Standard Operating Procedures

National Cancer Grid

Contract Research Organization

(NCG CRO)

NATIONAL CANCER GRID

COLLABORATION FOR CANCER CARE

Tata Memorial Centre

Tata Memorial Hospital

Dr. Ernest Borges Road,

Parel, Mumbai– 400012

INDEX

28/Feb/2023

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Compiled Abbreviations:

- AE: Adverse Event
- AV: Audio-Visual
- BioRRAP: Biological Research Regulatory Approval Portal
- CDA: Confidentiality Disclosure Agreement
- CDSCO: Central Drugs Standard Control Organization
- CIOMS: Council for International Organization of Medical Science
- Co-I: Co-Investigator
- Co-PI: Co-Principal Investigator
- CRA: Clinical Research Associate
- CRC-Clinical Research Coordinator
- CRF: Case Report Form
- CRO: Clinical Research Organisation
- CTA: Clinical Trial Agreement
- CTRI: Clinical Trials Registry –India
- CV: Curriculum Vitae
- DAE: Department of Atomic Energy
- DCF: Data Clarification Form
- DCGI: Drug Controller General of India
- DHR: Department of Health Research
- DST: Department of Science and Technology
- EC: Ethics Committee
- eCRF: Electronic Case Record form
- FQ: Feasibility Questionnaire
- GCP: Good Clinical Practice
- HMSC: Health Ministry's Screening Committee
- IB: Investigational Brochures
- ICD: Informed Consent Document
- ICF: Informed Consent Form
- ICH: International Council of Harmonisation
- ICH-GCP: International Conference on Harmonisation- Good Clinical Practice
- ICMR: Indian Council for Medical Research
- ICTRP: International Clinical Trials Registry Platform
- IEC: Institutional Ethics Committee
- IM-Investigator Meeting
- IMP: Investigational Medicinal Product
- IP: Investigational Product
- ISF: Investigator Site File

- IVRS: Interactive Voice Response System
- IW: Impartial Witness
- IWRS: Interactive Web Response System
- LAR: Legally Acceptable Representative
- MOM's: Minutes of Meetings
- MOU: Memoranda of Understanding
- MRC: Medical Registration Certificate
- MTA: Material Transfer Agreement
- NABH: National Accreditation Board for Hospitals
- NCG CRO: National Cancer Grid Clinical Research Organization
- NCG-National Cancer Grid
- NDCT rules 2019 : New Drugs and Clinical Trial rules 2019
- NTF: Note to File
- PD: Protocol Deviation
- PDF: Portable Document Format
- P-In: Project In-charge
- PI-Principal Investigator
- PM: Project Manager
- PV: Protocol Violation
- ROMV: Routine Onsite Monitoring Visit
- SAE: Serious Adverse Event
- SAV: Site Assessment Visit
- SCV: Site Close-out Visit
- SDV: Source Data Verification
- SIV: Site Initiation Visit
- SMP: Study Monitoring Plan
- SOP: Standard Operating Procedure
- S-PI: Sponsor-Principal Investigator
- SUSAR: Suspected Unexpected Serious Adverse Event
- TMF: Trial Master File
- TOM: Task Ownership Matrix
- TSIV: Telephonic Site Initiation Visit

Compiled Glossary:

- **Adverse Event:** Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. (ICH GCP E6R2).

- **Case Report Form:** A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

- **Central Drugs Standard Control Organization (CDSCO):** is the national regulatory body for Indian pharmaceuticals and medical devices, and serves parallel function to the European Medicines Agency of the European Union, the PMDA of Japan, the Food and Drug Administration of the United States and the Medicines and Healthcare products Regulatory Agency of the United Kingdom.

- **Clinical Trials Registry - India (CTRI):** A set up at the National Institute of Medical Statistics, ICMR, New Delhi is a free and online system for registration all clinical trials being conducted in India (www.ctri.nic.in). Registration of clinical trials in the CTRI is now mandatory, as per notification of the Drugs Controller General (India). Trials registered in the CTRI are freely searchable, both from the CTRI site as well as the International Clinical Trials Registry Platform (ICTRP).

- **Close-out visit:** Relates to the closure of a study at a participating site once all subjects have completed the study and all data queries have been resolved.

- **Contract Research Organisation**: A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

- **Drug Controller General of India (DCGI):** Under the gamut of Central Drugs Standard Control Organization is responsible for approval of licenses of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India.

- **Essential Documents**: Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (see 8. Essential Documents for the Conduct of a Clinical Trial).

- **Feasibility Questionnaire:** A set of questions related to the site resources and Investigator that is used to identify potential site for the conduct of Clinical Trial.
  used to gain further information about an approved use.

- **Good Clinical Practice:** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. (ICH GCP E6R2).

- **Health Ministry's Screening Committee (HMSC):** All biomedical and health research proposals involving foreign assistance and/or collaboration should be submitted to the Health Ministry's Screening Committee (HMSC) for consideration and approval before initiation. The secretariat for HMSC is located at the ICMR Headquarters, New Delhi. As per the requirements of HMSC, all research involving international collaboration – either technical, financial, laboratory or data management must be submitted to HMSC.

- **Impartial Witness:** A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject. (ICH GCP E6R2)

- **Indian Council of Medical Research (ICMR):** the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest and largest medical research bodies in the world. The ICMR is funded by the Government of India through the Department of Health Research, Ministry of Health and Family Welfare.

- **Informed Consent Form:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. (ICH GCP E6R2)

- **Institutional Ethic Committee (IEC):** An institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a type of committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical.

- **Investigator:** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

- **Investigator's Brochure:** A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects

- **Investigators Meeting**: It is nothing but a group meeting conducted on behalf of sponsor/CROs to train investigators and their lead clinical trial staff on trial related activities, standard operating procedures and to discuss the applicable regulatory picture. The content of an investigator meeting is usually trial specific, nevertheless a common agenda, on SOP's, Adverse Event Reporting, Source Documentation etc are also discussed.

- **Investigational Medicinal Product:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when

- **Investigator Site File:** The effective filing system which allows the storage and location of essential documents generated for a study in the form of project file (s)/ binder (s) at the site

- **Legally Acceptable Representative:** An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial. (ICH GCP E6R2)

- **Monitoring Plan:** A description of the methods, responsibilities and requirements for monitoring the trial (ICH GCP E6R2)

- **National Cancer Grid:** It is a network of major cancer centers, research institutes, patient groups and charitable institutions across India with the mandate of establishing uniform standards of patient care for prevention, diagnosis, and treatment of cancer, providing specialized training and education in oncology and facilitating collaborative basic, translational and clinical research in cancer.

- **National Cancer Grid Contract Research Organization:** CRO-like set up within NCG, which will undertake all monitoring related activities for the NCG, approved studies.

- **Standard Operating Procedure**: Detailed, written instructions to achieve uniformity of the performance of a specific function. (ICH GCP E6R2)

- **Site Assessment Visit:** The visit conducted for verifying the site facilities, Investigator and site staff qualification, expertise etc. as described in the feasibility questionnairefor selection of the sites for study conduct.

- **Serious Adverse Event:** Any untoward medical occurrence that at any dose:
    - results in death,
    - is life-threatening,
    - requires inpatient hospitalization or prolongation of existing hospitalization,
    - results in persistent or significant disability/incapacity, or
    - is a congenital anomaly/birth defect (ICH GCP E6R2)

- **Source Data Verification:** Commonly known as 'transcription checking', the process by which data within the CRF or other data collection systems are compared to the original source of information (and vice versa) to confirm that the data were transcribed accurately (i.e. data from source matches data in the CRF or other system and vice versa)

- **Sponsor–Principal Investigator:** An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

- **Task Ownership Matrix:** It is used for clarifying and defining roles and responsibilities in cross-functional or departmental projects and processes.

- **Trial Master File:** A standard filing system which allows the effective storage and location of essential documents, which is the large volume of regulatory documents and approvals needed for clinical research. The filing can be in the form of single project file or a number of files/filing cabinets depending upon the clinical trial.

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Title:

Standard Operating Procedure for Preparation of Standard Operating Procedure

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
01	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose:

This Standard Operating Procedure (SOP) provides general guidelines on creating SOPs on different topics, to maintain uniformity in carrying out various activities of the NCG CRO. The SOPs framed would be in compliance with New Drugs and CT Rules 2019, and directives from CDSCO from time to time, ICMR guidelines (2017), Indian GCP (2001) and revision when issued, ICH-GCP [E6 (R2)-2016] and other applicable guidelines and regulatory requirements.

2.0 Scope:

This SOP will serve as a manual for writing, reviewing, approving & amending SOPs of National Cancer Grid Contract Research Organization (NCG CRO) and to create a page layout for maintaining uniformity in the various chapters of the SOPs.

3.0 Applicable to whom:

Research team within NCG CRO

4.0 Procedure:

This describes the process of general guidelines for framing the SOPs of NCG CRO.

4.1 The page layout of the SOP chapters would be according to the specifications mentioned below.

- Page border would be inserted.

- Header:

Format:

(a) Font Style: Times New Roman

(b) Font size:10

Contents:

(a) Subject: NCG CROSOP

(b) SOP code: Chx/Vy(Ch-chapter, x-number (01,02,03,etc.)
(V-Version, y-number (1.0, 2.0, 3.0 etc.)

(c) Title:

- Footer:

Format:

(a) Font Style: Times New Roman

(b) Font size:10

Contents:

(a) Version number: Vx [V-version, x-number (1.0, 2.0, 3.0 etc.)]

(b) Version Date: dd-mmm-yyyy

(c) Page number:

4.2. Chapter Title
Font Size: 16
Font Style: Times New Roman, Bold

4.3. Sub-sections in Chapter
Font Size: 14
Font Style: Times New Roman, Bold

4.4. The font style will be Times New Roman and the font size will be 12 for the entire content under the subsections in the chapters.

4.5. The annexure will be coded as **Chx–Ay-Vz**; wherein

Ch = Chapter; x = number (01, 02, 03, etc.)
A = Annexure; y = number (01, 02, 03, etc.)
V = Version; z = number (1.0, 2.0, 3.0, etc.)

4.6. Each SOP chapter would be signed and dated by the preparer, reviewer and approver. The signature box would be placed before the reference section.

The layout of the signature box would be as follows:

Prepared By	Reviewed by	Approved by
Name: Signature: Date:	Name: Signature: Date:	Name: Signature: Date:

4.7. Abbreviation and Glossary will be placed after the index page of the SOP and the same will be presented alphabetically using bullets.

4.8. The effective date of the SOP will be considered as the date on which the SOP will be signed by NCG convener.

5.0 Preparation of SOP:

5.1. The draft SOP would be prepared by the team as appointed by the NCG Convener/NCG Project In-charge. The SOPs would be prepared by CRAs, CTAs, PM and any other members as decided by the Project In-charge.

6.0 Review of SOP:

6.1. The draft SOP would be reviewed by NCG Project In-charge or PM and signed and dated. Any modifications suggested by the reviewer would be incorporated by the team involved in the preparation of SOP.

7.0 Approval of SOP:

7.1. The final SOP would then be approved by the NCG Convener/designate and signed & dated.

7.2. All SOP chapters will be submitted to Director, TMC for final signature and date. The signature and date will be inserted on the signature page and not individually for respective chapters.

7.3. The SOPs would be implemented within 30 days from the date of signature of Director, TMC.

8.0 Revision of SOP:

8.1. Tri-annual Revision:

8.1.1. As a part of practice the Preparer/delegated NCG CRO team member would review the current SOP every 3 years for the purpose of required updates, if any. This version would be numbered as 2.0, 3.0, 4.0 etc.

8.1.2. The current version would be valid till 3 years from the effective date of the current SOP.

8.1.3. The process of review should be completed (+/-) 1 month from the expiry date of the current version.

8.1.3. The signature page for Director's approval of revised/amended SOP would be as per the format described in Annexure 4

8.1.4. The revised SOP would be implemented within 30 days from the date of signature of Director, TMC.

8.1.5. Once a revised SOP signed by Director TMC, the earlier SOP would be obsolete.

8.1.6. E-mail communication would be sent by Project In-charge/NCG Convener/Delegate -to NCG CRO staff with soft copies of the Final SOP/Revised SOP (as applicable).

8.1.7. NCG CRO staff would be trained by either Face to face training session or self-reading. Training records template would be maintained or a confirmatory e-mail will be sent by the trainee to the Project In-charge

8.2. Revision upon request:

8.2.1. Any individual CRO team member or NCG Project In-charge or NCG convener or any external personnel (for e.g. an auditor) can suggest revision in the existing SOP, giving reasons for the change requested.

8.2.2. The suggested changes would be required to be submitted to the NCG-CRO Project In-charge or PM in an email as per the Request form template for SOP amendment (Annexure 2).

8.2.3. In case of a request the Project In-charge would evaluate the request and if considered appropriate would appoint an individual/team to execute the relevant changes. In case of major change the SOP chapter would be re-drafted with new version details and reviewed by Project In-charge and approved by NCG Convener and Director-TMC-Mumbai. In case of a minor change the same would be documented in a NTF and incorporated during next tri-annual

revision. In SOP binder, NTFs would be filed in place of individual chapter revision requests. The version number and version date of SOP would remain the same.

8.2.3. Point 8.1.7. (as described above) would be applicable.

8.3. SOP Deviation:

A SOP deviation can be identified by any individual CRO team member or NCG Project In-charge or NCG Convener. The same would have to be documented in a SOP deviation form (annexure 5) and required corrective action would have to be implemented. The Project In-charge/NCG Convener/Delegate would review and approve the corrective action.

9.0 Archival of Obsolete SOPs:

9.1. The obsolete versions of the SOPs would be archived in NCG CRO office with proper labels for a span of 15 years from the effective date of the revised SOP.

10.0 History of Change:

10.1. The details of changes in the current SOP as compared to the obsolete ones would be enumerated in a tabular form (Annexure 6). The study team would be trained before the changes are implemented.

11.0 Reference:

11.1 Suitable references would be mentioned at the end of every chapter. Full title/link (where applicable) and all content of the reference (e.g. - author's name, edition etc.) would be added using bullets.

12.0 Annexure (s):

12.1. Logs, templates, checklists and tables relevant to the content of the particular SOP chapter would be listed after the references using bullets.

Prepared By	**Reviewed by**	**Approved by**
Name: Ms. Prachi Kokate Signature: RKokate Date: 21-Feb-2023	Name: Dr. Durga Gadgil Signature DMGadgil Date: 27 Feb 2023	Name: Dr. C S Pramesh Signature: CS Pramesh Date: 28/Feb/2023

13.0 Reference(s):

- Tata_Memorial_Centre-Standard_Operating_Procedure-Clinical_Research Secretariat_SOP01/V2 dated 22-Mar-2022

14.0 Annexure (s):

- Annexure 1- SOP Template (Ch01-A01-V3.0)
- Annexure 2-Index Page template for the list of SOPs (Ch01-A02-V3.0)
- Annexure 3- Request form template for SOP amendment (Ch01-A03-V3.0)
- Annexure 4-Signature sheet template for Director's approval on SOP revision/amendment(Ch01-A04-V3.0)
- Annexure 5-SOP deviation form template(Ch01- A05-V3.0)
- Annexure 6-Temaplate of History of Change (Ch01- A06-V3.0)

SOP Template (Ch01-A01-V3.0)

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Title:			
Chapter Number:	Version Number:	Effective Date:	Valid Upto:

1.0. Purpose-(SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization)
2.0. Scope-(The development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization)
3.0. Applicable to Whom-(Mentioned the personnel to whom SOP is applicable)
4.0. Procedure- (The brief procedure how to follow SOP)
5.0. Reference-(Suitable references would be mentioned which are refer during preparation of SOP)
6.0. Annexure(s)-(Logs, templates, checklists, and tables relevant to the content of the particular SOP chapter would be listed)

Index page template for the list of SOPs (Ch01-A02-V3.0)

Sr. No.	Chapter Title	SOP code

Request form template for SOP amendment (Ch01-A03-V3.0)

SOP code:	
SOP title:	
Identified by:	Signature &Date:
Details of the revision suggested:	
Rationale for the revision:	
For NCG CRO use only	
SOP revision required Yes ☐ No ☐ If No, please specify the reason:	

Revised SOP Prepared By	**Revised SOP Reviewed by**	**Revised SOP Approved by**
Name: Signature: Date:	Name: Signature Date:	Name: Signature: Date:

Signature sheet template for Director's approval on SOP revision (Ch01- A04- V3.0)

SOP Code
SOP Title:
Details of revision:
Rationale for change:

Prepared By:

Name and Designation	Signature and Date

Reviewed By:

Name and Designation	Signature and Date
Project In Charge NCG CRO	

Approved By:

Name and Designation	Signature and Date
NCG Convener	

Accepted By:

Name and Designation	Signature and Date
Director, Tata Memorial Centre, Mumbai	

SOP deviation form template (Ch01-A05-V3.0)

Deviation occurrence date:

Deviation details:

Relevant section of the SOP which is relevant for the deviation:

Corrective action taken:

Did it result in any change of SOP and its relevant sections:

If, Yes, please specify:

Identified by:

Name and Designation	Signature and Date

Corrective Action implemented by:

Name and Designation	Signature and Date

Reviewed and Approved by:

Name and Designation	Signature and Date

Template of History of Change (Ch01-A06-V3.0)

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Date	Prepared by

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Date	Prepared by
1.	Ch 01/V1.0	V_1.0_15-Jan-2018	1. Revision in section 4.8 and 8.1 2. Addition of Annexure 4(Ch 01-A04-V1.1)	V1.1_19-Sep-2018	Mr. Shirsha Chakraborty
2.	Ch 01/V 2.0	V_1.1 19-Sep-2018	1.Modification in section 1.0 2.Modification in section 4.0 subsection 4.7 and 4.8 3.Modification in section 7.0 subsection 7.2 and 7.3 4.Modification in section 8.0 5.The revision timelines were modified and the section on SOP deviation was added. 6.Modification in section 9.0 7.Modification in section 13.0 8.Modification in Annexure 1 to Annexure 6	V2.0_05-Feb-2020	Mr. Shirsha Chakraborty
3.	Ch 01/V3.0	V2.0_05-Feb-2020	1.Modification in subsection 4.1 and 4.8 2. Modification in section 8.0 3. Modification in section 11.1 4. Modification in section 13.0 5. Correction in Annexure 01 and Annexure 02	V3.0_10-Feb-2023	Ms. Prachi Kokate

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Title:

Standard Operating Procedure For Site Assessment Visit

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
02	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose

This SOP describes the procedure of site feasibility assessment to evaluate if a site is suitable for a given study conduct.

2.0 Scope

The SOP describes the process to be followed for creating a tool for site feasibility assessment and to review the completed assessment sheets. It will also be applicable for a site feasibility visit.

3.0 Applicable to Whom

This SOP is applicable to NCG CRO team embers (CTA/CRA/PM/P-In etc.) who would be assigned to create a tool for site feasibility assessment, site visit (if applicable) and to review the completed assessment sheet if requested by a Sponsor-Principal Investigator (S-PI)/NCG member.

4.0 Procedure

4.1. The site assessment process would be classified into following activities:

(a) Creating a site feasibility questionnaire.

(b) Administering the feasibility questionnaire.

(c) Site Assessment Visit (SAV)

Note: NCG CRO team can be contacted by S-PI/any other NCG member to carry out the entire site assessment process or only a part of it.

4.2. Creating a site feasibility questionnaire:

4.2.1. Sponsor-Principal Investigator will contact NCG-CRO to create protocol specific site feasibility questionnaire, based on the feasibility questionnaire template (annexure 01).

4.2.2 P-In/PM will assign the task to CRA/CTA.

4.2.3 Delegated CRA/CTA will be trained on the protocol by PI/S-PI/PM and will create the feasibility questionnaire based on the study specific requirements.

4.2.4 CRA/CTA will share the questionnaire with S-PI to finalize the same.

4.3. Administering the feasibility questionnaire:

4.3.1. The CRA/CTA would request Sponsor-Principal Investigator to provide the list of potential sites.

4.3.2 The Confidentiality Agreement (CDA) (Ch02-A05-V2.0) would be sent to the sites by the CTA/CRA.

4.3.3. After the receipt of the signed CDA, the CTA/CRA would send soft copy of the Feasibility Questionnaire (FQ) and the study synopsis/full Protocol/Summary of Product Characteristics/ Investigator Brochure to the sites as per the list provided by the Project Manager (PM)/P-In/Sponsor Principal Investigator(S-PI). The site would be requested to send back the scanned copy of the filled FQ within 14-21 working days from the day of receipt of the FQ by the site

4.3.4. In case the site does not provide the FQ within 14 working days the CTA/CRA should follow-up through email/telephone. If required CRA/CTA may provide assistance to the site in the FQ completion process. If no response is received after 21 days, the S-PI will be informed and site may not be considered for the study as per the discretion of the Sponsor PI.

4.3.5. On receipt of the FQ, the CTA/CRA should check that all details are completed and then forward the same to the S-PI/PM/P-In. The S-PI would review the FQ and take the final decision regarding site selection. If required, any query related to the FQ would be communicated to the site by the CTA/CRA.

4.3.6. The S-PI/P-In/PM may communicate to the site regarding the selection or rejection via an email.

4.4. Site Assessment Visit (SAV):

4.4.1. Prior to the conduct of SAV:

4.4.1.1The approach to plan a SAV may be applicable to:

(a) New Institution
(b) Institutes with new research set up
(c) New Investigator
(d) High Intensity Studies

4.4.1.2. The P-In/ PM should instruct the CRA/CTA to contact the selected sites for a suitable date of SAV after the evaluation of the FQ.

