	☐		☐
8)	Back translations of Informed consent documents	☒	☐		☐
9)	Translation and Back translation certificates of Informed consent documents	☒	☐		☐
10)	Amendments to the Informed consent documents	☐	☐		☒
11)	Case Record Form	☒	☐		☐
12)	Subject recruitment procedures : advertisements, notices	☐	☐		☒
13)	Patient instruction card, identity card, diary etc.	☒	☐		☐
14)	Patient/subject questionnaire(s) (No.: ____)	☐	☐		☒
15)	Insurance policy (only one copy is needed for submission)	☐	☐		☒
16)	Investigator's undertaking to DCG(I) (one copy)	☐	☐		☒
17)	DCG(I) approval (one copy)	☐	☐		☒
18)	Investigator's agreement with sponsor (copy of final signed document)	☐	☐		☐



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- | | | | | |
|-----|---|--------------------------|--------------------------|-------------------------------------|
| 19) | DCG(I) marketing/manufacturing licence for herbal formulations/nutraceuticals (one copy) | ☐ | ☐ | ☒ |
| 20) | Health Ministry Screening Committee (HMSC) approval, in case the study involves collaboration with any foreign laboratory/clinic/institution (one copy) | ☐ | ☐ | ☒ |

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

Reviewed by: Prof Siddhartha Roy
Ex- TMC-IRB Chairperson

Approved by: Dr Pattatheyl Arun
Head of the Institution

- | | | | | |
|-----|---|-------------------------------------|--------------------------|-------------------------------------|
| 21) | Bhaba Atomic Research Centre(BARC) approval in case study involves use of radioisotopes/ionizing radiations (one copy) | ☒ | ☐ | ☐ |
| 22) | Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy (one copy) | ☐ | ☐ | ☒ |
| 23) | Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis (one copy) | ☐ | ☐ | ☒ |
| 24) | Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions (one copy) | ☐ | ☐ | ☒ |
| 25) | Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator) (one copy) | ☒ | ☐ | ☐ |
| 26) | Ethics Committee clearance of other centres (Total No. : _____) (one copy) | ☐ | ☐ | ☒ |
| 27) | Log of delegation of responsibility of the study team members – sample format enclosed | ☒ | ☐ | ☐ |
| 28) | Document Receipt Form (one copy) | ☒ | ☐ | ☐ |
| 29) | Current status of ongoing studies conducted by Principal Investigator | ☒ | ☐ | ☐ |
| 30) | Documentation of CTIRI registration/any other WHO platform registry (whenever applicable) (one copy) | ☐ | ☐ | ☒ |
| 31) | GCP training certificates of principal investigator and co-investigator(s) | ☒ | ☐ | ☐ |
| 32) | Any other documents submitted | ☐ | ☐ | ☐ |

This Document is Electronically Signed

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

Reviewed by: Prof Siddhartha Roy
Ex- TMC-IRB Chairperson

Approved by: Dr Pattatheyl Arun
Head of the Institution

Checklist for EC form:

Contact Address of Sponsor

14 MAR (E-W), NEW TOWN, RAJARHAT,
KOLKATA - 700160.

Total Budget

TWO LAKH INDIAN RUPEES.

Information on Protocol

✓

Subject selection

✓

Privacy and confidentiality

✓

Use of biological/ hazardous
materials

Consent

✓

Risks & Benefits

✓

Data Monitoring

Compensation for participation

Compensation for injury

Statement on conflict of interest

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N.	Receive the study drug, document drug, dispensing, storage & accountability	☐	☐	☐	☐	☐	☐	☐
O.	Persons with whom subject should contact in case of adverse event	☒	☐	☐	☐	☐	☐	☐
P.	Report all Serious Adverse Events (SAE)	☐	☐	☐	☐	☐	☐	☐
Q.	Follow up of SAE	☐	☐	☐	☐	☐	☐	☐
R.	Maintaining study site master file	☐	☒	☐	☐	☐	☐	☐
S.	In-charge of inventory & supplies	☒	☐	☒	☐	☐	☐	☐
T.	Archiving of study documents	☐	☒	☐	☐	☐	☐	☐
U.	Resolution of queries	☒	☐	☒	☒	☒	☒	☐
V.	Overall coordination and supervision	☒	☐	☒	☐	☐	☐	☐

Annexure 5: Document Receipt form

Receipt No.

Protocol No.

Submission date

Type of submission

☒ Initial Review

☐ Resubmission for re-review

☐ Protocol Amendments

☐ Other

☐ Continuing Review of

☐ approved protocols

☐ Termination

☐ Completion

Protocol 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

Principal Investigator

Dr. Anirban Mukherjee

Department

Nuclear Medicine

Communication

E-mail address: anirban.mukherjee@tmckolkata.com

Documents submitted

☒ Complete

☐ Incomplete,

☐ Will submit on: _____

Documents to be submitted later

☐ Final signed clinical trial agreement

☐ Informed consent form

☐ Case report forms (CRF)

☐ Study budget

☐ Investigator's brochure

☐ Insurance document

☐ Others (Please Mention) _____

Received by, Name: Signature
and Date:

This Document is Electronically Signed

Prepared by : Dr Tanuj Chawla/ Dr Indranil Mallick

IRB Secretariat

Reviewed by: Prof Siddhartha Roy

Ex- TMC-IRB Chairperson

Approved by: Dr Pattatheyil Arun

Head of the Institution