4.4.1.3. The CRA/CTA should confirm with the site regarding the SAV date and would send a confirmation email (annexure 02) with the agenda of the SAV to the site. The agenda would be reviewed and approved by the PM/P-In

4.4.2. During the site assessment visit:

4.4.2.1. The activities during the SAV would comprise of any of the following but not limited to:

Sr. No.	Activities	Details
1.	Protocol Discussion	The following aspects of the Protocol detailed below but not limited to would be discussed: Study design Eligibility criteria Informed Consent process Study Procedures Sample size CRF(paper/electronic) Safety reporting Investigational Medicinal Product(IMP) Any Others.....
2.	Recruitment strategy	Access to target patient population- verification

		of database source Details of annual patient registration Expected monthly and annual recruitment target Any Others..... Any ongoing trial which might affect recruitment.....
3.	Ethics Committee set up	IEC registration IEC SOP IEC constitution and composition as per ICMR and New Drugs and Clinical Trial rules. frequency of meeting, Fees (if applicable) Any Others.....
4.	Assessment of resource and manpower	People: Qualification, experience, availability, of PI &Co-Investigators, Study Coordinators etc. Place: availability of space for the conduct of research activities, place for monitoring activity Time which can be provided by the Investigator: Number of ongoing trials under the Investigator, personal supervision. Study Budget: cost of investigations, remuneration of staff appointed for the study etc. Other resources: Computer systems- security and backup, other accessory devices, phone & fax etc. Any Others.....
5.	Facility tour, if possible	Local laboratory setup:

		Details of accreditation: Blood investigation facilities: Drug storage and destruction facilities: Radiology investigation facilities: Sample storage facilities (Blood sample and tissue storage): Archival facilities: Any Others.....
6.	Others	Source documentation procedures Site SOPs etc

4.4.2.2. The SAV report (annexure 03) should be filled by the CRA during the visit

4.4.3. Following Site Assessment Visit (SAV):

4.4.3.1. The CRA should submit the SAV report to the PM/P-In for review and finalisation within 7-10 working days of the visit. The approved report (along with recommendation for site selection) will be shared with S-PI for review and final decision with 1-2 working days from the date of finalisation.

4.4.3.2. The PM/P-In should recommend on the site selection (only FQ based or FQ and SAV) based on the following criteria but not limited to

(a) Clinical expertise of the Investigator
(b) Site staff (qualification & experience) and resource
(c) Site's access to potential study participants
(d) IEC set up
(e) Local Laboratory facility
(f) Radiology facilities
(g) Drug storage/Pharmacy and destruction facility
(h) Any others

4.4.3.3. The S-PI should communicate to the site regarding the selection or rejection via an email.

Prepared By	Reviewed by	Approved by

Name: Mr. Shirsha Chakraborty	Name: Dr. Durga Gadgil	Name: Dr. C S Pramesh
Signature: Shirsha Chakraborty	Signature: DAGadgil	Signature: CS Pramesh
Date: 23-Feb-2023	Date: 27 Feb 2023	Date: 28/Feb/2023

5.0 Reference(s):

- New Drugs and Clinical Trial rules 2019.
- Indian GCP guidelines (2001)
- ICH GCP E6 (R2) guidelines (2016)
- https://globalhealthtrials.tghn.org/site.../Pre-Study_Site_Selection_Visit_Checklist

6.0 Annexure(s):

- Annexure 01-Feasibility questionnaire template (Ch02-A01-V3.0)
- Annexure 02-SAV confirmation email template (Ch02-A02-V3.0)
- Annexure 03-SAV Report template (Ch02-A03-V3.0)
- Annexure 04- Site assessment visit follow up email template (Ch02-A04-V3.0)
- Annexure 05-Confidentiality Disclosure Agreement (Ch02-A05-V3.0)

Note: All the annexures can be customised as per the requirement of the study and/or as per discretion of CRA/PM//P-In.

Feasibility questionnaire template (Ch02-A01-V3.0)

Site Feasibility Questionnaire		
Sr. No.	**Feasibility criteria**	**Please fill in the details**
1	Name of site	
2	Contact details of the site	Address: Telephone: Fax: Email:
3	Type of site (Please tick)	o Government hospital o Private hospital o Charitable Trust Hospital o Primary care physician o Other
4	Does the site/PI have standard operating procedures (SOPs)?	o Yes o No
Comments (if any):		
Site Resources		
Research staff		
5	Details of the Principal Investigator	Name: Designation:

6	Credentials	o MD o MS o MCh o PhD o DM o Other
7	Contact details of the Principal Investigator-	Address: Telephone: Fax: Email:
8	Contact details of the coordinating person (Investigator/CRC)?	Name: Telephone: Email:
9	Does the PI have time to conduct this study?	o Yes o No
10	Does the PI have interest to conduct academic research?	o Yes o No
11	Professional Experience of the PI (in years)	
12	Clinical Research Experience of the PI (in years)	
13	Does the PI have experience in global clinical trials?	o Yes If Yes, please specify the phase of the trial: o Phase I o Phase II o Phase III o Investigator Initiate Study o Post Marketing Surveillance o No
14	How many clinical studies are currently ongoing under the PI's	

	supervision?	
15	Research publications of the PI	o Number of International publications- o Number of National publication-
16	Is the PI GCP Trained? (If Yes, Mention the date of training, Name of Training/Certification Body)	o Yes o No
17	Does site have dedicated staff to conduct Research?	o Yes o No
18	Number of research staff and supportive staff	Number of Co-Investigators- Number of Study Coordinators- Any other (Study Nurse/Pharmacist etc.)-Please specify the number
19	Does the staff have experience with e-CRF/electronic database?	o Yes o No
20	Is the site staff (other than the PI) GCP trained?	o Yes o No
Comments (if any):		
Laboratory details		
21	Is Local laboratory facility available?	o Yes o If No, please specify the name of the laboratory whose services would be used.
22	Is the laboratory accredited?	o NABL o CAP
23	Does the site have facility for Radiology Investigations?	o Yes o No
24	Please tick facilities available	o X-ray o CT scan o MRI o USG o Bone Scan o PET

		o ECG o 2D ECHO o Other (Please specify any additional investigational facilities in the comments section)
Comments (if any):		
Space and Infrastructural Facilities		
25	Does the site have dedicated space for research activities?	o Yes o No
26	Does the site have space for storage of study related materials (lab kits)?	o Yes o No
27	Does the site have separate room for Monitoring?	o Yes o No
28	Does the site have infrastructure (-20 degree/ -80 degree) refrigerator for storage of blood and tissue sample?	o Yes o No
29	Does the site have space for Archival of data after completion of the trial? If yes provide the details and procedures? If No specify the location where documents will be stored?	o Yes o No
30	Does the site have dedicated cupboard for study document storage.	o Yes o No
31	Does the site have dedicated Refrigerator (2 to 8 degrees) for IP storage facility with temperature control?	o Yes o No o NA
32	Does the site have sample processing facility? If Yes, Give details	o Yes o No o NA

33	Does the site have a separate room for AV recording?	o Yes o No
34	Does the site have Internet facility	o Yes o No
35	Does the site have STD/ISD/Fax call facility?	o Yes o No
	Comments (if any)	
Patient Recruitment Strategy		
36	What is the number of patients (per month) seen in the Hospital of particular indication involved in the trial?	
37	How does site recruit patient?	o Database o Referrals o Internet o Newsletters o Advertisements o Registries o Other
38	Besides English which other Vernacular ICDs/Patient related documents would be required?	
Protocol Specific(To be pre-filled by CRA/CTA before sending the FQ to site)		
39	Total sample size (all sites)	
40	Inclusion criteria	
41	Exclusion Criteria	
42	How many patients would fit the	Patients eligible for trial per month: ……

	eligibility criteria of the trial? How many patients would the site /PI be able to recruit?	Patients to be recruited per month: …….
43	Have the PI conducted any clinical trial with similar indication?	o Yes o No If Yes, please state the number-
44	Are there any ongoing competing clinical trials for a similar indication?	o Yes o No If, Yes, please specify details (Sample Size, No. of patients enrolled till date, CTRI No etc)
Comments (if any):		
Ethics Committee		
45	Does the Institute have any Institutional Ethics Committee?	o Yes o No
46	Kindly provide the contact details of EC administrator/ member secretary	IEC Contact person Address Telephone: Fax: Email:
47	a) Is the IEC registered with DCGI? b) Is the IEC registered with DHR (Department of health research, ICMR)?	o Yes o No If, Yes, please mention the registration number and the validity period- o Yes o No

	c) IS NABH assessment of IEC performed?	If, Yes, please mention the registration number and the validity period- o Yes o No If Yes, please mention the accreditation number and the validity period-
48	Is the EC constituted as per the New drugs and CT rules/ ICMR?	o Yes o No
49	Does IEC have a written SOP?	o Yes o No
50	What is the frequency of IEC meetings? Please provide the dates of the previous and upcoming IEC meeting	
51	How many days prior to the meeting should the study documents be submitted?	
52	Is checklist for submission of documents for IEC review available	o Yes o No
53	How many copies of documents are required for submission?	
54	How many days after the meetings will the approval letter be issued?	
55	EC fees (if any) for academic research studies	Initial review:…….. Amendments documents Review:…….. Any other review fee:…….
Comments (if any):		

Finance		
56	Does the site have any research specific account where study related payments can be made? I f Yes, please mention the mode of payment(cheque/fund transfer), PAN & GST details	
57	Admission Charges-	
58	Bed Charges-	o General ward : o Semi-private ward : o Private ward :
59	ICU charges-	
60	Please specify the cost of Blood Investigations(Enclose the current schedule of charges/ Rate card)	Haematology: Biochemistry: Others:
61	Please specify the cost of radiology and other investigations(Enclose the current schedule of charges/ Rate card)	o X-ray o CT scan o MRI o USG o Bone Scan o PET o ECG o 2D ECHO
Comments (if any):		

Prepared by:

Signature	Name	Date

Reviewed by:

Signature	Name	Date

Approved by:

Signature	Name	Date

SAV confirmation email template (Ch02-A02-V3.0)

To,

{The Principal Investigator}

{Designation}

{Site details}

Reference : {Protocol Title and ID}

Dear {PI name}

Greetings !

Thank you for confirming your availability for the Site Assessment Visit (SAV) for the above mentioned study.

As discussed we would be conducting the SAV at your site on (date) and the duration of the visit wouldbe of …… day/s. I would be accompaniedby (designated person) during the visit.

Please revert in case of any queries regarding of the visit.

Kindly find the enclosed the SIV agenda for your reference.

I also requestyou to send the acknowledgement copy of this letter for our record.

Thanking you for your cooperation and the interest in the study. I look forward to meeting you during the visit.

Regards,

Yours Sincerely,

Name of the CRA

SAV Report template (Ch02-A03-V3.0)

Study Title:

Name of CRA:

Date of visit:

Investigator Information	
Name of the Investigator	
Title/Department	
Site/Institution Name	
Address:	
Email :	
Telephone:	
Fax:	

Protocol Information :	
Protocol Title	
Protocol Version	
Protocol / Project Code	

Attendance of the Site Personnel during visit :		
Sr. No	**Name of the Personnel**	**Designation**

Sr. No	**Activity**	**Yes**	**No**	**N/A**
01	Did Principal Investigator sign Confidentiality agreement?			
02	Has the feasibility Questionnaire been filled by site?			
03	I. Brief discussion on essential study documents: (a) Protocol (b) Study design and visit schedule (c) Eligibility criteria (d) Informed Consent Process (e) Source documentation (f) IP-storage, accountability, dispensing, return, destruction (g) Safety reporting (h) Concomitant medications (i) Paper/electronic CRF/Quality of Life forms II. Discussion on Monitoring frequency and expectation from site			
04	Were cost of investigations/ other study related costsdiscussed?			

Comments:				
Manpower				
05	(a)Is the Principal Investigator (PI) qualified to conduct the trial? (b) Is updated CV available?			
06	Does the PI have sufficient experience relevant to therapeutic area of investigational medicinal product (IMP)/intervention?			
07	Is the PI having the necessary facilities, time and support staff, to carry out the proposed research?			
08	(a)Is the Co- Investigator qualified to conduct the trial and have relevant experience? **(b)** Is updated CV available?			
09	Are the Investigators aware of and trained on ICH-GCP and Indian GCP guidelines? Also DCGI regulations/ICMR guidelines?(as per the requirements)			
10	(a)Is the Study Coordinator qualified to conduct the trial and have relevant experience? (b)Is updated CV available?			
11	Does the site have Standard operating procedure (SOP)?			
Comments:				
Recruitment strategy				
12	Was Time-line for target patient enrolment discussed?			
Comments: Please specify the monthly and annual target enrolment after verifying the details (database/other sources) of site's access to target patient population				
IRB/IEC Procedure:				

13	a) Is the IEC registered with DCGI? b) Is the IEC registered with ICMR (Department of health research)			
14	Is the IEC constituted as per New drugs and Clinical Trial rules?			
15	Does the IEC have SOPs?			
16	Was IRB/IEC meeting frequency & documents required for submission & time-lines discussed?			
17	Whether the IEC submission checklist was collected from the site?			
Comments				
Informed consent procedure				
18	Does the principal investigator/Co-Investigator administer the consent? If others (study coordinator)Please specify			
19	a) Does the site require the ICD translations? If Yes specify the languages required…….. b) Is back translation required by IEC?			
20	Does the site have a dedicated room for AV recording of Consent process (if applicable)?			
Comments				
Facility/Resource Assessment :				
21	(a) Is there an accredited local laboratory available? (b) Normal laboratory ranges available?			
22	Does the site have facility for radiology investigations?			
23	Does the site have emergency medical treatment facility?			

24	Does the site have adequate bed for inpatient admission if required?			
25	Does the site have facilities of storage of blood and tissue samples?			
26	Is there internet facility available at trial site?			
27	Is Fax machine available at trial site?			
28	Is Photocopier machine available?			
29	Is Printer/scanner available?			
30	Are adequate records maintained for Clinical supplies Inventory Tracking and Reporting?			
31	Adequate archival facility available at trial site?			
32	Does the site have space for study conduct and monitoring activity?			
Comments:				
Pharmacy				
33	Is Drug storage facility available?			
34	(a) Is Refrigerator (2°- 8°c) available for drug storage? (b) Is deep freezer (-20° and/or -80°c) available forsample storage?			
35	Is thermohygrometer and its calibration certificate available at the site? (if applicable)			
Comments:				
Access of the Source Document & Archiving assessment:				
36	How are source documents maintained at the site: (a)Electronic (b) Paper (c) Hybrid			
37	Will the NCG CRO Monitors/Auditor have Access to source			

	documents and subject medical records?			
38	Does the Institute have some Medical Records retention and destruction policy? If yes, for how many years the medical records are retained?			
Comments:				

CRA comments about suitability of site for study:
Site recommended☐ Yes ☐ No Recommended with conditions ☐ Yes ☐ No Site not recommended☐ Yes ☐ No Please specify reason:

Report reviewed and approved by:
Signature:
Date:

Prepared by:

Signature	Name	Date

Reviewed by:

Signature	Name	Date

Approved by:

Signature	Name	Date

Site assessment visit follow up email template (Ch02-A04-V3.0)

To,

<The Principal Investigator name>

<Designation>

<Site details>

Reference: < Protocol Title and ID>

Dear <PI name>

Greetings!

I thank you and your staff for the cooperation extended during the site assessment visit held on <date>. I appreciate the time spared by you from your busy schedule for the visit.

The following were reviewed and discussed during the visit:

1. Study Protocol

2. Recruitment strategy

3. Ethics Committee set up

4. Site resource and man power

Tour facilities were conducted at the following departments:

During the discussion it was agreed that the site would be able to enrol <number> of patients per month based on the eligibility criteria.

<If selected>we are pleased to inform you that your site has been considered for the conduct of the study. Requesting you to proceed with the Institutional Ethics Committee submission for approval of the study related documents

<If rejected> we regret to inform you that at present your site cannot be considered for the study. We look forward to working with you on other studies in future.

Please revert in case further information/assistance is required and kindly share the acknowledgement copy of the letter for our records.

Regards,

Yours sincerely,
Name of the CRA

Confidentiality Disclosure Agreement (Ch02-A05-V2.0)

This CONFIDENTIAL DISCOSURE AGREEMENT (the "Agreement") is entered into by and between **<Sponsor PI name and designation>** (hereinafter called "SPONSOR PI") and(which expression shall mean and include unless repugnant to the context, its successors and permitted assigns) represented by its Director, **<Name>**, and <SITE ADDRESS> (hereinafter called "SITE") and represented by **<Site S-PI Name>** (hereinafter called "investigator")

This Agreement shall govern the conditions of disclosure by SPONSOR PI to SITE of certain confidential information relating to Project **"STUDY TITLE**" including without limitation, information as specified below (collectively, the "Information"):

"Information" shall mean any and all information including information without limitation, relating to Intellectual Property Rights and **" STUDY TITLE** "I on _____<dd/mm/yyyy>becoming aware of such information in the process of supporting this project, or even at the preliminary stage of discussions between TMC and SITE while seeking expression of interest from TMC, in the proposed project.

WHEREAS, in consideration for the opportunity to be considered as an investigator, Investigator is willing to receive the Confidential Information subject to abiding by the terms and conditions set forth below;

NOW, THEREFORE, in consideration of the benefits set forth herein, the parties hereby agree as follows:

1) SPONSOR PI is willing to disclose Confidential Information to Investigator on the following terms and conditions:
   a) Investigator will receive, maintain, and hold the Confidential Information in strict confidence and will NOT use such information at any time for other than the purpose for which it has been provided;
   b) Investigator will treat such information as it would its own proprietary and confidential information and not to disclose such information to any third party;
   c) Investigator will take all precautions to prevent the disclosure of such information to any third party.
   d) Investigator will not use such information at any time for exploiting or causing to exploit it directly or indirectly by the Investigator or through any third party, for any commercial interest or otherwise.
2) The investigator shall be relieved of any and all obligations under the paragraph '1' above, regarding information which
   a) was known to or independently developed by Investigator prior to disclosure of the Confidential Information as demonstrated by written records of the investigator, and it was not acquired directly or indirectly from SPONSOR PI, or their affiliates;

b) was generally available to the public through no act or omission or negligence on the part of Investigator;
c) was furnished to Investigator on a non-confidential basis by any third party having a legal right to do so; or,
d) was required by law, regulation, government order or judicial order to be disclosed, provided that Investigator promptly notifies SPONSOR PI of such required disclosure and provides SPONSOR PI an opportunity to contest the disclosure requirement, by appropriate legal action.

Confidential Information shall not be deemed to be in the public domain merely because it may be derived from one or more items which are publicly known.

3) The investigator shall only disclose the Information to those employees of the investigator who need to know such Information for the above-stated purpose. The investigator shall make all such employees aware of this Agreement and the obligations and restrictions imposed herein, and obtain necessary confidentiality agreements from them, and shall inform TMC accordingly. The investigator shall also ensure that such employees comply with the obligations and restrictions of this Agreement. The investigator shall be held responsible for disclosure of Information by its past employees if such information was acquired by them during tenure of their employment with the investigator.

4) The Confidential Information is the exclusive properly of SPONSOR PI and neither this Agreement nor any disclosure shall be deemed, by this implication or otherwise, to vest in Investigator any license or other ownership rights to or under any patents, know-how, or trade secrets disclosed to Investigator by SPONSOR PI, or their affiliates or agents.

5) At any time upon the request of SPONSOR PI, or immediately if Investigator and/or SPONSOR PI determine that Investigator will not be participating in the services under discussion Study, Investigator shall return to SPONSOR PI, or, at SPONSOR PI's option, destroy, (a) the Confidential Information, including all copies, and (b) all other embodiments of the Confidential Information in the possession of Investigator, including all copies and/or any other form or reproduction and/or description thereof made by Investigator.

6) The investigator recognizes that TMC may suffer irreparable damages if the information or any portion thereof is disclosed or any breach of any of the undertakings given by the investigator herein and accordingly the investigator agrees that TMC shall be entitled to specific performances of investigator's obligations and/or any other remedies available in law or equity.

7) Neither party shall (i) issue a press release or make any other public statement that references this Agreement; or (ii) use the other party's or its affiliates' names or trademarks for publicity or advertising purposes without the prior written consent of the other party.

8) No failure or delay by SPONSOR PI in exercising any right, power, or privilege under this Agreement shall act as a waiver thereof. This Agreement constitutes the entire understanding of the Parties with respect to the matters contained herein, superseding all prior oral or written

understandings or communications between the Parties. Any amendments or modifications to this Agreement must be in writing and signed by both the Investigator and SPONSOR PI.

9) Correspondence with SPONSOR PI, respecting this Agreement shall be addressed to**<Name>,** at the address set forth above, Correspondence with Investigator with respect to this Agreement shall be addressed to **<Site PI Name>,**Address:

10) This Agreement shall be construed and interpreted in accordance with the laws of the Republic of India.

11) This Confidentiality Agreement is effective from Notwithstanding the termination of this Agreement for any reason whatsoever, this Confidentiality Agreement shall survive for 10 years from the date of termination of the Agreement

12) Nothing hereinabove shall commit or obligate, or be legally binding on either party to agree to any potential business relationship or to enter into any further agreements or negotiations with the other or to refrain from entering into an agreement or negotiations with any third parties.

AGREED TO AND EFFECTIVE AS OF THE DATE LAST SIGNED BELOW:

(Sponsor Principal Investigator)	(Site Principal Investigator)
Signature: _____	Signature: _____
Name:	Name:
Title: _____	Title: _____
Date: _____	Date: _____

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Effective date	Prepared by
1.	Ch02/V2.0	V1.0_09-Jan-2018	1.Modification in section 1.0 2.Modification in section 2.0 3.Modification in section 3.0 4.Modification in section 4.0 subsection 4.1,4.2,4.3 and 4.4 5.Modification in section 5.0 6.Modification in section 6.0	V2.0_05-Feb-2020	Mrs. Kalyani Madhu
1.	Ch02/V3.0	V2.0_05-Feb-2020	1.Modification in section 3.0 2.Modification in section 4.0 3.Modification in section 6.0 4.Addition of Annexure 05	V3.0_10-Feb-2023	Mr. Shirsha Chakraborty

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai- 400012	राष्ट्र की सेवा में परमाणु टी एम सी TMC ATOMS IN THE SERVICE OF THE NATION

Title:

Standard Operating Procedure for Ethics Committee Submission

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
03	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose

This Standard Operating Procedure (SOP) describes the procedure involved in submitting the documents to the Ethics Committees (EC) for the review of the study related documents, for the EC approval

2.0 Scope

The SOP would serve as a guide for preparing the documentation with regards to the EC submissions and the tasks to be done from the time of submission to the receipt of final approval of the study it also applies to all subsequent submission in a timely manner (Except SAE related submission)

Note: As requested by Sponsor-Principal Investigator(S-PI), NCG CRO would carry out assigned EC related activities.

3.0 Applicable to whom

This SOP is relevant to the research team within the National Cancer Grid Contract Research Organization (NCG CRO) conducting the studies funded or supported by the NCG.

4.0 Procedure

Responsibility:

Clinical Research Associate (CRA)/ Clinical Trial Assistant (CTA) with assistance from Project Manager (PM)/Project In-charge will perform the following activities (as applicable):

4.1. The NCG CRO would prepare/assist the sites to compile the submission dossier for the EC submission based on the site EC SOP. The Sponsor-Principal Investigator is responsible for making the site SOPs available for NCG CRO team

4.2. The NCG CRO personnel will verify that the following:

a) EC is registered with the CDSCO and DHR,
b) The EC is constituted as per the NDCT rules 2019.

4.3. EC Submission

4.3.1. The essential documents that would be submitted to EC (including but not limited to) :

- Covering letter(Annexure2)
- Study protocol with version control.
- Informed Consent Document (ICD) English and all relevant vernacular language(s) with version control and certificate if applicable.
- Informed Consent Document_Back Translation(s) with version control and certificate (If applicable)
- Assent Form (If applicable) English and all translation with version control and certificate (If applicable)
- Assent Form_Back Translation (If applicable) with version control and certificate (If applicable)
- Case Report Form (CRF) with version control
- IB/pack insert (if applicable)
- Clinical Trial Agreement
- Insurance Certificate (if applicable)
- Investigator Undertaking (Annexure3)
- Conflict of Interest (Annexure 4)
- CV, MRC (where applicable) and GCP certificates of the study team members (PI, Co-PI, Co-I, Co-ordinators, Study nurse, etc)
- Recruitment strategy (Optional)
- Ethics Committee Project Submission Form (Annexure 1) (Optional)
- DCGI approval (If applicable)
- HMSC approval, (If applicable)
- CTRI registration
- Lay summary of the Protocol
- Any other study specific document (Recruitment advertisement, Patient Diary Card, Questionnaire with translations, etc) (If applicable)
  Note: The submission dossier will be as per site IEC submission checklist or site EC SOPs.

4.3.2. The acknowledgement of the submission of the dossier to EC, will be collected from site Principal Investigator/CRC

4.4. EC Response(s)

4.4.1. Post review from the EC, NCG CRO to retrieve the soft copy of the EC response.

4.4.2. In case of query raised by EC, the NCG CRO team may assist the Sponsor-Principal Investigator/Principal Investigator for drafting the response.

4.4.3. NCG CRO reviews the final approval letter received meets with the NDCT 2019 rule format, if discrepancy found the discrepancy to be communicated to the Sponsor-Principal Investigator/Principal Investigator:
Note: Third Schedule-Table 1 as per the New Drug and CT rules, 2019 can be referred red to. (Annexure 5 attached for reference)

4.4.4. The final CTRI registration number once obtained should be notified to the EC before initiation of the study at the site.

4.4.5. Once EC approval received the Sponsor-Principal Investigator will be informed and all documents sent to Sponsor-Principal Investigator for records.

4.5. Ongoing communication with the EC

4.5.1. The annual progress report, any renewals or amendments in any of the study related documents (Protocol, IB, ICD, etc) should to be submitted to the EC and approval/ confirmation receipt of notifications for the same needs to be obtained if applicable.

4.5.2. The scanned copy of the initial IEC approval(s) and the correspondence with the EC would be shared with NCG CRO and filed in the TMF at NCG CRO if applicable

Prepared By	Reviewed by	Approved by
Name: Ms. Prachi Kokate Signature: Pkokate Date: 21-Feb-2023	Name: Dr. Durga Gadgil Signature: DAGadgil Date: 27 Feb 2023	Name: Dr. C S Pramesh Signature: C S Pramesh Date: 28/Feb/2023

5.0 Reference

- NDCT rules 2019
- ICH Guidelines for Good Clinical Practice (E6 R2) section 3.1 – Responsibilities
- ICH Guidelines for Good Clinical Practice (E6 R2) section 4.10 – Progress Reports
- ICH Guidelines for Good Clinical Practice (E6 R2) section 4.4 – Communication with IEC

- Tata Memorial Centre Institutional Ethics Committee SOP 02a/V6_28-Apr-2021_ AX4-V2/SOP02a/V2

6.0Annexure

- Annexure 1: Project Submission template(Ch03 –A01-V3.0)
- Annexure 2: Covering Letter template for EC submission(Ch03 –A02-V3.0)
- Annexure 3: Investigator Undertaking(Ch03–A03-V3.0)
- Annexure 4: Declaration of Conflict of Interest template (Ch03 –A04-V3.0)
- Annexure 5: IEC approval letter template (Ch03-A05-V3.0)

Project Submission template (Ch03 –A01-V3.0)

A. Study Summary

I	**STUDY DETAILS**	
1	Study Project No. (Post EC approval)	
2a	Study Title	
2b	Short Title	
II	**INVESTIGATOR DETAILS**	
1a	Name of Principal Investigator (PI)	
1b	Name of Co-Principal Investigator (Co-PI)	
1c	Name of Co-Investigator(s) (Co-I)	
2	Number of ongoing studies in which Principal Investigator is involved? (as PI only)	
3	Contact number of Principal Investigator	
III	**TYPE OF STUDY**	
1	Study Type (multiple options if applicable)	☐ Investigator Initiated study ☐ Pharmaceutical sponsored Study ☐ Thesis ☐ Multicentric study- Tata Memorial Centre as co-ordinating centre ☐ Multicentric study ☐ Retrospective Study
2	a) If retrospective study, mention time frame from which data is to be collected b) The total number of participants whose	

	data is to be analyzed	
IV	**SITE DETAILS**	
1	Co-ordinating centre	
2	Site(s) where study is to be conducted	
V	**FUNDING DETAILS**	
1	Funding Agency	
2	Total estimated budget (in Rs.)	
VI	**RECRUITMENT DETAILS**	
1	Duration of the Project (in months)	
2	Total number of participants to be accrued in study	
3	Number of participants from the site to be accrued	
VII	**PI SIGNATURE AND DATE**	
	Signature of PI	
	Date of submission	

B. Study Overview

I	**STUDY DETAILS**	
1	**Study Title**	
2	**Principal Investigator**	
3	**Introduction/ background**	
4	**Study Rationale**	
5	**Objectives**	
5.1	Primary Objective	
5.2	Secondary Objective	
II	**STUDY DESIGN**	
1	**Treatment /Interventional**	
		☐ Randomized Controlled Trial (RCT) ☐ Double-blind RCT

		☐ Single-blind RCT ☐ Open Label ☐ Adaptive Clinical Trial ☐ Non Randomized Trial ☐ Any other (Please Specify) :
1.1	Phase of the study	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Not Applicable
1.2	Pharmacokinetics/Pharmacodynamics (PK PD)	☐ Yes ☐ No ☐ Not Applicable
1.3	Feasibility Study	☐ Yes ☐ No ☐ Not Applicable
1.4	Pilot	☐ Yes ☐ No ☐ Not Applicable
1.5	Pivotal	☐ Yes ☐ No ☐ Not Applicable
2	**Observational**	
		☐ Prospective Cohort ☐ Time series study ☐ Nested case-control study ☐ Retrospective Cohort ☐ Case-control Study ☐ Nested case-control Study ☐ Cross-sectional Study ☐ Community survey ☐ Longitudinal Study ☐ Epidemiological Study

		☐ Survey(Others) ☐ Any other (Please Specify) :
3	**Study methodology** Explain i. Conduct of study ii. Data collection procedures. iii. Describe the trial related procedures and investigations. iv. Study arms v. Randomization procedure (if applicable) vi. Procedure involved in banking of biological samples. (if applicable) vii. Define stop points and criteria for withdrawing subjects from the study.	
III	**ELIGIBILITY AND RECRUITEMENT**	
1a	**Inclusion Criteria**	
1b	**Exclusion Criteria**	
2	**Subjects/samples to be screened**	
IV	**STASTICAL ANALYSIS**	
1	**Power estimates** Describe power calculations, if the study involves statistical comparisons between two or more groups. Mention evidence to support that adequate number of subjects can be enrolled during the study period by the investigators.	
2	**Variables to be estimated** (e.g. response, survival, toxicity, age, etc) Enumerate the variables, outcomes and end	

	points that will be measured. Try to separate variables as response and explanatory variables. Describe the type and frequency of tests, admissions, outpatient visits, etc used to obtain these variables or variables.	
3	**Analysis of the variables** Describe how the variables obtained during the study will be statistically analyzed. e.g. Univariate comparison or Cox- proportional hazards model, etc	
V	**INFORMED CONSENT**	
1	Describe the participant recruitment strategy adopted Please tick in the box:	☐ OPD basis ☐ EMR data base ☐ Referrals ☐ Advertisements ☐ Any other (please specify)
2	Describe (i) How, where, when and by whom the Informed Consent will be obtained., (ii) Describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates and geriatric population	
3	Are your seeking waiver of consent Specify reasons (If Yes)	☐ Yes ☐ No
VI	**DRUG/DEVICE/BIOLOGICS DETAILS**	
1	Approval status in the market ☐ Drug ☐ Device ☐ Biologics Please attach copy of DCGI permission/DCGI Application. If marketed drug, please attach copy of package insert/product insert.	☐ Already approved ☐ New

2	Does your 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
VII	**REGULATORY PERMISSION(s)**	
1	Does the study require permission from regulatory authorities?	☐ Yes ☐ No
2	If yes, attach a copy of relevant permission (s)	
2a.	Health Ministry's Screening Committee(HMSC)	☐ Yes ☐ No
2b.	DCGI	☐ Yes ☐ No
2c.	Others, please specify	
3	Has Investigator-Sponsor and the foreign party signed agreement/MOU for that? If yes, attach a copy of agreement/MOU	☐ Yes ☐ No
VIII	**STUDY MONITORING DETAILS**	
1	Does the study have provisions for monitoring the data to ensure the safety of participants and data integrity?	☐ Yes ☐ No
1.1	If Yes, who has the responsibility of monitoring the study?	
IX	**DATA SHARE**	
1	The results of the study will be reported via	☐ Peer reviewed scientific journals ☐ Other publication ☐ Conference presentation ☐ Internal report ☐ Submission to regulatory authorities ☐ Access to raw data and right to publish

		freely by all the investigators in study or by independent steering committee on behalf of all investigators ☐ Other (Please Specify):

C. Budget Sheet for the Proposed Study

1	Title of the Project:		
	INVESTIGATOR DETAILS		
1	Name of Principal Investigator		
2	Designation of the PI		
3	Source of funding		
	Address, phone, fax. E-mail of sponsor with the name of the contact person		
	No funding required		
6	Total Budget for the entire project (in Rs.)		
7	Duration of the Project (in months)		
8	Proposed date of starting the project		
9	Direct payments to investigators, if any		
10	Any other benefits to the investigators		
11	Name of PI:	Signature:	Date:

Detailed Budget for the Proposed Study*

	1st Year	2nd Year	3rd Year	Total
1. **Salaries-personnel (Numbers)**				
1.1 Doctor / Post-Doc (Research Fellow)				
1.2 Research Nurse				
1.3 Data operator				
1.4 Any other specify				
2. Equipment and Hardware				
-				

3. Drugs and Consumables				
-				
4. Clinical Investigations				
-				
5. **Hospitalization**				
-				
6.**Travel expenditure for investigators**				
-				
7. Travel expenditure for trial subject and one attendant				
8. **Honorarium to doctors/technicians**				
9. Insurance				
9.1 for investigators				
9.2 any unforeseen, accidental trial related injury				
10. **Any other expenditures**				
11.**Miscellaneous (<5% of budget)**				
12. **Service Charge (10% of total applicable for pharma sponsored studies)** (TMC, CRI, DAE, ICMR, DBT, DST, IAEA, WHO, IARC etc. funded project are exempted)				
13. Estimated Professional charges for clinical services. **(15% at the end of the study on actual applicable for pharma sponsored studies)**				
Grand Total				
Name of PI:	**Signature:**			**Date:**

Note:

- PI should devise incremental budget whenever necessary.
- Please provide the complete break-up of item nos. 3, 4 & 5 on separate sheet.

- Please specify year-wise total in grand total column

Covering Letter template for EC submission (Ch03 –A02-V3.0)

Date:

To,

The Member Secretary,

<EC name>

<EC address >

Reference :< Study Title>

Subject: Submission of study related documents for EC approval

Dear Sir/Madam,

I/ We am/are submitting the following study related documents to the Ethics Committee for the approval of the above mentioned study

Please find enclosed <no. of copies as per site SOP>of the following study documents for your review and approval

Sr.No.	Document Type
1	Study Protocol_<Version Number>_<Date>
2	<Language>_Informed Consent Form_<Version Number>_<Date> with Certificate (If required)
3	<Language>_Informed Consent Form_Back Translation_<Version Number>_<Date> with certificate (If required)
4	<Language> Assent Form and Parental Consent Form _<Version Number>_<Date> (If applicable) with certificate (If required)
5	<Language> Assent Form_and Parental Consent Form _Back Translation_<Version Number>_<Date> (If applicable) with certificate (If required)
6	Case Record Form_<Version Number>_<Date>
7	Clinical Trial Agreement
8	Insurance Certificate
9	Investigator Undertaking
10	Conflict of Interest
11	CV, MRC and GCP certificates of the study team

I/we would request you to review the above mentioned documents and approve the study

Please do not hesitate to contact us for clarification

Thanks & Regards,

<Signature of PI>
<Name of the PI>
<Designation>
<Site Name and address>

Investigator Undertaking (Ch03–A03-V3.0)

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator):

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 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:

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study:

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):

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator:

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 or favourable opinion from the ethics committee of the amendment, except where necessary to eliminate an immediate hazard to the trial subject or when the changes involved are only logistical or administrative in nature.

(iii) I agree to personally conduct or supervise the clinical trial at my site.

(iv) I agree to inform all trial 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 New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.

(v) I agree to report to the Sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and Good Clinical Practices guidelines.

(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 or inspection by the Sponsor, ethics committee, Central Licencing Authority or their authorised representatives, in accordance with regulatory provisions and the Good Clinical Practices guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorised representatives of the Sponsor.

(ix) 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.

(x) I agree to inform all serious adverse events to the Central Licencing Authority, sponsor as well as the ethics committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

(xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licencing Authority, the Chairperson of the ethics committee and the Head of the institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.

(xii) I will maintain confidentiality of the identification of all participating subjects and assure security and confidentiality of study data.

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

Signature of Investigator with Date:

Template for Declaration of Conflict of Interest template (Ch03 –A04-V3.0)

1. **Employment or Leadership Position**
   Check yes if you or an immediate family member currently holds any full-time or part-time employment or service as an officer or board member for an entity having an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

2. **Consultant or Advisory Role**
   Check yes if you or an immediate family member holds or has held any consultant or advisory arrangements with an entity having an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

3. **Stock Ownership**
   Check yes if you or an immediate family member currently holds any ownership interest in any company (publicly traded or privately held) that has an investment, licensing, or other commercial interest in the research study under consideration.

   ☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

4. **Honoraria**
   Check yes if you or an immediate family member has been paid directly any honoraria (reasonable payments for specific speeches, seminar presentations, or appearances) from an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

5. Research Funding

Check yes if you or an immediate family member currently conducts any clinical research project(s) funded, in whole or in part, or has received any post study awards by an entity that has an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

6. Patent or Royalty interests

Check yes if you or an immediate family member has received any patent or royalty from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

7. Other Remuneration

Check yes if you or an immediate family member has received any trips, travel, gifts, or other in-kind payments at any point from an entity having an investment, licensing, or other commercial interest in the research study under consideration.

☐ Yes ☐No If yes, amount received in last 12 months in Rs. _____

I hereby agree to recuse myself from any deliberations and actions involved in the approval or re-approval of a protocol for which I have a real or apparent conflict of interest, and from discussions of these matters unless my presence for discussions is requested by the IEC Chair.

☐ I hereby declare that I have no conflict of interest in my project.

☐ I have above conflict of interest:

_____ _____

Signature of PI **Date**

Template for IEC approval letter template (Ch03-A05-V3.0)

To,

Dr.

Dear Dr._____

The Institutional ethics committee or independent ethics committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "…….. "on…….(date). The following documents were reviewed:

(a) Trial protocol (including protocol amendments), dated…….version No.(s) ……

(b) Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.

(c) Investigator's brochure dated ....., Version no…… Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

(d) Principal investigator's current Curriculum Vitae.

(e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

(f) Investigator's agreement with the sponsor.

(g) Investigator's undertaking (Table 4 of NDCT rule 2019).

The following members of the ethics committee were present at the meeting held on (date, time, place). ……Chairperson of the ethics committee;

…….Member-Secretary of the ethics committee;

…….Name of each member with designation;

We approve the trial to be conducted in its presented form.

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.

Yours sincerely,

Member Secretary,

Ethics Committee

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_ Date	Prepared by
1	Ch03/V2.0	V1.0_17 Jan 2018	1.Modification section 1.0 2. Modification in section 2.0 3. Modification in section 4.0 subsection 4.1,4.3,4.4 and 4.5 4. Modification section 5.0 5. Modification section 6.0	V2.0_05-Feb-2020	Ms. Lochana Bandekar
2	Ch03/V3.0	V2.0_05-Feb-2020	1.Modification section 4.0 & 5.0 2.Addition in Annexure 1.0 & 3.0	V3.0_10-Feb-2023	Ms. Prachi Kokate

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai- 400012	राष्ट्र की सेवा में परमाणु टी एम सी TMC ATOMS IN THE SERVICE OF THE NATION

Title:

Standard Operating Procedure for Preparation of Trial Master File

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
04	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0. Purpose

This SOP is to describe the procedure of preparing the NCG CRO specific Trial Master File (TMF) for each study assigned to the CRO.

2.0. Scope

This SOP covers the procedures of preparing and maintaining the Trial Master File for studies where this responsibility is assigned to NCG CRO.

3.0. Applicable for whom

This SOP is applicable for research team within the NCG CRO

4.0. Procedure:

4.1. Whenever the study is finalized the Clinical Research Associate (CRA) or the Clinical Trial Assistant (CTA) should Prepare Trial Master File (TMF) with index containing list of all essential documents.

4.2. Trial Master File has index with appropriate study title and contents. File should be properly labelled (Annexure 02). It is necessary to retain a hard copy of the essential documents and a Note to file should be prepared if documents are maintained as soft copies/placed in other files (Annexure 04).

4.3. The Trial Master File (TMF) is maintained on an ongoing basis as the trial progresses and documents should be arranged in chronological order (latest document placed first in the relevant section) so that they can be easily accessed.

4.4. The NCG CRO TMF must be retained within a secure place with appropriate storage conditions. Access should be allowed only for authorized personnel (NCG Convenor, Project In-Charge, Project Manager, CRA, CTA, etc.)
4.5. Storage cupboards should be properly labelled (Annexure 03)
4.6. The process for preparing and maintaining essential documents for the NCG funded or supported studies in TMF can be categorized into the following:

4.6.1. Preparation of NCG CRO TMF.
4.6.2. Creation of TMF to support the Sponsor- Principal Investigator
4.6.3. Preparation of TMF as part of Project Management

4.6.1. Preparation of NCG CRO Trial Master File:

The following list of essential documents to be placed in the Trial Master File.
To refer Annexure 01b-Index for NCG CRO trial master file (Ch04-A01b-V3.0)

a) Protocol (protocol amendments if applicable) and its training records, Signature and Duty Delegation log
b) CDA between NCG and the peer reviewer, Peer review scoring sheet and feedback and other relevant documents.
c) Clinical trial Agreement (work order) between the NCG and Sponsor-Principal Investigator
d) Finance (fund release letter, annual status report and utilization certificate)
e) Study Monitoring Plan (if applicable)
f) Monitoring related (visit confirmation letter, monitoring report, follow- up letter etc.)
g) Informed Consent Documents, Case Report Forms (if applicable)
h) Miscellaneous

4.6.2. Creation of TMF to support the Sponsor-Principal Investigator:

This Standard Operating Procedure provides instructions for preparing and maintaining the Trial Master File in accordance with the International Council for Harmonization guidelines (Section 8) and Indian Good Clinical Practices guidelines (Appendix V)

When approached, the NCG CRO personnel can assist the Sponsor- Principal Investigator team member in creation of TMF. The essential documents may be place in the TMF as per the Annexure 01a-Index for trial master file for study sites (Ch04-A01a-V3.0)

4.6.3. Preparation of TMF as part of project management:

When the NCG CRO is allotted the responsibility of the project management, then the CRA with the assistance of the CTA will create the TMF as per Annexure 1a-Index for trial master file for study sites (Ch04-A01a-V3.0).

Note: For section 4.6.2. and 4.6.3, while preparing the various logs, the following templates can be used as a reference, for e.g.

a) Screening log (Annexure 08)
b) Randomization log (Annexure 09)
c) Training log (Annexure 05), etc

Prepared By	Reviewed by	Approved by
Name: Ms. Prachi Kokate Signature: PKokate Date: 21-Feb-2023	Name: Dr. Durga Gadgil Signature: Date: 27 feb 2023	Name: Dr. C.S. Pramesh Signature: Date: 28/Feb/2023

5.0 Reference:

- Indian GCP guidelines (Appendix 5)
- ICH GCP (E6)R2 guidelines (Section 8)

6.0 Annexure-

- Annexure 01a-Template-Index for trial master file for study sites (Ch04-A01a-V3.0)
- Annexure 01b-Template-Index for NCG CRO trial master file (Ch04-A01b-V3.0)
- Annexure 02-Template-Labels for file (Ch04-A02-V3.0)
- Annexure 03-Template-Labels for cupboard (Ch04-A03-V3.0)
- Annexure 04-Note to file template (Ch04-A04-V3.0)
- Annexure 05-Site Personnel Training Log Template (Ch04-A05-V3.0)
- Annexure 06- Template for Duty Delegation Log (Ch04-A06-V3.0)
- Annexure 07-Subject Identification Log template (Ch05-A07-V3.0)
- Annexure 08- Screening Log template (Ch04-A08-V3.0)
- Annexure 09- Randomization Log template (Ch04-A09-V3.0)
- Annexure 10-Protocol Waiver Request Log template (Ch04-A10-V3.0)
- Annexure 11- SAE form template (Ch04-A011-V3.0)
- Annexure 12- Template for Adverse Event/Serious Adverse Event Log (Ch04-A12-V3.0)
- Annexure 13- Template for SUSAR/CIOMS Event Log (Ch04-A13-V3.0)
- Annexure 14- Template of Protocol Deviation/Violation reporting form (Ch04-A14-V3.0)
- Annexure 15- Template for Protocol Deviation/Violation Log (Ch04-A15-V3.0)
- Annexure 16- Temperature Log template (Ch04-A16-V3.0)
- Annexure 17- Template for IMP Accountability Log- Master (Ch04-A17-V3.0)
- Annexure 18- Template for IMP Accountability Log- Patient Specific (Ch04-A18-V3.0)
- Annexure 19- Template for Telephonic Communication Log (Ch04-A19-V3.0)
- Annexure 20-Template for Contact details of Study Member (Ch04-A20-V3.0)

Template-Index for Trial Master File for study sites (Ch04-A01a-V3.0)

Sr.No.	Content
1.	**Contact details-**
	A. Contact detail of Principal Investigator, Co- Investigator, Clinical Research Coordinator, Research Nurse etc.
	B. Signed and dated CV, MRC, GCP certificate of PI, Co-I and other site research staff
2.	**Agreements-**
	A. Confidentiality Disclosure Agreement (CDA)
	B. Clinical Study Agreement(CSA)/Clinical trial Agreement (CTA)
	C. Financial Disclosure Form(FDF) If Applicable
	D. Material Transfer Agreement
	Finance
	A. Grant offer letter
	B. Payments of investigator sponsor from NCG
	C. Accounts statement/ Utilization Certificate
	D. Expense statement for Investigators Meeting
	E. Payments to other sites
3.	**Insurance-**
	A. Insurance Policy
	B. Other documents
4.	**Ethics Committee-**
	A. Composition of ethics committee, EC SOP
	B. Submission letter/Notification
	C. Approval letters
	D. Annual/Interim Progress report
	E. Other communication
5.	**Major Documents related to conducting of the trial**
5.1	**Protocol**
	A. Current approved protocol
	B. Protocol Signature Page
	C. Amendments (If Any)
5.2	**Investigational Brochure (IB)**
	A. Current approved Investigational Brochure
	B. Amendments (If Any)
5.3	**Informed Consent Form(ICF)**
	A. Current EC approved version of ICF with translations in other vernacular languages
	B. Assent form (if applicable)
	C. Translation and Back translation certificates
5.4	**Case Report Form (CRF)**
	A. Current EC approved Case Report Form
	B. Amendments (If Any)

6.	**Subject details-**
	A. Randomization log(templates and completed copies)
	B. Screening log(templates and completed copies)
	C. Subject identification code list (templates and completed copies)
	D. Note to Files (completed copies)
7.	**Regulatory-**
	A. Approval letter of (If applicable) • DCGI • HMSC • Import/Export License
	B. CTRI registration
8.	**Safety reporting-**
	A. Blank Templates of • Adverse Event (AE) • Serious Adverse Event (SAE)
	B. Copies of completed- • Serious Adverse Event (SAE) form • Serious Adverse Event (SAE) report as per table 5 of New Drug and Clinical Trial Rule 2019
	C. Safety report (SAE)log (templates and completed)
	D. Annual safety report
9.	**Research team training**
	A. Duty delegation log and signature log
	B. Study Specific Training Log
10.	**Lab details**
	A. Accreditation and certificates of local lab
	B. Accreditation and certificates of central lab (if applicable)
	C. Normal value/range for medical lab
	D. Other validation (where required)
11.	**Monitoring**
	A. Feasibility report
	B. Visit Confirmation letter/E-mail
	C. Pre trial Visit Report
	D. Study monitoring plan (if applicable)
	E. Site initiation visit (SIV) report
	F. Monitoring visit log
	G. Follow up letters/E-mail
	H. Deviation/violation log
	I. Close –out Visit Report
	J. Audit certificate (if available)
	K. Clinical Study report
12.	**Investigational Medicinal Product (IMP)- (if Applicable)**
	A. Manufacturing and authorization license
	B. IMP Shipment record

	C. IMP accountability log (templates and completd)
	D. IMP order record
	E. IMP Return Records / Forms
	F. Temperature log (templates and completed copies)
	G. Documentation of IMP destruction
	H. IP labels/ package insert
	I. Certificate of Analysis of the IP shipped
13.	**Miscellaneous**
	A. Investigator Meeting (IM) presentation, agenda including attendance sheet, minutes of the IM
	B. MOMs of teleconference between NCG CRO and Sites or Investigator sponsor
	C. Newsletters and any other communications
	D. Recruitment advertisement, Patient Diary Card, Questionnaire with translationsetc (If applicable)

Template-Index for NCG CRO Trial Master File (Ch04-A01b-V3.0)

Sr. No.	**Content**
1.	A. Protocol (protocol amendments if applicable) and its training records B. Signature and Duty Delegation log
2.	A. CDA between NCG and the peer reviewer B. Peer review scoring sheet and feedback and other relevant documents
3.	Clinical trial Agreement (work order) between the NCG and Sponsor- Investigator
4.	Finance related A. Fund release letter B. Annual status report C. Utilization certificate
5.	Study Monitoring Plan (if applicable)
6.	Monitoring related (visit confirmation letter/email, monitoring report, follow- up letter etc.)
7.	A. Informed Consent Documents (if applicable) B. Case Report Forms(CRF) (if applicable)
8.	Miscellaneous

Template-Labels for files (Ch04-A02-V3.0)

Study title	
Study code/ Short study title	
Name of Principal investigator	
File No.-	_____ Of ____

Template-Labels for storage Cupboard (Ch04-A03-V3.0)

Shelf No.	Study title	Study code	Name of Principal Investigator	No. of files

Note to file template (Ch04-A04-V3.0)

Study title:
Sponsor:
Site Name:
Section:
Statement:
Sign of Principal Investigator: Date:

Site Personnel Training Log Template (Ch04-A05-V3.0)

Purpose of training:

Topics covered:

Training attended by:

Sr. No.	Name of the Trainee	Designation	Signature and Date

Name of the trainer:

Signature and Date:

Template for Duty Delegation Log (Ch04-A06-V3.0)

Study No.:	**Study Site:**
Study Title:	
Principal Investigator:	

Sr. No	**Complete Name**	**Signature**	**Initials or short signature**	**Study role**	**Key delegated tasks**	**Start Date**	**Investigator's signature and date**	**Stop Date**	**Investigator's signature and date**

Key Delegated Study Task Codes:

A. Concept development B. Study Design C Screening of patients/eligibility check D. (i) Selection, Recruitment, Consenting of patients and Randomization E. Laboratory investigations F. Laboratory report interpretation G. Treatment decision H. Patient evaluation I. AE and SAE management, evaluation and reporting J. Examination of patients on follow-up	K. Data collection and Data entry (i) Case Report Form Completion (ii) Data entry from Data Base (iii) Query Resolution L. Monitoring of data M. Interpretation of data N. Statistical analysis & Interpretation O. Maintaining patients file and master file of project P. Drafting final report Q. Publication Z. Any other, please specify: (i) IP Dispensing(ii) IP Accountability (iii) Unbinding (iv) Documentation in Source File

Investigator's Signature and Date :

Subject Identification Log template (Ch04-A07-V3.0)

Study Title	
Site Number	
Study Site Name	
Principal Investigator's Name	

(To maintain study subject confidentiality, this form is to remain solely at the clinical site. The monitor(s) will only note that this form has been completed correctly and that it is maintained in the Investigator Site File)

Sr. No.	Name	Acronym of first name, middle name & surname	Gender	Date of Birth	Hospital Registration Number	Address & Contacts	Trial ID (Registration Number)

Investigator's Signature: Date :

Screening Log template (Ch04-A08-V3.0)

Study Title	
Site Number	
Study Site Name	
Principal Investigator's Name:	

Sr. No	Subjects Initials	Date of signing of ICD by Subject and PI	Details Signed ICD		Date of Screening	Screen failure (Yes/ No)	If Yes, please specify reason for screen failure	Authorized Site Staff Initials and Date
			Language of the ICD	Version of the ICD				

Investigator's Signature: Date :

Randomization Log template (Ch04-A09-V3.0)

Study No.:	**Study Site:**
Study Title:	
Principal Investigator:	

Randomization Number	Case Number	Subjects Initials	Date of obtaining the consent	Date of Randomisation	Randomisation Arm	Authorized Site Staff	
						Initials	Date

Investigator's Signature: Date :

Protocol Waiver Request Log template (Ch04-A10-V3.0)

Study Title	
Site Number	
Study Site Name	
Principal Investigator's Name	

Sr No	Trial ID	Date of Request	Reason for which waiver was request	Waiver granted by Sponsor		Authorised site staff sign and date
				Date of Approval	Waiver Code	

Investigator's Signature: Date:

SAE form template (Ch04-A11-V3.0)

SERIOUS ADVERSE EVENT REPORT **National Cancer Grid**	**NCG PROJECT NO:** **Regulated by DCGI: Yes / No** **CTRI Reg. No:**

As per ICH-GCP:

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) is: Any untoward medical occurrence (due to the participation in the concerned trial) that at any dose that:

- **Results in death,**
- **Is life-threatening,**
- **Requires inpatient hospitalization or prolongation of existing hospitalization,**
- **Results in persistent or significant disability/incapacity,**
- **is a congenital anomaly/birth defect**
- **important medical events that may not result in death, be life threatening, or require hospitalisation may be considered serious when , based upon appropriate medical judgement, they may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.**

Investigator(s) shall report all SAE's including Death to the IEC, Sponsor-Investigator, CDSCO and NCG CRO within 24 hours of their occurrence of the knowledge of the PI. If a delay is expected kindly notify the same by email.

1.	Title of project:
2.	Principal Investigator:
3.	Report Date : Report Type : ☐ Initial ☐ Follow-up _____If Follow-up report, State Date of Initial report_____ ☐ Final _____If Final report, State Dates of Initial/Follow up report_____
4.	Date of Occurrence of SAE :
	If report is delayed, provide reasons-
5.	Subject Case No :

	Subject Trial ID : Date of Birth : Height: Weight: Gender : ☐ Male ☐ Female
6.	Study Arm to which subject is randomized : ☐ Test ☐ Standard Arm ☐Both arms are Standard ☐ NA
7.	Mention the total number of SAE (prior) occurred at this site : _____ Other site(s) : _____
8.	Mention number of similar SAEs (prior) occurred for same study at this site :_____ Other site(s) : _____
9.	A] State SAE Event term : B] CTCAE Grade : (Kindly refer to CTCAE V5.0 where applicable) (where applicable)
10.	Does the Principal Investigator feel this SAE is related to participation in the trial ☐ Yes ☐ No Principal Investigator to provide justification for causality assessment:
11.	Tick whichever is applicable for serious adverse event : (Kindly note that this refers to IP/intervention being evaluated and NOT disease process) A] ☐ Expected Event ☐ Unexpected Event
	B] ☐ Hospitalization ☐ Increased hospital stay ☐ Death ☐ Others In case of Death, state probable cause of death_____ (If others, please specify) : In case of Hospitalisation, kindly provide number of days of the hospitalization: Date of Discharge:
	C] ☐ No permanent significant functional/ cosmetic impairment ☐ Permanent significant functional/ cosmetic impairment ☐ Not applicable
12.	The cost of treatment/hospitalization was borne by, ☐ Patient ☐ Institute ☐ Sponsor/CRO Reimbursement done: ☐ Yes ☐ In-process ☐ No ☐ NA
Drug information (refers to drug/ device/ procedure under investigation)	
13.	IP/ Placebo (include generic name)/device/intervention: Generic Name: Indication:
14.	Dose : Dosage Form :

15.	Route(s) of administration :
16.	Therapy Dates : Start Date: Stop Date: Therapy Details:-
17.	Therapy duration :
18.	Was study intervention discontinued due to event? ☐ Yes ☐ No ☐NA
19.	Did the reaction decline after stopping the drug / procedure (De-challenge & Re-challenge information) ☐ Yes ☐ No ☐ NA
	Concomitant drugs and history (drugs that the patient maybe on)
20.	Concomitant drug(s) including OTC drugs and date of administration : Non-drug therapies(if any):
21.	Patient relevant history (e.g. diagnosis, allergies): (Tick in the applicable box) (This is applicable only for regulated clinical trials) R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under: a) 0.5 Terminally ill patient (expected survival not more than (NMT) 6 months) ☐ b) 1.0 Patient with high risk (expected survival between 6 to 24 months) ☐ c) 2.0 Patient with moderate risk ☐ d) 3.0 Patient with mild risk ☐ e) 4.0 Healthy Volunteers or subject of no risk ☐
	SAE Details
22.	Description of serious adverse event (indicate if this is follow-up report and if so, include follow-up information only)
23.	Describe the medical treatment provided (if any) to the research subject: This is an update on treatment given during hospitalization and /or used for management of the SAE.

Medication	Dose	Start date	Stop date

De-challenge and re-challenge information(if any):

24.	Outcome was ☐ Resolved ☐ Ongoing ☐ Death In case of death please mention cause of death, post mortem findings (if any) and its possible relationship to suspected event.
25.	Was the research subject continued on the research protocol? ☐ Yes ☐ No ☐ NA (Mark 'NA' in case of death)
26.	What phase of the research protocol is the patient in? ☐ On active treatment ☐ Short term follow-up ☐ Long term follow-up ☐ Surveillance/ Monitoring ☐ NA
27.	In your opinion, does this report require any alteration in trial protocol? ☐ Yes ☐ No ☐NA If yes then please specify. Name of Principal investigator : Address of the PI: Contact No. of PI: _____ Signature of Principal Investigator _____ Date: _____

For NCG use only

Template for Adverse Event/ Serious Adverse Event Log (Ch04-A12-V3.0)

Study No.:	**Study Site:**
Study Title:	
Principal Investigator:	

Number	AE Term	Start Date	End Date	CRF entry completed	Related to IP (Y/N)	SAE (Y/N)	Comments

Investigator's Signature: Date:

Template for SUSAR/CIOMS Event Log (Ch04-A13-V3.0)

Study Title	
Site Number	
Study Site Name	
Principal Investigator's Name	

Study	Report date	Report type	Date of onset	Subject Initials	Country	Event	Date of Letter/SAE Report received at the site	Date of the EC Notification	Date of EC Acknowledgement	Outcome

Investigator's Signature: Date:

Template of deviation/violation reporting form (Ch04-A14-V3.0)

Specify if D/V- _____

Note:

Protocol deviation: Changes or alterations in the conduct of the trial which do not have a major impact on the participant's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

Protocol violation: Changes or alterations in the conduct of the trial that may affect the participant's rights, safety, or well being or alter the risk benefit ratio, and/or affect the participants' willingness to participate in the study, and/or impact the completeness, accuracy and reliability of the study data.

Project Title:

Participant Case No. :

Trial Id :

Occurrence date:

Total number of deviations /violations/ reported till date on the study:

Total number of similar deviations /violations/ occurred for the same trial:

Phase of Study i.e Active Intervention/Completed Intervention/Follow up:

Study status:

IEC approval Date-

Target recruitment -

No. of participants recruited:

D/V identified by- ☐ **Principal Investigator / study team**

☐**Sponsor / Monitor**

☐ **IEC members**

Classify the lapse (Tick the appropriate box) :

☐ **Consenting**

☐ **Enrollment**

☐ **Protocol procedure**

☐ **Laboratory assessment**

☐ **Investigational Product**

☐ **Safety Reporting**

☐ **Source documentation**

☐ **Staff**

☐ **Participant non-compliance**

☐ **Others (Please specify)**

D/V details:

Corrective action taken:

Impact on (if any):

Trial participant ☐ **Yes** ☐ **No**

If yes, please specify:

Quality of data ☐ **Yes** ☐ **No**

If yes, please specify:

Are any changes to the project/protocol required?

☐ **Yes** ☐ **No**

If yes, please specify the changes of Protocol:

Name of PI/Co-I:

Sign of PI/Co-I:

Date:

Template for Protocol Deviation / Violation Log (Ch04-A15-V3.0)

Study No.:	**Study Site:**
Study Title:	
Principal Investigator:	

Sr. No.	Subject Number	Subject Initials	Type of Event *(Code)*	Date of Event (DD/MM/YY YY)	Date of Notification to EC	Action Taken (*Code)*	Brief Description

Type of Event (Code**):**
1 - Inclusion/Exclusion criteria
2 - Concomitant Meds
3 - Visit Schedule
4 – Randomization
5 - Protocol Specific Criteria
6 - Investigational Product
7 - Laboratory procedures
8. - Other Procedures/Tests
9 -. Safety Reporting
10 - Other (Specify):_____

Action Taken (Code**):**
1 - Patient withdrawn
2- Patient continues with the study
3 - Patient remains on study but data analysis will be modified
4 - Notified to Sponsor and EC
5 - Waiver requested/granted
6 - Other (Specify):_____

Investigator's Signature: Date:

Temperature Log template (Ch04-A16-V3.0)

Site Name:-							
Study Title:-							
Name of the Principal Investigator							
Sr. No.	Date	Time	Temperature(°C/F)			Comments (if any)	Initials and date of the designated personnel
			Temperature at one time point	Min.(if applicable)	Max (if applicable)		

Investigator's Signature: Date:

Template for IMP Accountability Log- Master (Ch04-A17-V3.0)

Study Title	
Principal Investigator	
Site address	

IP Name: _____ Dosage Form: _____

Date	Manufacturer Lot No./ Batch No.	IP Quantity						IP Quantity sent back to pharmacy	Date of return	Recorder Initials	Reviewer Initials	Comments (if any)
		Stock Received	Stock at Site (x)	Dispensed (y)	Balance Forward (z =x-y)	Dispensed to (Subject No.)	Destroyed (if any) & Date					

Investigator's Signature : Date :

Template for IMP Accountability Log- Patient Specific (Ch04-A18-V3.0)

Study Title	
Principal Investigator	
Site address	

IP Name: _____ Dosage Form: _____

Trial ID:					Subject Initial:					
Sr. No	Date of Dispensing	Visit number	Batch No./ Lot No	Quantity Dispensed	Date of return	Quantity Returned	Quantity not Returned	Reason for not returning	Recorder's Initials	Comment

Investigator's Signature : Date :

Template for Telephonic Communication Log (Ch04-A19-V3.0)

Study Title	
Principal Investigator	
Site address	
Log Using for	☐ Site Contact ☐ Patient Contact ☐ Any Other (Please specify)_____

Date	Name of the person contacted	Name of person conducting the call	Purpose	Outcome/Comments	Signature and date

Template for contact details of Study Member (Ch04-A20-V3.0)

Study Title	
Site Name	
Site Address	
Updated on	

Name of the Person	Designation: Principal Investigator/Co-Investigator/Project Manager /CRC/Research Nurse/Any Other (Please Specify)
	Phone details:
	Email ID:
To add relevant rows for every study team member.	

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Date	Prepared by
1.	Ch04/2.0	V1.0 _17-Jan-2018	1. Modification in section 1.0 2. Modification in section 2.0 3. Modification in section 4.0subsection 4.1,4.2 and 4.3 4. Modification in section 5.0 subsection 5.4, 5.5 and 5.6 has been combined into one subsection 5.4 5. Modification in section 6.0 6. Modification in section 7.0	V2.0_05-Feb-2020	Ms. Valencina Silviera
2.	Ch04/3.0	V2.0_05-Feb-2020	1. Modification in section 2.0 2. Modification in section 4.0 3. Modification in section 6.0 4. Modification in Annexure 01b 5. Modification in Annexure 08, 11 6. Addition of Annexure 07, 10, 13, 19 and 20	V3.0_10-Feb-2023	Ms. Prachi Kokate

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai- 400012	राष्ट्र की सेवा में परमाणु ATOMS IN THE SERVICE OF THE NATION टी एम सी TMC

Title:

Standard Operating Procedure for Organizing Investigator Meeting

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
05	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose:

This SOP describes the process of planning the Investigator Meeting (IM).

2.0 Scope:

This SOP is applicable to all studies which are funded or supported by NCG CRO

3.0 Applicable for whom-:

This SOP is applicable for research team within NCG CRO

4.0 Procedure:

4.1. Prior to the meeting:

4.1.1. The purpose of the Investigator Meeting (IM) is to provide training on Protocol, GCP and trial logistics to all the Investigators and study coordinator of the participating sites for a multi-centric study before site initiation. The Investigator Meeting provides an ideal opportunity to raise questions regarding the study for discussion with the Sponsor Principal Investigator and/or other participating investigators.

4.1.2. The Sponsor Principal Investigator (who had applied for NCG funding/support and have received the necessary approval and sanctions) may approach the NCG CRO for the organization of the Investigator's meeting.The proposal would be reviewed by Project In-charge and approved by the NCG Convener. The Project In-charge would allocate the responsibility to the members of NCG CRO after the proposal is approved.

4.1.3. The delegated NCG CRO research team member(s) would contact the Sponsor Principal Investigator requesting to provide preliminary information regarding the tentative date, duration, venue agenda, details of other participating sites, budget, reimbursement method etc.

4.1.4. The draft agenda and plan (venue, travel, accommodation, meals etc.) to be reviewed by the Project In-charge/PM and approved by the Sponsor Principal Investigator.

4.1.5. After the approval, the concerned NCG CRO personnel (if requested) would communicate with the PI/site and ask for a final confirmation from the PI/ delegates on their availability.

4.1.6. After the confirmation from site, the NCG CRO personnel would initiate the process of organization of the Investigator meeting.

4.1.7. The NCG CRO personnel would then contact the vendors (travel, accommodation, caterer, IM kit etc.) with the requirements. The quotations would be reviewed by the /Project In-charge/PM and approved Sponsor-Investigator.

4.1.8. After the necessary administrative approval, the concerned vendor/event organizers would be informed about the final quotation.

4.1.9. The invitation letter would be sent to PIs and delegates for attending the IM.

4.1.10. The sites would be sent a reminder mail one week prior to the IM scheduled date.

4.1.11. The NCG CRO personnel would ensure that all the arrangements are in place prior to the scheduled date of IM

4.2. During the meeting: attend the meeting when invited and record the discussions.

4.2.1.The Investigators/sites would be requested to submit the hard copy boarding pass, other travel receipts (including local travel from airport to venue and vice versa, venue to accommodation and vice versa) during the IM and send the return boarding pass and travel receipts via courier for the purpose of reimbursement. The same would be collected by NCG CRO personnel/PI site team and sent to the Sponsor Principal Investigators applicable.

4.3. After the meeting:

4.3.1. Designated personnel from NCG CRO would be responsible for recording the minutes of the meeting and preparing the draft MOM. The draft soft copy/ hard copy of the MOM would be shared with the Sponsor Principal Investigator within 5 working days. The Sponsor Principal Investigator to finalize the MOM. . One hard copy of the agenda, final minutes of the meeting, training log would be filed in the NCG CRO Study Specific Trial Master file.

Prepared By	Reviewed by	Approved by
Name: Ms. Prachi Kokate Signature: Pkokate Date: 23-Feb-2023	Name: Dr. Durga Gadgil Signature: DGadgil Date: 27 Feb 2023	Name: Dr. C S Pramesh Signature: CS Pramesh Date: 28/Feb/2023

5.0 Reference:

None

6.0 Annexure:

- Annexure 1: Attendance sheet template (Ch05-A01-V3.0)

Attendance sheet template (Ch05-A01-V3.0)

Study Title				
Day and Date-				
Venue				
Sr. No	Name of Attendee	Designation PI/Co-I/CRC	Name of Institute	Signature (Date)

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_ Date	Prepared by
1	Ch05/V2.0	V1.0 _17 Jan 2018	1. Modification in section 1.0 2. Modification in section 2.0 3.Modification in section 4.0 subsection 4.1, 4.2 and 4.3	V2.0_05-Feb-2020	Ms. Lochana Bandekar
2	Ch05/V3.0	V2.0_05-Feb-2020	1. Modification in section 4	V3.0_10-Feb-2023	Ms. Prachi Kokate

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai- 400012	राष्ट्र की सेवा में परमाणु टी एम सी TMC ATOMS IN THE SERVICE OF THE NATION

Title:

Standard Operating Procedure For Preparation of Monitoring Plan

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
06	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0. Purpose:

A monitoring plan is designed based on the Protocol to ensure that the objectives and purpose of monitoring are met, namely participant safety, quality and integrity of data.

The monitoring plan generally describes the monitoring strategy, methods and the rationale for its use. The plan has to be designed as per Protocol, guidelines, SOP and applicable regulations, .

This SOP provides a guideline for preparing a study monitoring plan (SMP).

The monitoring plan would help to achieve uniformity of monitoring the study at each study site.

2.0. Scope:

The information provided in the SOP serves as a guideline for developing the study monitoring plan for all NCG funded trial or trials supported by NCG CRO.

3.0. Applicable to whom:

The SOP would be applicable to the Project In-charge /Project Manager (PM), Sponsor–Principal Investigator(S-PI), supported by Clinical Research Associate (CRA), for preparing of the SMP. The monitoring plan would be followed by the PM, CRA and the CTA.

4.0. Procedure:

4.1. The monitoring plan should outline the Critical data and processes from the Protocol which would affect participant's safety and data quality.

4.1.1. The method and extent of monitoring critical data and processes would be incorporated into the monitoring plan.

4.1.2. Apart from the critical data, the frequency and nature of monitoring would also be determined by the nature of the disease, drug/intervention, objective, purpose, specific study design, study complexity, blinding, sample size, and endpoints of the trial.

4.1.3. The monitoring plan should address the following:

(a) Site Initiation Visit
(b) Routine Monitoring Visit
(c) Site Close-out Visit

4.1.4. Site Initiation Visit:
The site initiation visit should not be conducted if it is scheduled within 4-8 weeks of the Investigator Meeting with following exceptions:

- When the study involves multiple online systems for data capture and other study related activities.
- When certain topics relevant to SIV agenda was not covered in the Investigators Meeting

Note: 1. If applicable only SIV would be conducted (for e.g.- no IM)

2. A telephonic site initiation visit (TSIV) would be planned (if applicable)..

4.1.5. Routine Monitoring Visit:

- P-I/Project Manager and Sponsor Principal Investigator will decide on the frequency of monitoring visits in the plan.

4.2. The monitoring plan would be drafted based on the complexity of the Protocol which can be assessed by the following criteria(s)-but not limited to:

a) Phase of the study
b) Studies involving pediatrics, women of child bearing potential, elderly or vulnerable populations.

c) Interventional or non-interventional (screening Protocols, epidemiological studies, sample repository studies, behavioral studies, correlative studies, registries, preventive trials etc.
d) Established intervention or new(experimental) intervention
e) Sample size
f) Number of investigations as per Study Protocol
g) Complexity of study
h) Study Endpoints/outcomes

4.3. The study monitoring plan template will consist of the following sections:

a) Study title, site details, Principal Investigator details
b) Purpose of Monitoring: Site Initiation Visit, Routine (first visit after SIV/ subsequent visits), Site Close Out Visit
c) Frequency of monitoring
d) Elements of the Plan
e) Description of approach-Onsite/Remote

NOTE: In case of pandemic, other health emergencies or natural disaster, travel restrictions may be imposed at the national, state and institutional levels. Due to this physical routine monitoring visits maybe discontinued based on the prevailing situation.
However, in order to ensure patient's safety and data credibility routine monitoring visits can be conducted at the sites through remote means (apart from TMH, Mumbai) till the physical visits can be resumed.

This plan would remain applicable till the time physical visits cannot be conducted at the sites. When the emergency subsides and logistic constraints are eased physical routine monitoring visit would be reinitiated.

The following considerations need to be addressed for the conduct of the remote monitoring visits:

I. The remote monitoring plan will be prepared by CRA, reviewed and finalized by the Sponsor Principal Investigator(S-PI). The same would have to be notified to the site IECs through the site PI(s)
II. In case of electronic CRF the relevant read only access would have to be provided to the CRA.
III. The Sponsor Principal Investigator or team would reach out to the site Principal Investigators/CRC for availability of the site for the visit
IV. Upon receipt of confirmation from the site, Microsoft Teams video call or Zoom call will

be setup by the S-PI/site PI/study team/ NCG CRO CRA. The calls will be of short durations (2-3 hours at a stretch) and can be conducted over multiple days depending on the review target. To ensure data confidentiality the call would not be recorded by the Host i.e., Sponsor PI.

V. A visit confirmation email with the detailed agenda will be shared with the study team by the CRA, before the scheduled day of the monitoring.

VI. Remote monitoring with sharing of documents should be approved/notified to each site IECs, as per the Site policies. The S-PI and team will carry out this activity.

4.4. Elements of the plan (section IV of template):

The study monitoring plan should be decided on the following elements

4.4.1. Essential Elements:

Patient data:

a) Consent/Re-consent
b) Eligibility Criteria
c) Efficacy evaluation
d) Investigational Product-storage, handling, dispensing and accountability(if applicable)
e) Safety reporting (AEs and SAEs)
f) Laboratory Investigations for safety
g) Data entry timelines
h) Source documentation (paper/electronic)

Study file data:

a) Investigator site file
   i. Ethics Committee approval on amendment and communication including annual status report to IEC.
   ii. Health Ministry Screening Committee approval (if applicable)
   iii. Clinical Trial Registry of India details

b) Duty delegation and signature log
c) Protocol Training Log

4.4.2. Other Elements (If Applicable):

Patient data:

a) Patient demography
b) Sample /specimen storage

Study files data:

a) Finance, only if requested by S-PI
b) Clinical study agreement
c) Screening and enrollment logs

4.5. Responsibilities:

4.5.1. The monitoring plan would be prepared by CRA/PM, reviewed and approved by the Project In-charge / Project Manager and the Sponsor-Principal Investigator by signing and dating the study monitoring plan.

4.5.2. The Project In-charge should allot the study to a PM and CRA (who would conduct the monitoring activities). A CTA may also be allocated for the study by the Project In-charge /PM who will assist the CRA and the PM.

Note: Till the time the monitoring plan is not prepared for a particular study, the frequency of visit would be decided in consultation between S-PI/P-In /PM.

4.6. Revision:

4.6.1. Monitoring plan is a dynamic document and the monitoring approach can be modified if required within the life cycle of the study. Once it is reviewed and approved the same can be followed for subsequent Monitoring visits.

4.6.2. The monitoring plan will have a version number and date in the footer. All the SOP identifiers to be placed in the header.

Prepared By	Reviewed by	Approved by
Name: Mr. Shirsha Chakraborty	Name: Dr. Durga Gadgil	Name: Dr. C S Pramesh
Signature: Shirsha Chakraborty	Signature: DGadgil	Signature: C S Pramesh
Date: 24/Feb/2023	Date: 27 Feb 2023	Date: 28/Feb/2023

5.0. Reference(s):

- NDCT Rules 2019Indian GCP guidelines (2001)
- ICH GCP-E6(R2) guidelines (2016)
- ICMR-guidelines (2017)
- https://www.nidcr.nih.gov/research/toolkit/.../Level_of_Monitoring
- https://www.nidcr.nih.gov/research/toolkit/.../CMP_template

6.0. Annexure:

- Annexure 1-Standard template for designing of study Monitoring plan.(Ch06-A01-V2.0)

Template for preparing Monitoring plan (Ch06-A01-V3.0)

Note: The elements can be customized as per the requirement of the Protocol. Incorporation of all the elements is not mandatory.

Monitoring Plan

I. (a) Study Title:

(b) Sponsor Investigator:

(c) Coordinating Centre:

(b) Details of the site(s) and Principal Investigators::

Name of the site	Name of the PI
1.	1.
2.	2.
3.	3.
4.	4.

II. Purpose of Monitoring: Site Initiation Visit/Routine Visit/Site Close Out Visit

III. Frequency of Monitoring:

Frequency of visit: e.g.-4,8,12 weeks etc.

IV. Elements of patient and study file data:

Essential Elements:

Patient data:

a) Consent/Re-consent
b) Eligibility Criteria
c) Efficacy evaluation
d) Investigational Product-storage, handling, dispensing and accountability(if applicable)
e) Safety reporting (AEs and SAEs)
f) Laboratory Investigations for safety

Study file data:

1. Study site file

a) Ethics Committee approval on amendment and communication including annual status report to IEC.
b) Health Ministry Screening Committee approval (if applicable)
c) Clinical Trial Registry of India details

2. Duty delegation log
3. Protocol Training Log

Other Elements:

Patient data:

a) Patient demography
b) Sample /specimen storage

Study file data:

a) Finance
b) Clinical study agreement
c) Screening and enrollment logs

Note: Consider high medical risk elements while preparing the plan.
V. Description of monitoring approach 1. 100 %Source data verification-enumerate essential elements of patient and study file data. 2. Note: The Monitoring plan will mention the % of the files to be reviewed. For those files, SDV will be 100%. 3. Intensity of monitoring of other elements.
<u>Sponsor-Investigator/Project Incharge/Project Manager</u> Name: Name: Signature: Signature Date: Date:

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Effective date	Prepared by
1.	Ch 06 V 2.0	V1.0_15-Jan-2018	1.Modification in the Title 2.Modification in section 1.0 3.Modification in section 2.0 4.Modification in section 3.0 5.Modification in section 4.0 subsection 4.1, ,4.4, 4.5 and 4.6 6.Modification in section 5.0	V2.0_05-Feb-2020	Mr. Shirsha Chakraborty
2.	Ch 06 V 3.0	V2.0_05-Feb-2020	1.Modification in section 3.0 2.Modification in section 4.1, 4.3 , 4.4 3.Modification in section 6.0 4.Modification in Ch06-A01-V3.0	V3.0_10-Feb-2023	Mr. Shirsha Chakraborty

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Title:

Standard Operating Procedure for Site Initiation Visit (SIV)

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
07	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0. Purpose

This Standard Operating Procedure describes the procedures for the Site Initiation Visit (SIV) of the study site.

2.0. Scope

This SOP ensures that the site study team members are trained by NCG CRO personnel on all study related processes and all procedures are in place to start recruitment at the site.

3.0. Applicable to Whom

This SOP applies for all studies which are funded or supported by NCG. This SOP applies to Project Manager (PM), Clinical Research Associates (CRA) and Clinical Trial Assistants (CTA) of NCG CRO.

Note: If an Investigators Meeting (IM) has been conducted and the study will be initiated at a site within 4-8 weeks of the IM, then SI may not be conducted at site.

The SIV at the site may be conducted as site visit (Annexure- 1) or telephonically (remote) as per the Study Monitoring Plan (Annexure- 7).

4.0. Procedure

4.1 Prior to Site Initiation Visit (SIV)

4.1.1. For preparing the site for initiation, the Clinical Research Associate (CRA) with the help of Clinical Trail Assistant (CTA) will:

4.1.2. Prepare an agenda for the visit and the Project Manager/Project In-charge will review and approve the agenda.

4.1.3. Confirm through email about the available date and time with the Investigator in advance and send a written SIV confirming the detail and agenda (Annexure - 1) with explanation of the purpose of the visit, the duration of the meeting and request all site study staff to be present for the visit.

4.1.4. The CTA/CRA can file the e-mail communications in the TMF.

4.1.5. Ensure that the following SIV prerequisites , have been shipped to the site prior to the Site Initiation visit, wherever applicable:

- Investigator Site File (ISF) Binder
- Paper CRFs/e-CRF in active phase and completion guidelines
- Investigational Product (IP), if applicable
- Laboratory kits and supplies, if applicable
- Informed Consent Form in English and other Translations as required by site
- Investigational Brochure (IB)/ relevant package inserts for the study drugs/IP, if applicable
- Additional Trial related materials, if any

Note: After the site receives the Investigational Product (IP) if applicable, CRA must ensure that the IP is stored as per the protocol in the site Pharmacy.

4.1.6. The CRA with the help of CTA reviews and ensures the availability of all essential documents in the Trial Master File (TMF) which are listed below, but not limiting to.

- Protocol version [current approved version by the Ethics Committee (IEC)].
- The IEC approval letter for Study
- IEC approved Informed Consent Documents (Current version)
- Case Report Forms (CRF) approved by IEC (Current version)
- Regulatory authority approvals or valid clinical/other laboratory accreditation (If applicable)
- Laboratory normal value ranges
- Notice that indicates the study has been submitted to the regulatory authorities (If applicable)
- Investigational Brochure (IB)/ Summary of Product Characteristics / Package insert. (If applicable)
- Investigational Product inventory management forms (If applicable)
- Duty delegation and Signature Log
- Protocol training log
- CVs, GCPs and MRCs (if applicable) of all Investigators and study personnel involved
- IEC Details including EC SOPs and EC composition etc
- Site SOPs
- Vendors Manuals (e.g. IWRS/IVRS), (If applicable)

- Clinical trial materials/supplies

Note: If applicable, the PM or the CRC of the Sponsor Principal Investigator is responsible for intimating the NCG CRO that the site is ready for SIV after all necessary checks. The above activity of checking the availability of essential documents in the ISF (4.1.4 and 4.1.5) may not apply to NCG CRO team.

4.1.6. Provide storage instructions for the Investigational Product (IP) if it reaches the site prior to the visit. (if applicable)
4.1.7. Complete the SIV Preparation Checklist (Annexure- 2) prior to the visit if applicable.
4.1.8. Project manager will review the SIV Preparation Checklist and provide approval to the CRA to proceed with SIV if applicable.

4.2 During the Site Initiation Visit (SIV)

4.2.1. The following points to be included in the agenda (but not limited to the following):

4.2.1.1. The visit starts with introductions with all the study site staff and completion of monitoring visit log followed by the investigators training and Investigator's role and responsibilities as per the applicable regulatory requirements.
4.2.1.2. Potential study subject availability and enrolment strategy
4.2.1.3. Discussion on the Salient features of protocol on subject eligibility, study procedures, source documentation and Informed Consent process and its documentation.
4.2.1.4. Discussion on Safety Reporting: Discuss in detail safety reporting procedures and timelines as per the protocol and applicable regulatory requirement.
4.2.1.5. Discussion on Laboratory procedures (if applicable):
a) Laboratory manuals and supplies
b) Handling of kits
c) Transport of laboratory specimens
d) Kit re-supply procedures
e) Contact details
f) Local Laboratory reports
g) Local laboratory accreditation and related documents
4.2.1.6. Discussion on IP management to be discussed in detail (if applicable):-for e.g. inventory, dispensing record, destruction record etc.
4.2.1.7. Discussion on Randomization process, blinding and un-blinding procedures, if applicable

4.2.1.8. Discussion on guidelines for paper/electronic Case Record Form (CRF) completion, correction and retrieval.
4.2.1.9. Discussion on the monitoring frequency for the study and expectations like availability of ICDs, source documents, ISF etc. during monitoring

4.2.1.10. Discussion IEC communication responsibilities of Protocol/ICD amendments, safety and any relevant updates from the Sponsor, Protocol Deviations etc.

4.2.2. The Duty Delegation log and Trainings records should be completed. The updated log should then be filed in the Investigator's Site File (ISF).
4.2.3. CRA to check the Investigational product (IP) storage area. To check the shipment records, storage conditions and temperature logs as applicable.
4.2.4. Collect any outstanding documents if required for the Trial Master File (TMF) if applicable.
4.2.5. The CRA has to sign the site visit log.
4.2.6. If time permits, the Site Facility tour will be done by CRA. CRA should document any change in the facility and personnel from the Site Assessment Visit.

4.3. Following Site Initiation Visit (SIV):

4.3.1. The CRA/PM would complete the Monitoring Report (Annexure 3) within 5 working days of the visit and forward it to the Project Manager(PM)/Project-In charge(P-In)

4.3.2. The PM/P-In should review the report and finalize the report within 3 working days of receipt of the report from the CRA/PM.

4.3.3. Once report is finalized the PDF version of the report would be generated and back up would be taken.

4.3.4. After finalization, the CRA should send the SIV report through an email (Annexure 6) to the Investigator within 2 working days keeping the Sponsor-Principal Investigator, NCG CRO PM/P-In in the cc list.

4.3.5. The hard copy of the above email communication to be placed in the NCG CRO specific TMF.

Prepared By	Reviewed by	Approved by
Name: Ms. Shirsha Chakraborty Signature: Shirsha Chakraborty Date: 23/Feb/2023	Name: Dr. Durga Gadgil Signature: Date: 27 Feb 2023	Name: Dr. C S Pramesh Signature: Date: 28/Feb/2023

4. References:

- Indian GCP guidelines (2001)
- ICMR guidelines (2017)
- New Drug and Clinical Trial Rule 2019

5. Annexure (s):

- Annexure 1- Confirmation Email template for the Site Initiation Visit (Ch07–A01-V3.0)
- Annexure 2-Template for Site Initiation Visit Preparation checklist (Ch07–A02-V3.0)
- Annexure 3- Site Initiation Visit Report template/ telephonic SIV report (Ch07–A03-V3.0)
- Annexure 4- Template for Thanking email enclosed with a copy of SIV report (Ch07–A04-V3.0)
- Annexure 5- Monitoring Visit Log template (Ch07–A05-V3.0)

Confirmation Email template for the Site Initiation Visit (Ch07–A01-V3.0)

{Investigator Email-Id}
Subject: Confirmation of Site Initiation Visit at your site on <DD/MM/YYYY>
Dear Dr. {Name of the Investigator}
Reference: {Study Number, Study Title}

This is with the reference to the discussion we had with you. This is to confirm the site Initiation visit at your site on [day] [date] at [Time (24 hours format)] for [Study name].
The visit will last for [Number of days].
During the visit we would conduct the training for the entire study site team members listed below via presentation and interactive sessions.

Sr. No.	Name	Role in Study

In order to accomplish these objectives, we request that the site study team members are available for the above mentioned date.

During the visit, we will accomplish the following:

1. Study overview and Timelines

2. Protocol overview
3. Screening and Enrolment expectations
4. Investigational Product Management
5. Randomization Process
6. Informed Consent procedure and documentation
7. Laboratory specimen collection storage and shipment
8. CRF completion and verification/retrieval
9. Adverse Event recording and reporting
10. Regulatory Documents and Investigator Site File Overview
11. Source Documentation andRecruitment
12. ICH GCP and Monitoring Expectations

Following items have been dispatched to the site prior to the visit:

Sr. No.	Item(s)

As I am the assigned site monitor for this at your site, if you have any queries please contact me at [Phone/Mobile Number] or [email id].
Thank you all your support and collaboration on this study.
Looking forward to meeting you and the site study team

[Senders Name]
[Designation]

Template for Site Initiation Visit Preparation checklist (Ch07–A02-V3.0)

Name of the Site:	
Name of the CRA:	
Date of Visit:	

Particulars to be verified:

Sr. No.	Particulars	Yes	No	NA
1.	Final EC Approval Letter for the Study			
	Comments (if any):			
2.	Regulatory Approval letter (if applicable) • DCGI • HMSC • Import/Export license			
	Comments (if any):			
3.	CTRI registration details			
	Comments (if any):			
4.	EC Registration – DCGI			
	If yes provide the registration number and validation:			
5.	EC Registration –ICMR			
	If yes provide the registration number and validation:			
6.	EC Accreditation - NABH			
	If yes provide the accreditation number and validation:			
7.	Current / updated copy of the EC composition and EC SOPs			
	Comments (if any):			
8.	Institutional Ethics Committee (IEC) submission			

	dossier/cover letters where submitted documents are specified for each site			
	Comments (if any):			
9.	EC approved version Protocol			
	Protocol Signature Page			
	Comments (if any):			
10.	EC Approved Informed Consent Form, Translations, Back Translation and translation certificate			
	Comments (if any):			
11.	EC Approved Assent form, translation, back translations and translation certificate			
	Comments (if any):			
12.	CV of Forward and Backward Translators(if applicable)			
	Comments (if any):			
13.	EC approved version of Investigational Brochure (if applicable)			
	Comments (if any):			
14.	Investigator Undertaking of the PI			
	Comments (if any):			
15.	All the various study logs and forms: Screening log, Randomization log, IP accountability (master and individual), Temperature log, Duty delegation logs, Training records, Serious adverse event form, Deviation/ violation reporting forms, etc.			
	Comments (if any):			
16.	Confidentiality Disclosure Agreements			

	Comments (if any):			
17.	Final Signed copy of Clinical Trial Agreements (CTA)/ Memorandum of Understanding (MoU) notified to EC			
	Comments (if any):			
18.	Valid Insurance Certificate (if applicable)			
	Comments (if any):			
19.	In case of paper CRF, has the site received the CRF?			
	Comments (if any):			
20.	Has the e-CRF training and access (Demo/Production) been received by the site?			
	Comments (if any):			
21.	Has the IWRS/IVRS training and access (Demo/Production) been received by the site, if applicable?			
	Comments (if any):			
22.	Has the IP been received by the site? (if applicable)			
	Comments (if any):			
23.	Have the IP labels/expiry/ storage conditions been reviewed?			
	Comments (if any):			
24.	Have the Randomization code envelopes been received by the site? (if applicable)			
	Comments (if any):			
25.	Have the Investigator site Files and subjects labels been received by the site? (if applicable)			
	Comments (if any):			

26.	Have the Laboratory kits been supplied to the site? (if applicable)			
	Comments (if any):			
27.	Are adequate trial related facilities / infrastructure available at the site? e.g. Computer, Refrigerator, Deep Freezer, Internet facilities, stationary, etc.			
	Comments (if any):			
28.	GCP certification			
	CV, MRC, GCP of each study team members			
	Comments (if any):			
29.	Accreditation and certificates of Central lab			
	Comments (if any):			
30.	Manufacturing and authorization license of Investigational Medicinal Product			
	Comments (if any):			
31.	Any other study specific documents etc:			
	Comments (if any):			

Prepared by:

Signature	Name	Date

Reviewed by:

Signature	Name	Date

Approved by:

Signature	Name	Date

Site Initiation Visit Report template/ telephonic SI report (Ch07–A03-V3.0)

Name of the Site:	
Name of the CRA:	
Date of Visit:	

Sr. No.	Particulars	Yes	No	NA
A.	**Investigator and Staff**			
1.	Was Site-Assessment visit (SAV) done?			
	Comments (if any):			
2.	Have any changes occurred in the study staff /facility at site since the SAV? If so, were the essential documents collected?			
	a) Staff			
	b) Clinical Laboratory			
	c) Ethics Committee			
	d) Others			
	Comments (if any):			
3.	The Signature and Duty Delegation has been obtained from the site?			
	Comments (if any):			
4.	Does the site have adequate resources?			
	Comments (if any):			
B.	**Training of the Site Staff**			
1.	ICH GCP/ Indian GCP (Stakeholders responsibilities)			
	Comments (if any):			
2.	Study objectives			
	Comments (if any):			
3.	Inclusion/Exclusion criteria			
	Comments (if any):			

Sr. No.	Particulars	Yes	No	NA
4.	Safety and Efficacy parameters			
	Comments (if any):			
5.	Schedule of Assessment			
	Comments (if any):			
6.	Randomization/blinding procedures (if any)			
	Comments (if any):			
7.	Laboratory Procedures			
	Comments (if any):			
8.	Investigational Products (if applicable)			
	Comments (if any):			
9.	Subject completion/Early discontinuation procedures			
	Comments (if any):			
10.	Investigator responsibilities for study conduct			
	Comments (if any):			
11.	SAE and AE reporting			
	Comments (if any):			
12.	Enrollment Requirements			
	Comments (if any):			
13.	Study timelines and monitoring Expectations			
	Comments (if any):			
14.	Informed consent process related and AV consenting (if applicable)			
	Comments (if any):			
15.	Study Completion/ Early termination procedures			
	Comments (if any):			
16.	Archival Procedures			
	Comments (if any):			
17.	Study Logs completion			
	Comments (if any):			
Sr.	**Particulars**	**Yes**	**No**	**NA**

No.				
18.	Other, specify			
	Comments (if any):			
C.	**Site File Review**			
1.	Signed and dated Protocol and its Amendments, if any			
	Comments (if any):			
2.	Investigational Brochure (IB)/ Product Information/ Package insert.(if applicable)			
	Comments (if any):			
3.	Case Report Forms (CRFs) Templates and CRF filing guidelines			
	Comments (if any):			
4.	Ethics Committee approved Informed Consent Forms current versions and date (with all applicable translations)			
	Comments (if any):			
5.	Regulatory Submission, Notifications and Approvals (if applicable)			
	Comments (if any):			
6.	EC SOPs, Composition, Registration Number, Notifications and Approvals			
	Comments (if any):			
7.	Confidential Disclosure Agreement			
	Comments (if any):			
8.	Clinical Trial Agreement			
	Comments (if any):			
9.	Insurance certificate			
	Comments (if any):			
10.	CVs, GCPs and MRC of the site staff			
	Comments (if any):			
11.	Vendors /online system Manuals (e.g. IWRS,IVRS, central laboratory, etc.)			
	Comments (if any):			
12.	Shipping Documents(e.g. laboratory kits, stationary, printer etc.)			
	Comments (if any):			

Sr. No.	Particulars	Yes	No	NA
13.	Safety updates (if any)			
	Comments (if any):			
D.	**Investigational Product (IP) Study Supplies and Storage**			
1.	Was the Storage area inspected?			
	Comments (if any):			
2.	Have storage conditions been discussed with the site personnel?			
	Comments (if any):			
3.	Was the initial IP shipment inventoried to the Site?			
	Comments (if any):			
4.	Were any discrepancies/problems noted in quantity, condition or labeling IP and supplies?			
	Comments (if any):			
5.	Have the Batch Numbers and expiry dates been checked?			
	Comments (if any):			
6.	Were the proper dispensing and accountability procedures of the IP reviewed with the Study personnel and pharmacy personnel?			
	Comments (if any):			
7.	Did the CRA discuss documentation of IP receipt, dispensing and return?			
	Comments (if any):			
8.	Did the CRA Train the site on Procedures and documentation of IP destruction at site?			
	Comments (if any):			
9.	Did the CRA discuss emergency un-blinding procedures?			
	Comments (if any):			
E.	**Facilities and Equipment's**			
1.	Were all relevant departments visited?			
	a) Pharmacy			
	b) Radiology			
	c) Laboratory facilities			
	d) Emergency Room/ Casualty			
	e) Intensive Care Unit (ICU)			
	f) Consulting Rooms			
	g) OPDs			

	Comments (if any):			
2.	Does the site continue to have adequate space and equipment for conducting the study (e.g. ECG machine, refrigerator, Deep Freezer, Centrifuge and other equipment's as per the study)?			
	Comments (if any):			
3.	Did the site have an appropriate location for Consenting Subjects?			
	Comments (if any):			
4.	Availability of adequate locked storage area for the investigational products with access limited to the delegated study staff?			
	Comments (if any):			
5.	If there is requirement of any special equipment for the study, were the instructions for use provided to the site personnel?			
	Comments (if any):			
6.	Are following Facilities available for at site?			
	a) Desktop/Laptop			
	b) Fax, Printer, Copier and Scanner			
	c) STD/ISD facility			
	d) High Speed internet connection			
	Comments (if any):			
7.	Did the phone or Desktop work on the IVRS/IWRS?			
	Comments (if any):			
F.	**Documentation Procedures**			
1.	Availability and access to the source documents?			
	Comments (if any):			
2.	Does the site have electronic records?			
	Comments (if any):			
3.	Review, Signatures and certification of laboratory reports			
	Comments (if any):			
4.	Documentation of protocol violations, deviations and exemptions			
	Comments (if any):			
Sr. No.	**Particulars**	**Yes**	**No**	**NA**
5.	Documentation of SAE and AE reporting procedures			

	Comments (if any):			
G.	**Laboratory facilities (if applicable)**			
1.	Have the laboratory been visited?			
	Comments (if any):			
2.	Are the list of normal ranges for Local/Central labs have been collected			
	Comments (if any):			
3.	Have the CV of HOD of Lab for Local/Central Lab been obtained			
	Comments (if any):			
4.	Have the Central Lab procedures been discussed			
	Comments (if any):			
5.	Have the accreditation certificates for Local/Central Lab been collected			
	Comments (if any):			
6.	Receipts of Lab Kits and Lab instruction manual			
	Comments (if any):			
7.	Have the sample storage facilities been checked			
	Comments (if any):			
8.	Contact Details of the Lab Sample pick-up provided			
	Comments (if any):			
J.	**Others**			
1.	Have the monitoring procedures and frequency been discussed			
	Comments (if any):			
2.	Has the possibility of audits/inspections and related procedures been discussed			
	Comments (if any):			
3.	Completion of Signatures and Dates on Duty Delegation log			
	Comments (if any):			
4.	Monitoring visit Log Collected?			
	Comments (if any):			

Sr. No.	Particulars	Yes	No	NA
5.	Has the Training Log been signed and dated?			
	Comments (if any):			
6.	Any other study specific issues			
	Comments (if any):			

Planned Subject Recruitment and Period Details

Total Number of Subjects Planned for this Site:	
Projected initial Subject enrollment date:	
Projected Subject Accrual per month:	
Projected Study Completion Date:	

Brief Summary:

Prepared by:

Signature	Name	Date

Reviewed by:

Signature	Name	Date

Approved by:

Signature	Name	Date

Template for Thanking email enclosed with a copy of SIV report (Ch07–A04-V3.0)

{Investigator Email-Id}
Subject: Follow-up for the Site Initiation Visit conducted on [DD/MM/YYYY].
Dear Dr. {Name of the Investigator}
Reference: {Study Number, Study Title}
This is with reference to the onsite/telephonic SIV which was conducted for the above mentioned study at the site on <date>.
The primary purpose of this visit was to train you and your study staff on Protocol specific study procedures.
I would also like to thank you and your Study Team for their availability and support during the visit.
If you should have additional questions regarding the initiation visit or study, please contact me at [Phone/Mobile Number] and [Email id].
I look forward to your kind cooperation and support.

[Sender Name]
[Sender Designation/Title]

Enclosed: A copy of Site Initiation Visit (SIV) report

Monitoring Visit Log template(Ch07–A05-V3.0)

Sr. No.	Date	Type of Visit	Name of Monitor/ Representative	Monitor/ representative		Principal/Sub Investigator	
				Signature	Date	Signature	Date

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Effective date	Prepared by
1.	Ch07/V 2.0	V_1.0_15-Jan-2018	1. Modification in section 1.0 2. Modification in section 2.0 3. Modification in section 3.0 4. Modification in section 4.0 subsection 4.1, 4.2, 4.3 5. Modification of section 5.0 6. Modification in 6.0 (Site Personnel Training Log annexure has been shifted to SOP chapter 08)	V2.0_05--Feb-2020	Ms. Valencina Silveira
1.	Ch07/V 3.0	V2.0_05-Feb-2020	1.Modification in Section 1.0 2.Modification in section 4.0 3.Modification in section 6.0 4.Removal of Annexure 06	V3.0_ 10-Feb-2023	Mr. Shirsha Chakraborty

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai- 400012	राष्ट्र की सेवा में परमाणु टी एम सी TMC ATOMS IN THE SERVICE OF THE NATION

Title:

Standard Operating Procedure For Routine Monitoring Visit (RMV)

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
08	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0. Purpose

This Standard Operating Procedure (SOP) gives an overview about the tasks to be performed at site at the time of Routine On-site/Remote Monitoring Visit to ensure that the conduct, recording and reporting of clinical trial is in compliance with, Indian GCP (2001), ICMR Ethical guidelines 2017, New Drugs &Clinical Trial Rules (NDCT Rules), 2019 other applicable guidelines and regulatory requirements.

The RMV also aims to ensure that the staff personnel and the facilities remain adequate throughout the conduct of the trial, determine protocol compliance, identify and resolve concerns and queries faced by the site and to verify the correctness of the data. Also to ensure that participant safety, rights, well being and confidentiality is safeguarded and the integrity and quality of the data generated is credible and accurate.

2.0. Scope

This SOP will serve as a guide for preparing for the RMV, the tasks to be performed on site at the time of monitoring and after the completion of the visit. It aims to give an overview for preparation, planning, conduct and documentation of the visit.

3.0. Applicable To Whom

This SOP is relevant to the research team within the National Cancer Grid Contract Research Organization (NCG CRO) delegated to conduct the monitoring of the studies funded/supported by the National Cancer Grid CRO (NCG-CRO)/TMC as well as monitoring of studies requested by the PIs of various Disease Management Groups at Tata Memorial Hospital/any other institute in India.

4.0. Procedure:

4.1. Prior to Routine Monitoring Visit (RMV):

4.1.1. Responsibility: CRA (with assistance from CTA)

- The RMV should be scheduled on the basis of the monitoring plan
- Prior to the Visit, the CRA should:

(a) Review the enrollment status.
(b) Review the reported Adverse Events (AEs) / Serious Adverse Events (SAEs) and other safety related issues.
(c) Refer to the previous RMV reports and / or follow-up letters to check for any pending open issues or queries from the previous visit (Action Item List: Annexure 03-section 2.4)
(d) Communicate (either telephonically and/or via email) for the closure of pending open actions (e.g. pending data entry, open queries etc.).
(e) CRFs: To review the CRF entries and raise queries, if any.
(f) Make a list of documents that is/are to be either retrieved from the site or to be placed in the site file.
(g) To study the Monitoring Visit Report Template (Annexure 03) in order to capture report specific details at the time of monitoring.

4.1.2. The CRA should confirm the date and time and also mention about the additional personnel from the NCG CRO accompanying the CRA for the visit (when applicable) with the PI and/or the study site personnel for the monitoring visit.

4.1.3. The RMV confirmation (Annexure 02) should be emailed to the investigator and the study site personnel.

4.1.4. The RMV should be scheduled on the basis of the monitoring plan. To be added, If monitoring plan not available, refer section 4.5.2 of chapter 06.

4.2.During the Routine Monitoring Visit (RMV):

4.2.1. At the time of monitoring, the CRA(s) may simultaneously refer to the monitoring visit checklist (Annexure 01) which would act as reference (but not limited to) for the conduct of the monitoring.

The CRA should sign and complete the site monitoring visit log.

4.2.2. The Investigator Site File

The Investigator Site File (ISF) should be checked for any updates or additions during the study (at least every second or third visit).

For example:

(a) Updates in the duty delegation and signature log, training of the personnel and update in the training log, documents (CV, MRC (where applicable) and GCP certificates) for addition of personnel in the study site team Stop date and signature for personnel in the study site team who have discontinued their role in the study
(b) Updated laboratory certifications, normal/reference ranges and Insurance certificates
(c) Reporting of safety events as per the timelines should be confirmed through the documentation available in the file
(d) Interim (as per site SOP) / annual study status reports should have been submitted by the investigator to the EC
(e) Amendments to the study related documents should have been notified to the EC and the approval for the same should have been obtained
(f) IEC communications like notification of protocol deviations, safety reporting, relevant communications from sponsor.
(g) The following logs (as applicable and not limited to) should be checked for completeness

- Subject Screening log
- Subject enrollment and randomization log
- Drug accountability logs
- AE/ SAE log
- Protocol deviation/violation log submitted to IEC
- Duty delegation and signature log
- Temperature log
- Site personnel training log

4.2.3. Subject Accrual

The evaluation of the overall progress of the subject accrual rate should be based upon,

(a) Total subjects to be randomized/accrued in the study
(b) Total subjects screened
(c) Total subjects randomized
(d) Total subjects who are under active treatment
(e) Total subjects who are on follow up
(f) Total subjects who have completed the study
(g) Total subjects who withdrew consent
(h) Total subjects who discontinued
(i) Total subjects lost to follow-up-including documentation to check for contacting patient

4.2.4. Informed Consent Documents and Process and Eligibility Criteria

All ICD/assent form/Re-consents (if applicable) will be reviewed during the ROMV.

The CRA should check that:

(a) IEC approved ICDs/Assent forms have been used at the time of consenting (and where applicable to check if re-consenting has been done)
(b) Whether in case of illiterate patients IW has been appropriately used and in case of minors/relevant scenarios LAR has been appropriately used.
(c) The details in the ICDs/Assent forms have been filled completely and have been signed and dated by the subject, and/or the Impartial Witness (IW) and Legally Acceptable Representative (LAR) (if applicable) and the PI/designee.
(d) The IC narrative (consenting procedure) is documented in the patient's source file or electronic medical record
(e) The consent has been administered by delegated personnel.
(f) The ICD/Parental ICD/Assent form has been signed and dated by the delegated site personnel after the subject has signed the ICD/Parental ICD/Assent form/Audio Visual (AV) consenting (If applicable)

4.2.5. Source Data Verification (SDV):

4.2.5.1. The CRA should ascertain that original source documents / certified documents are available for review which would be reviewed for attributability, legibility, contemporaneousness, accuracy and completeness.SDV would be done for ICDs/assent forms, Eligibility, Efficacy parameters and in (S)AEs capture as per the Study Monitoring Plan.

- For Observational studies, 100% SDV may not be feasible.
- For Interventional studies, it is preferable that 100% SDV is carried out for checking eligibility criteria, efficacy and safety variables.

4.2.5.2. Paper/ Electronic Case Report Form (CRF):

- The CRA should ensure that data entered in the CRF is supported by source documents.
- The following (as a minimum) to be checked for verifying the source and the CRF:
  (i) The AEs/SAEs recorded in the CRFs are reflected in the source document and vice versa, as well as any other reporting documents/proformas.
  (ii) The Investigational Product (IP) administered and dispensed to the subjects as per the protocol requirements, if applicable
- To verify that the study specific laboratory and radiological reports are available and checked for clinically significant laboratory values. Any missing parameters identified during the ROMV should be brought to the notice of the site staff.

4.2.5.3. Safety Related.

The CRA during the monitoring visit would follow the steps described below to ensure that the SAE reporting is compliant with the Protocol and the regulatory norms, as per Indian GCP Guidelines, ICMR Ethical Guidelines 2017 and New Drug & Clinical Trials Rules, 2019 and applicable site SOP.

(a) Whether the event can be considered as SAE:

- Serious adverse event" means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalization of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalization where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event, any other medically important event;
- Hospitalization: The Protocol will specify criteria of admission.
- The Protocol will specify whether death due to disease progression or events after the subject have completed study schedule and or survival follow up would be reported to the concerned authorities

(b) Whether SAE has been reported as per stipulated timelines (as specified NDCT 2019(for regulated trials)/ ICMR Ethical Guidelines 2017/ Protocol/SOP) to the concerned authorities.

(c) The source notes, SAE form (EC/Sponsor, if applicable) and CRF related to SAE documentation will be compared for concordance.

(d) The SMF will be reviewed trial reimbursement of medical management and receipt of compensation (if applicable).

4.2.5.4 . Protocol Compliance:

- The CRA should verify compliance to the protocol and review if protocol specific deviations have been reported to the EC as appropriate.
- In case of non-compliance to the protocol, the study team may be retrained and the same should be documented in the training log.

4.2.5.5. Subject Recruitment Logs

The CRA should verify if the screening-enrollment logs and subject identification logs are complete and are being updated with respect to the recruitment

4.2.5.6. Resolution of Queries:

Any discrepancy that has been noted by the CRA should be discussed with the delegated study team member and corrections should be made accordingly in the source data.

The corrections made should be counter signed and dated by the authorized study team member.

4.2.6. Investigational Product (IP), if applicable

(a) The CRA should review and confirm if appropriate documentation with respectto IP quantity received at site, IP dispensed to the subject, the batch/lot number received, expiry date, the packs sent back to the pharmacy and the packs destroyed at site (where applicable)

(b) The CRA should review the accountability log

(c) The CRA should also review the drug storage area, condition and temperature. Temperature logs should also be reviewed during the visit

(d) Randomization information should be checked in order to verify that the drug packs (if applicable) have been dispensed properly to the subjects

(e) I.P destruction would be carried out at the respective site as per site SOPs/CTA.

4.2.7. Training of new personnel added in the study as applicable.

4.2.8. Exit Meeting: To be preferably conducted with the PI. In absence of PI, Co-I can be updated. The CRA/PM should give a summary of activities done at the site during the visit. The CRA/PM should also discuss the following (not limited to) aspects with the investigator (if possible) and the site staff and to suggest corrective actions wherever necessary

- Summary of the important findings that have been encountered at the time of monitoring. (Eg: Protocol deviations, eligibility criteria, safety parameters etc.)
- If the recruitment rate is found to be slow, corrective measures should also be discussed
- Any other (resolved/pending) issues from the previous monitoring report

4.3. Following Routine Monitoring Visit (RMV):

4.3.1. The CRA/PM would complete the Monitoring Report (Annexure 03) within **5 working days** of the visit and forward it to the Project Manager(PM)/Project-In charge(P-In)

4.3.2. The PM/P-In should review the report and finalize the report within **3 working days** of receipt of the report from the CRA/PM.

4.3.3. Once report is finalized the PDF version of the report would be generated and back up would be taken.

4.3.4. After finalization, the CRA should send the RMV report through an email (Annexure 04) to the Investigator (if study specific email ID is used by the Sponsor PI team ,the same to be included in the email list)within **2 working days** keeping the Sponsor-Principal Investigator, NCG CRO PM/P-In in the cc list.

4.3.5. The printout of the email communication will be filed in the NCG CRO trial master file by the CTA/CRA.

NOTE:

- The page layout of the RMV report and follow-up letter can be customized.(if applicable)
- The ICD and SDV Observations can be attached as enclosures.(if applicable)
- Ref.: Annexure (Ch08 –A03-V3.0), Section 5.0: The signatories can be modified as per the study.

Prepared By	Reviewed by	Approved by
Name: Mr. Shirsha Chakraborty Signature: Shirsha Chakraborty Date: 21 | Feb | 2023	Name: Dr. Durga Gadgil Signature: Date: 27 feb 2023	Name: Dr. C S Pramesh Signature: Date: 28/Feb/2023

4.0Reference

- ICH Guidelines for Good Clinical Practice (E6 R2) section 5.18 – Monitoring
- CDSCO Good Clinical Practices section 3.1.13 – Monitoring
- Ethical Guidelines for Biomedical Research on Human Participants chapter II – Monitoring. (ICMR Guidelines, 2017)
- NDCT Rules, 2019.

5.0Annexure

- Annexure 01: Routine Monitoring Visit Checklist template(Ch08 –A01-V3.0)
- Annexure 02: Monitoring Visit Confirmation Letter/email template (Ch08 –A02-V3.0)
- Annexure 03: Routine Monitoring Visit (RMV) Report Template (Word Format) (Ch08 – A03-V3.0)
- Annexure 04: Routine Monitoring Visit Follow Up Letter template(Ch08–A04-V3.0)

Routine Monitoring Checklist Visit template (Ch08 –A01-V3.0)

Details of the items that need to be checked for at the time of monitoring has been mentioned in the format given below

SR. NO.	ITEMS	YES	NO	NA
1	Review of Investigator Site File			
Comment/Action:				
2	Review of Informed Consent Forms of each subject			
2a	Correct Version and date			
2b	Completeness			
2c	ICF narrative in source/electronic medical record			
Comment/Action:				
3	Review of CRF and comparison to source documentation			
Comment/Action:				
4	Review of drug accountability			
Comment/Action:				
5	Review of facilities and study related supply			
Comment/Action:				
6	Verification that only eligible subjects are enrolled			
Comment/Action:				
SR. NO.	**ITEMS**	**YES**	**NO**	**NA**
7	Verification of subject dropouts and withdrawal documentation			
Comment/Action:				
8	Verification that the delegated staff have made entries in the source			
Comment/Action:				
9	Verification of notification of AEs/SAEs			
Comment/Action:				

10	Verification of notification of protocol deviations/violations			
Comment/Action:				
11	Verification that missed visits have been captured in the source/CRF			
Comment/Action:				
12	Verification that any therapy modification has been documented			
Comment/Action:				
13	Verification that corrections made are counter signed and dated			
Comment/Action:				
14	Verification of validity of CV,GCP certificates of study staff			
Comment/Action:				
15	Annual Status Report of the study			
Comment/Action:				
16	Verification of study specific investigations/travel reimbursement			
Comment/Action:				

Prepared by:

Signature	Name	Date

Reviewed by:

Signature	Name	Date

Approved by:

Signature	Name	Date

Monitoring Visit Confirmation Letter template (Ch08 –A02-V3.0)

Date:
To,
<PI name>
<PI designation>
<Site Address>

Reference: <Protocol Number and Title>

Subject: Confirmation of Routine Onsite Monitoring Visit on <Date>

Dear Dr. <PI's last name>,

Thank you for confirming the date for the routine onsite monitoring visit at your site.

As confirmed, I/We <Complete name and designation> would be arriving at the site on <Date(s), Day > at <Time> for monitoring the above mentioned study. I/We would request you for the delegated study team member(s) to be present during the monitoring

During this visit, I/We plan to verify

- If the trial is carried out in compliance with the protocol, GCP, applicable SOPs and regulatory requirements
- The eligibility of the new staff (if any) added into the study and also to check for the documentation related to the staff being trained on study related procedures
- If the enrollment is in compliance with the protocol
- If the facilities at site and study related supplies remain available and adequate during the conduct of the study
- If CRF data queries have been resolved
- AEs & SAEs have been reported to the applicable authorities within the stipulated timeline
- IP accountability and appropriate storage facility

At this Visit, I/We would be requiring

- Informed Consent Forms of the subjects
- Investigator Site File
- CRF binders of patients and the hospital files / source documentation associated with the data entry
- Study specific logs that have been completed by the study site team

- Open action items from previous visit (s).

I/We would also discuss with you to close the outstanding issue(s), if any and to determine if open issue(s) from the follow up letters of previous visits have been addressed and resolved.

I/We thank you in advance for your time and look forward to meeting you and the site team

Please feel free to contact in case of further queries.

Thanks & Regards,

<Sign off>

Routine Monitoring Visit (RMV) Report Template (Ch08 –A03-V3.0)

Project Title **Short title**	
Monitoring Date(s) ***DD-Month-YYYY***	
Prepared By	
Contact ***Telephone, email***	

1. SUMMARY OF FINDINGS **(To be entered after the entire report is completed by the CRA, prior to PM review)**
Investigator Study File related
Informed Consent related
Inclusion/Exclusion Criteria
Source Document related
Study Drugs related
Others **(IRB, Compensation, Administration related)**

2.INTRODUCTORY INFORMATION	
2.1 Date/Time of monitoring visit ***DD-Month-YYYY***	
2.2 Purpose of monitoring ***Site Qualification Visit*** ***Site Initiation Visit*** ***Routine Monitoring Visit*** ***Site Close-Out Visit***	
2.3 Date of Last monitoring visit ***DD-Month-YYYY***	
2.4 Enumerate the open queries from the last monitoring visit if any	
2.5 Mention the study file numbers (subject IDs) which were reviewed at this visit	

3.PROJECT DETAILS	
3.1 Study Title	
3.2 Project Type*(Investigator initiated/sponsored)*	
3.3 Any changes in the study team since last monitoring visit	
3.4 If Yes mention the details	
3.5 Have the changes been notified to the IRB	
3.6 Project start date ***DD-Month-YYYY***	

4.PROJECT STATUS	
4.1 Current protocol version and date	
4.2 Current status ***a. Ongoing*** ***b. Completed*** ***c. Accrual Completed*** ***d. Follow-up*** ***e. Suspended*** ***f. Terminated*** ***g. Closed*** ***h. Closed Prematurely***	
4.3 If the response to the above question is option e, f or h, kindly provide relevant explanation	
4.4.1 Total patients to be randomized	
4.4.2 Total Subjects screened	
4.4.3 Total subjects randomized	
4.4.4 Recruitment status on schedule*(Yes/No)* ***Comments(if any)***	
4.4.5 Total subjects who withdrew consent	
4.4.6Total Subjects who discontinued ***Comments/Reasons***	
4.4.7 Total Subjects who completed the study ***Comments/Reasons***	
4.48 Total Subjects who are active in the study	

5. INFORMED CONSENT									
Trial ID	**ICD (Language, Version Number, Consent Date)**	**Observations**					**IC narrative**	**Corrective Actions**	**Status Open/Closed**
		Demographic details/Others	**Signature Section**						
			Patient	**LAR**	**IW**	**Investigator**			

Kindly add separate word pages to this sheet if needed

6. PROTOCOL SPECIFIC DEVIATIONS/VIOLATIONS					
	Subject IDs	***Details***	***Reported to IRB (Yes/No)***	***Issues Closed/Open***	***Corrective Action/Suggestions/Comments***
a. Inclusion/Exclusion criteria related					
b. Efficacy parameters related					
c. Visit windows related					
d. Labs related					
e. Others please specify in details section e.g. PK sampling related					

****Kindly add separate word pages to this sheet if needed***

7.SAEs						
o Total number of SAEs occurred at site till date: o Total number of SAEs occurred at site since the last ROMV:						
Subject ID	***SAE Criteria with clinical diagnosis***	***Initial/Follow Up/Final***	***Source Documentation***	***Reported to IRB (Yes/No)***	***Issues Closed/Open***	***Corrective Action/Suggestions/Comments***

8.STUDY DRUG MANAGEMENT				
	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)
8.1- Is there sufficient IMP on site/held in the pharmacy?				
8.2- Are the drug accountability records correct and up-to-date?				
8.3- Are IMP returns being destroyed appropriately & destruction certificates available?				
8.4- Is IMP being stored in a secure location & under the correct storage conditions?				
8.5- Is there an automated or min/max temperature monitoring procedure in place?				
8.6- Has the temperature stayed within the correct range throughout the duration of the study?				
8.7- If not, has this been reported and resolved?				
8.8- Are the code-breaks intact / has the blind been maintained?				

9. SITE PERSONNEL, FACILITIES & EQUIPMENT / STUDY SUPPLIES				
	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)

9.1- Have there been any changes in facilities or equipment?				
9.2- Do the facilities & equipment remain adequate for the conduct of the study?				
9.3- Are there adequate study supplies (CRFs, lab kits etc) available on site?				
9.4- If yes, are lab ranges documented and updated?				
9.5-Do the facilities & equipment remain adequate for the conduct of the study?				
9.6- Are there adequate study supplies (CRFs, Lab kits etc) available on site?				
9.7-If yes, are Lab ranges documented and updated?				
9.8-Does the study involve reimbursement of: **(a) Study specific investigations** **(b) Medical Management of SAEs** **(c)Travel**				
9.9 -Have the proof of reimbursement been maintained inform of voucher/ledger/any other? Please specify in the comment section				

10. ETHICS COMMITTEE RELATED

10.1. General Information

	Yes/No	If Yes please provide details	*Issues Closed/Open*	*Corrective Action/Suggestions/Comments*
10.1.1. Change in IEC membership		-	-	-
10.1.2. Change in IEC SOP		-	-	-
10.1.3. Change in IEC registration		-	-	-

10.2. Details of Study Documents

Documents	Version Number	Version Date	Approval/ Notification	IEC approval/notification acceptance date
10.2.1. Protocol				
10.2.2. IB (if applicable)				
10.2.3. IB updates (if applicable)				
10.2.4. ICD				
10.2.5. ICD Back translation				
10.2.6. CRF				

11. SOURCE DATA VERIFICATION

	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)
11.1.Is the Source Data Verification done?				
11.2. Have the data queries been resolved?				

11.3 The patient wise observations have been presented below:

Trial ID	Visit	In Source	In CRF	Corrective actions	Status (Open/Closed)

12.INVESTIGATORS SITE FILE RELATED

	Yes	No	NA	Comments (if applicable include a comment and describe any corrective actions that were initiated)
12.1. Was the ISF reviewed for accuracy and completeness?				
12.2. Have the required documents being filed in the relevant section of the ISF?				

13.GENERAL COMMENTS

Signature and Date of Monitor	Name and Title
Signature and date of Reviewer	**Name and Title**
Signature and date of Approver	**Name and Title**

Routine Monitoring Visit Follow Up Letter template(Ch08–A04-V3.0)

Date:
To,
<PI name>

Reference: <Protocol Number and Title>

Subject: Follow up letter of the routine monitoring visit on <Date>

Dear Dr. <PI's last name>,

I would like to thank you and the study team for your time and co-operation during the monitoring visit which was scheduled on <Date(s)>, <Day (s)>

As a follow up to the monitoring visit, the details of the tasks performed during the visit is as follows

I. Recruitment Summary:

The subject enrollment status was reviewed and the details of the same is as follows:

RECRUITMENT DETAILS											
SCREENED		**SCREEN FAILURE**		**ENROLLED**							
At the site	Since last visit	At the site	Since last visit	At the site	Since last visit	Under active treatment	On follow up	Completed Study	Withdrawn by PI	Withdrew consent	Lost to follow up

II (a).The details of the general and patient wise observations and actions suggested are presented below:

Particulars	**General Observations in Details**	**Corrective Action/Suggestions/Comment**
1. Informed Consent Related		
2. Source Document Verification Related		
3. Protocol Deviation/Violation Related		
4. Investigational product related		
5. Ethics Committee Related		
6. Investigator Site File		
7. Others		

(b) Patient specific		
Trial ID	Particulars	Corrective Action/Suggestions/Comment
XXX001 (for example)	1. Informed Consent Related:	
	2. Protocol Deviation:	
	3. Source Document Verification:	
	4. Investigational Product Related:	
	5. Safety Reporting	
	6. Others	
XXX002 (for example)	1. Informed Consent Related	
	2. Protocol Deviation	
	3. Source Document Verification	
	4. Investigational Product Related	
	5. Safety Reporting	
	6. Others	

Action(s)/Comment(s) (if any):

The tentative date of the next routine onsite monitoring is <Date>, <Day>.

Thank you once again for your time and ongoing efforts on this study.

Please revert in case of any queries or further clarification.

Thanks & Regards,

<Sender's signature>
<Sender's Name>
<Sender's designation>

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_ Date	Prepared by
1	Ch09/V1.1	V1.0_15-Jan-2018	1. Addition of word format of ROMV report 2. Addition of another Follow up letter template	V1.1_17 Sep 2018	Ms. Aishwarya Iyer
2	Ch08/V2.0	V1.0_17-Sep-2018	1. Modification in section 1.0 2. Modification in section 3.0 3. Modification in section 4.0	V2.0_05-Feb-2020	Ms. Roma Khot
3	Ch08/V 3.0	V2.0_05-Feb-2020	1.Modification in section 1.0 2.Modification in section 3.0 3.Modification in section 4.0 4.Modification in section 6.0	V3.0_10-Feb-2023	Mr. Shirsha Chakraborty

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai- 400012	राष्ट्र की सेवा में परमाणु ATOMS IN THE SERVICE OF THE NATION टी एम सी TMC

Title:

Standard Operating Procedure for Study Close Out Visit (SCV)

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
09	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose

This Standard Operating Procedure describes the procedures for the Site Close-out Visit (SCV) of the study site.

2.0 Scope

The SCV should be conducted after all subjects have completed study participation at the site and all open issues are closed and database is locked.

The site close out could be due to any of the following reasons

a) Site which has completed the study
b) Site for which study has been terminated by the investigator, sponsor, EC and the regulators.

3.0 Applicable to Whom

This SOP applies to all studies which are funded /supported by NCG and also for the studies requested by an Investigator in the NCG centres. . This SOP applies to Clinical Research Associate (CRA)/Project manager (PM)/ Project In-charge (P-In) and Clinical Trial Assistant (CTA) of NCG CRO.

4.0 Procedure

4.1 Prior to Site Close-out Visit (SCV):

4.1.1. An intimation to conduct a study close out visit/ activity will be received from Sponsor Principal Investigator (S-PI).

4.1.2. An agenda for the visit will be prepared by the CRA and the Project Manager/Project In-charge will review and approve the agenda.

4.1.3. The email confirmation about the available date and time, duration of the meeting, and agenda (Annexure–01) with explanation of the purpose of the visit will be sent to the Investigator. The email confirmation will be filed in the NCG specific Trial Master File (TMF) for records.
4.1.4. Previous open actions items will be reviewed.
4.1.5. All pending essential documents to be filed in site ISF or to be collected from site for S-PI TMF filing will be reviewed, if applicable.

4.2 During the Site Close-out Visit (SCV):

4.2.1. Photocopies of logs will be collected for the TMF at Sponsor Principal Investigator/NCG CRO as per the task ownership matrix/allocation in section 4.1.1, 4.2.1 and 4.3.1 in chapter 4.

4.2.2. Following photocopy of completed logs, if requested by Sponsor Principal Investigator, to be collected from the site, but not limited to:

a) Monitoring visit Log
b) Duty Delegation and signature Log
c) Training Log
d) Subject Activity Log
e) Screening and Enrolment Log
f) Temperature Logs
g) Final IP Accountability Logs
h) IP Return Form
i) Protocol Deviation/ Violation Log
j) Subject Identification Log to be checked for completeness and to be retained in Investigator Site File (ISF). No photocopy will be collected by NCG CRO personnel.
k) Financial Disclosure Forms (FDF) (if applicable)
l) Curriculum Vitae (CV) and Good Clinical Practices (GCP) certificate

4.2.3. The CRA will verify that Final drug accountability and any other applicable material that is provided for the study is complete.
4.2.4. The Drug packs for destruction would be packed and kept ready.
4.2.5. The CRA to ensure that the drug destruction is performed as per Clinical Trial Agreement (CTA) between Sponsor Principal Investigator and site / site SOP/ institutional policy. Site to share the destruction certificate.
4.2.6. The CRA will verify that code break documentation is still intact and any code that has been broken or lost during the study has been appropriately documented, if applicable. Remaining blind treatment codes will be retrieved by CRA.
4.2.7. The CRA will ensure that all the biological samples have either been shipped for analysis, stored or are prepared for destruction at site. CRA to obtain confirmation of destruction from site, if applicable.

4.2.8. The CRA will also ensure that all used and unused lab kits are prepared for destruction/return as per the CTA in accordance with site SOP.CRA to obtain confirmation of destruction from site, if applicable.
4.2.9. The CRA will ensure that all Adverse Events & Serious Adverse Events been recorded in source documents & that all Serious Adverse Event (SAE) have been reported by the investigator to the IEC & other regulatory agencies as per applicable guidelines and that the Investigator is aware of any future reporting. The CRA has to check completeness of Source data verification & resolution of queries.
4.2.10. Trial documentation at the Site will be archived according to the site SOP/institutional policy/CTA between Sponsor Principal Investigator and site.
4.2.11. Any pending payments (if any) informed by the site will be further communicated to the Sponsor Principal Investigator.
4.2.12. CRA to ensure that all equipment's or devices provided by the sponsor (if any) has been returned.
4.2.13. The CRA will ensure that the Investigator is aware of their responsibility to notify the Ethics Committee about site closure after all the issues are resolved and share a copy of the EC Notification letter to NCG CRO for filing in TMF.

4.3. Following the Site Closeout Visit (SCV):

4.3.1. The CRA/PM would complete the Monitoring Report (Annexure 2) within **5-7 working days** of the visit and forward it to the Project Manager(PM)/Project-In charge(P-In)

4.3.2. The PM/P-In should review the report and finalize the report within **3-5 working days** of receipt of the report from the CRA/PM.

4.3.3. Once report is finalized the PDF version of the report would be generated and back up would be taken.

4.3.4. After finalization, the CRA should send the SCV report and follow up letter through an email (Annexure 2) to the Investigator within **2 working days** keeping the Sponsor-Principal Investigator, NCG CRO PM/P-In in the cc list.

4.3.5. CRA to ensure that EC has been notified about site close out.

4.3.6. The Project Manager will ensure the review and archival of TMF(s) related to the study are completed.

Prepared By	Reviewed by	Approved by
Name: Mr. Shirsha Chakraborty Signature: Shirsha Chakraborty Date: 21/Feb/2023	Name: Dr. Durga Gadgil Signature: Date: 27 feb 2023	Name:Dr. C S Pramesh Signature: Date: 28/Feb/2023

4. Reference (s)

- Indian Good Clinical Practices
- ICH Guidelines for Good Clinical Practice-E6R2 (2016)
- New Drugs and Clinical Trial Rules 2019

5. Annexure (s)

- Annexure 1 - Site Close-Out visit /Email confirmation template (Ch09 –A01-V3.0)
- Annexure 2 -Site Close-Out Visit Report template (Ch09 –A02-V3.0)
- Annexure 3 - Thanking Email template enclosed with a copy of SCV Report (Ch09 – A03-V3.0)
- Annexure 4: IEC notification of Site Closure Template (Ch09 –A04-V3.0)

Note: All the annexure (s) can be customised as per the requirement of the study and/or as per discretion of CRA/PM/S-PI/P-In

Site Close-Out visit /Email confirmation template (Ch09 –A01-V3.0)

{Investigator Email-Id}
Subject: Confirmation of Site Close-out Visit at your site on <DD/MM/YYYY>
Dear Dr. {Name of the Investigator}
Reference: {Study Number, Study Title}
As per my discussion with <name of site staff>, Thank you for confirming the Site Close-out Visit at your site for the above mentioned referenced study to be conducted on {Dates}. I (Name and Designation) will arrive at your site on {Day and Date} at {Time}.

The study has been completed / Premature termination as {reason to be mentioned for the site close-out visit for e.g. all the subjects which were enrolled at the site have been completed 'end of trial' visit (last subject, last visit)}.

During this visit, I plan to accomplish the following:

- Verifying the final status of all the subjects and completion of all the subjects tracking records.
- Review all the essential documents and collect any new or revised documents.
- Verify that copies of all the completed CRFs are at the site.
- Sign the Monitoring Visit log.
- Collection of all completed Logs from the site for Trial Master File (TMF)
- Verify final IP accountability and inventory for either IP destruction at site or IP return to the Investigator-Sponsor.
- Ensure that all Adverse Events (AE) and Serious Adverse Event (SAE) occurrence have been filed appropriately.
- To retrieve destruction record of any unused extra clinical trial material
- Discuss about archival facility and access control

In order to accomplish these objectives please ensure that (Name of the study site staff) is available for (Time period) and all the original study records are available for the review.

I would like to meet you post close-out session as per your convenience for feedback and discussion.
Please revert in case of any Queries.
Regards

{Sender Name}
{Designation}

Site Close-Out Visit Report template (Ch09 –A02-V3.0)

Name of the Site:	
Name of the CRA:	
Date of Visit:	

Reason for Site Close-out:

Sr. No,	Reason	Yes	No	NA
1.	**End of study**			
2.	**EC Decision**			
3.	**Investigator Request**			
4.	**Sponsor's Request**			
5.	**Other (Specify):**			

Site Staff:

Sr. No.	Name	Role in study

Items to be verified:

Sr. No.	Items	Yes	No	NA
A	**Investigator Obligations and Study Outcome**			
1.	Were the rights, integrity, and confidentiality of subjects protected?			
	Comments (if any):			
2.	Have all issues identified at the previous monitoring visits been resolved?			
	Comments (if any):			
B	**Source Documentation and CRFs**			
1.	Have all the CRFs been signed off by the Investigator/ study delegated site staff?			
	Comments (if any):			
2.	If there are no open data queries, have all the original signed DCF been sent to Data Management?			
	Comments (if any):			

3	Were all source documents available to substantiate CRF data?			
	Comments (if any):			
C	**Study related Material and Other Study Supplies** Have the following been accounted for?			
1.	All study related material received by the site			
	Comments (if any):			
2.	Randomization codes/ Code envelopes			
	Comments (if any):			
3.	Other study supplies			
	Comments (if any):			
D	**Have the following been shipped back from the site?**			
1.	Other study supplies			
	Comments (if any):			
E	**Study related supplies (if any) to be retained at the site?**			
	Comments (if any):			
Sr. No.	**Items**	**Yes**	**No**	**NA**
F	**Biological Samples (if applicable)**			
1.	Have storage area / conditions been checked?			
	Comments (if any):			
2.	Has removal / destruction been arranged?			
	Comments (if any):			
G	**Drug Supplies and Accountability (if applicable)**			
1.	Have drug accountability records adequate to account for all clinical supplies been shipped to the site? (Comment on discrepancies)			
	Comments (if any):			
2.	Have all remaining drug supplies been returned or destroyed as instructed and an Authorization for Drug Return completed?			
	Comments (if any):			
H	**Laboratory Procedures and Supplies**			

1.	Have all laboratory samples been shipped to the appropriate laboratories?			
	Comments (if any):			
2.	Were the remaining lab supplies and kits destroyed?			
	Comments (if any):			
I	**Study Documents**			
1.	Has the monitoring visit log been signed by site staff and CRA for this SCV?			
	Comments (if any):			
2.	Has study report/Final status report been submitted to EC by the Investigator?			
	Comments (if any):			
3.	Has EC been informed about site closure?			
	Comments (if any):			
4.	Are copies of all SAE reports in the Investigator's files?			
	Comments (if any):			
5.	Is the Investigator Site File complete?			
	Comments (if any):			
Sr. No.	**Items**	**Yes**	**No**	**NA**
6.	Have the investigator's obligations regarding retention of all study records been discussed?			
	Comments (if any):			
7.	Are the arrangements for archiving the study CRFs and other documentation adequate?			
	Comments (if any):			
J	**Has the possibility of trial related communication including primary and secondary and/or audits / inspections been discussed?**			
	Comments (if any):			
K	**Miscellaneous**			
1.	Did the Investigator agree to comply with the following?			
	a) Submission of Study Closeout Letter / final report to EC			
	b) Any pending EC notification?			

	c) Record Retention requirement for the study			
	Comments (if any):			

Study Status:

Study Initiation Date		
Sr. No.	**Participation Status**	**Number of Subjects**
1.	Planned	
2.	Screened	
3.	Enrolled / Randomized	
4.	Screen Failures	
5.	Discontinued	
6.	Completed	
7.	Follow up	
8.	Total SAE Reported at site	

Documents retrieved from the site:

Sr. No.	**Documents**	**Yes**	**No**	**NA**	**Original/Copy**
1.	Monitoring visit Log				
2.	Duty Delegation and signature Log				
3.	Training Log				
4.	Screening and Enrollment Log				
5.	Subject identification log				
6.	Temperature Logs				
7.	Drug Inventory Log				
8.	Drug Dispensing Log				
9.	Drug Destruction Log				
10.	Protocol Deviation/ Violation Log				
11.	SAE logs				
12.	Others (Please specify):				
Comments/Actions (if any):					

Other Comments (including reason for site close out):

Prepared by:

Signature	Name	Date

Reviewed by:

Signature	Name	Date

Approved by:

Signature	Name	Date

Thanking Email template enclosed with a copy of SCV Report (Ch09 –A03-V3.0)

{Investigator Email-Id}
Subject: Follow-up of Site Close-out Visit at your site on <DD/MM/YYYY>
Dear Dr. {Name of the Investigator}
Reference: {Study Number, Study Title}

This is with reference to the Site Close-Out Visit (SCV) conducted at your site on [Date/s].
I thank you and the site study team for the valuable time and co-operation extended during the visit.
Following is the status of subject's recruitment at your site as of the SCV:

Subjects Screened:	[No.]	Subjects Discontinued:	[No.]
Subjects Randomized:	[No.]	Subjects Completed:	[No.]
Subjects Screen Failed:	[No.]	SAE Reported at Site:	[No.]

The close out at your site is conducted due to [reason for the close out for e.g. all the subjects which were enrolled at the site have been completed "end-of-trial" visit (last subject, last visit)].
The following were discussed during this visit:

a) Open Issues
b) Inform EC about the site close out and to keep a copy of the same in ISF.
c) Archival of all trial related documents at site.

Kindly revert if you have any queries.

Sincerely,
[Sender's Name]
[Sender's Designation]
Enclosed: A copy of Site Close-out Visit (SCV) Report

IEC notification of Site Closure Template (Ch09 –A04-V3.0)

To,

The Member Secretary,

<IEC Name>,

<Site Name>

Reference: <Study Title>

Subject: Notification of Site Closure

Dear Sir/ Madam,

This is with reference to the site closure of the above mentioned study.

Please note the following details.

The site was initiated on <DATE> and the last patient was recruited on <date>.

The following are the recruitment details of the study participants:

Trial ID	Date of Randomization	Present Patient Status

As there are no active patients at the site, the Site Close out Visit was conducted on <date> by < name and designation of NCG CRO personnel> All relevant Open Actions from previous monitoring visits have been closed. The source documents,Investigator Site File has been archived.

This is for your information and records.

Yours Sincerely,

<PI Siganture and Date>
<PI Name

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Date	Prepared by
1	Ch09/V2.0	V1.0_15-Jan-2018	1. Modification in section 4.0 2. Modification in section 6.0	V2.0_05-Feb-2020	Mrs. Kalyani Madhu
2.	Ch09/V3.0	V2.0_05-Feb-2020	1. Modification in section 3.0 2. Modification in section 4.0 3. Modification in section 6.0: Annexure2: Ch09 – A02-V3.0 4.Addition of Annexure 04	V3.0_10-Feb-2023	Mr. Shirsha Chakraborty

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai- 400012	राष्ट्र की सेवा में परमाणु टी एम सी TMC ATOMS IN THE SERVICE OF THE NATION

Title:

Standard Operating Procedure for Training of NCG CRO Research Personnel

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
10	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose:

To define the standard procedures and documentation for training of clinical research personnel (CTA, CRA & PM) participating in research activities within the NCG CRO.

2.0 Scope:

The SOP will apply to training on all NCG funded trial or NCG approved trial or both, NCG CRO SOPs, monitoring process, GCP and regulations.

3.0 Applicable to Whom:

This SOP is applicable to personnel (CTA & CRA/ PM/P-In-charge) of NCG CRO who would be assigned various responsibilities of trial conduct.

4.0 Procedure:

According to the New Drugs and CT Rules 2019, guidelines and site SOP, the individuals involved in trial conduct should be qualified by education, training, and experience to perform respective tasks. Before a research team member is delegated certain responsibilities he/she should be adequately trained on the topic and the training provided needs to be documented.

4.1. Good Clinical Practice training:

4.1.1. The research team members should attend the basic, advanced GCP training and Clinical Research Methodology workshop organized by Clinical Research Secretariat, Tata Memorial Hospital, Mumbai. GCP certification to be updated once in 2 years.

4.2. Regulatory requirement training:

4.2.1. Any regulatory update or revision in the guidelines should be informed and if required trained to the team by the Project In-charge (P-In) Training records to be maintained including agenda, certificate and presentation material. Where certificates are not available, the agenda, presentation email and attendance details can be maintained.

4.3. Protocol specific training:

4.3.1. The research personnel assigned a specific study (together with other NCG team member who may be available for training) would undergo training on the following:

(a) Protocol and disease under the study
(b) Monitoring Plan
(c) Other relevant topics as per the job description and delegated tasks.

4.3.2. The Protocol specific training would be imparted by the Clinician (Project Clinician/ Investigator/ Sub-Investigator)/delegated person by the Sponsor Principal Investigator/team

4.4. SOP training:

4.4.1. Existing NCG CRO Research team would be trained on the various SOPs and retrained by Project In-charge on its renewal or change as applicable. New Research team member would be trained on the SOPs by CTA/CRA/PM as assigned by the Project In-charge.

4.5. Documentation of training:

4.5.1. After the conduct of the training, the details of the topics covered and trainee will be captured in a 'Training Record Template' (Annexure 01) by the trainer. This record template would be signed and dated by both the trainee and the trainer. Also Agenda and training material to be filed in the training file.

4.5.2. The start date in the duty delegation log would be entered by Project manager/ Project In-Charge (if applicable).

4.5.3. The general training file would consist of the following:

(a) Signature and Duty delegation log, Job Description and CV,GCP, MRC (if applicable) of NCG CRO personnel.

(b) SOP training records of NCG CRO personnel.

(c) Protocol specific training record of NCG CRO personnel (copy). The original training record will be filed in the study specific file.

(d) If Protocol training is conducted during the Investigator's meeting, then the copy of attendance sheet of the IM can be filed, together with agenda.

Note: The training record template (annexure) can also be used for the purpose of site staff training during site initiation/routine monitoring visit.

4.6. Roles And Responsibilities:

Sr. No	**Personnel Responsible**	**Responsibilities**
1	Project In-Charge/ Project Manager	• Allocation of studies to the CRA/PM. • to ensure that the Protocol training has been conducted for the CRA by Sponsor-PI/ delegated representative. • To train the CRAs on conducting ROMV on the basis of the monitoring plan, including but not limited to i. Disease ii. ii. Protocol iii. iii. CRF iv. iv. CRF completion guidelines and study specific documents v. v. Guidelines for storage of Investigational Product (IP) vi. Reporting & escalation of protocol deviations. Training log to be maintained. • To review and approve the monitoring report prepared by the CRA/PM.
2	Project Manager (PM)	• To review and comment about the monitoring report prepared by the CRA. • To accompany the CRA(s) in co-monitoring visits (if applicable). • To conduct monitoring visit if allotted with primary responsibility.
3	Clinical Research Associate (CRA)	• To keep a track of site recruitment and data entry • To schedule the ROMV/RMV as per the monitoring plan. • To send (via email) the confirmation and agenda to the site. • To conduct the ROMV/RMV. • To prepare and forward the monitoring report to the PM/Project In-Charge for review within timelines. • To prepare and send the follow up email to the site Principal

		Investigator (PI) within timelines. • To follow up with the site for closing of the open queries raised as per the report and follow up letter. • To review the documents retrieved from the sites and handover the documents to the CTA retrieved from the site for filing. • To complete the procedures related to the ROMV travel reimbursement. • The Senior CRA can train a newly appointed CRA on the monitoring process, by co-monitoring and/or in-house training.
4	Clinical Trial Assistant (CTA)	• CTA to assist CRA in retrieving the open action items from m the previous visit/(s). • To review for pagination, quality & correctness of the site documents and file the site documents obtained by the CRA into the respective In-house site master file. • To help CRA in making travel arrangements and claims.

4.7. Study Handover:

4.6.1. When a research team member is planning to leave or resign, he/she would ensure that hand over is given to the newly appointed person/ existing person identified by the Project In-charge before conclusion of tenure. The stop date of the member leaving the study team would be inserted in the signature and duty delegation log by the Project In-charge/PM and signed and dated. The organogram to be updated after the insertion of the details of the new member. The start date can be inserted by the Project In-charge/NCG Convener and signed. After relevant training has been imparted, the details of the new study team member would be added in the training record template and filed in the training records file. The Project Manager/Project In-Charge/NCG Convenor must provide appropriate oversight & guidance/support to ensure the handover is adequately completed.

4.8. Training of newly appointed CRA:

4.8.1. The monitoring training activity of the new CRA would comprise of:

1. Observation of at least 2 monitoring visit with CRA/PM.
2. Conduct of at least 3 Co-monitoring visits with CRA/PM.

During the co-monitoring visit, the following procedure to be followed:

a. The Senior CRA and the trainee CRA would review at least 1 file together.
b. The Trainee CRA would review at least 4-5 files individually. These files would also be reviewed by the Senior CRA.
c. The trainee CRA would collate and share the IC and SDV related observations with the Senior CRA. The Senior CRA would compare these observations with his/her

observations for consistency. Any additional observations would be discussed by the trainer with the trainee.

d. The details of the training would be documented in Training Record Template (Ch10-A01-V2.0). The co-monitoring activity would also be recorded in the Others Section of the SUMMARY OF FINDINGS of the Routine Onsite Monitoring Visit (ROMV) Report (Ch08 –A03-V2.0).
e. The visit report would be a composite one incorporating findings of trainee CRA and the trainer CRA.

4.8.2. Before the new CRA is allowed to undertake independent monitoring, the above activities to be completed. A training checklist (Ch10-A03-V3.0) would be completed and signed off by Project Manger.

4.9. Training of short terms trainees: MSc Clinical Research–Students/other short term trainees/observers are posted in NCG CRO for a duration of 3-4 months. The details of the training imparted would be documented in the curriculum specified work log.

4.10. Self-Assessment of CRO personnel:

4.7.1. Annual self-assessment would be performed by the NCG CRO research personnel (CTA, CRA, and PM). The self-assessment would comprise of performance and achievements, individual strength and weakness, training records, scope of improvement. This would be used for the purpose of annual appraisal. The NCG CRO research team members would submit the self-assessment for review to the Project In-charge in the 'Self Appraisal Form Template' (Annexure 04). The appraisal interview would be conducted by Project In-Charge (P-In) and/or NCG Convener and finally approved by the NCG Convener. This activity would be completed before completion of 1 year in the position and annually thereafter.

Prepared By	Reviewed by	Approved by
Name: Mr. Shirsha Chakraborty	Name: Dr. Durga Gadgil	Name: Dr. C S Pramesh
Signature: Shirsha Chakraborty	Signature: D Gadgil	Signature: C S Pramesh
Date: 23-Feb-2023	Date: 27 Feb 2023	Date: 28/Feb/2023

5.0 Reference(s):

- New Drugs and CT Rules, March 2019
- Indian GCP guidelines (2001)
- ICH GCP E6(R2) guidelines (2016)
- ICMR guidelines (2017)
- Tata Memorial Centre_Clinical Research SOP Ver 2.0 Mar 2022_Chapter-17-Study team training and handover-http://tmc.gov.in/research/sop/SOP_CRS/CRS_SOP_Final.pdf
- Performing and Documenting Training for Research Staff (V2.0: 21 July 2014). Basildon and Thurrock University Hospitals NHS FT Research & Development.
- Study team training and study handover SOP - Global Health Trials-https://globalhealthtrials.tghn.org/resources/templates

6.0 Annexure(s):

- Annexure 01-Training Record Template (Ch10-A01-V3.0)
- Annexure 02-Duty Delegation and Signature Log template of NCG CRO (Ch10-A02-V3.0)
- Annexure 03: Handover Checklist (Ch 10-A03-V 3.0)
- Annexure 04- CRA training checklist template (Ch10-A04-V3.0)
- Annexure05 Annual appraisal form template of NCG CRO research personnel (Ch10-A05-V3.0)

Training Record Template (Ch10-A01-V3.0)

Training Record Template

Purpose of training:

Topics covered:

Training attended by:

Sr. No.	Name of the Trainee	Designation	Signature and Date

Name of the trainer:

Signature and Date:

Duty Delegation& Signature Log template of NCG CRO (Ch10-A02-V3.0)

Study No.:	**Study Site:**
Study Title:	

Sr. No.	**Complete Name**	**Signature**	**Initials**	**NCG CRO role**	**Key delegated tasks***	**Start Date**	**Project In-charge/** Project Manager **signature and date**	**Stop Date**	**Project In-charge/** Project Manager **signature and date**

*** Key delegated tasks:** Job descreption to be referred

Handover Checklist (Ch10-A03-V2.0)

Particulars	Please tick	Comments
Introduction to the study and Sponsor PI team		
Protocol training conducted by Sponsor PI (Specify version in the comment section)		
Training record available		
Addition in duty delegation log/ NCG CRO organogram		
CV-GCP-MRC(if applicable) filed in ISF		
Briefing on the various sites and study teams		
Site contact details shared		
Update on any Study specific Investigator Meetings/Sponsor PI-site calls		
Additional Comments(if any):		
Protocol, ICD, CRF , Monitoring Plan and other relevant essential documents received		
Previous Monitoring reports, follow up letters received		
Site wise Open action Item tracker received		
SDV tracker received		
Training on the requirements of TMF filing(especially monitoring communications)		
Handover of any supportive study (ISF briefing and IEC portal training) provided if applicable		
Additional Comments(if any):		

Handover provided by: Name: Signature and date:	Handover taken by: Name: Signature and date

CRA Training Checklist template (Ch10-A04-V3.0)

Particulars	Please tick if completed	Comments
NCG CRO & site & IEC SOP self reading		
SOP training assessment done		
Observation of at least 2 monitoring conducted by Senior CRA		
At least 3 Co monitoring with Senior CRA		
I hereby confirm that the < Name of the CRA> can conduct independent monitoring of studies under the purview of NCG CRO. Signature of the Project Manager/Project In-charge:		

Self Appraisal Form Template (Ch10-A05-V3.0)

Self Appraisal by CTA/CRA/PM Evaluation Period: Name of the Employee: Designation: Department: Date of appraisal:
Performance Rating Definitions:

Rating	Performance definition
5	**Exceptional –** Performance at this level is clearly unique and far in excess of established expectations. The employee consistently exceeds expectations in the outcomes achieved in work quality, quantity and timeliness. The employee exhibits leadership among peers in all dimensions of the field work performed.
4	**Exceeds Expectations –** Performance at this level often exceeds established expectations and standards of work quality, quantity and timeliness. The employee exhibits mastery of most dimensions of the field of work performed.
3	**Meets Expectations –** Performance at this level meets established expectations and standards for work quality, quantity and timeliness. The employee competently achieves the requirements of the position.
2	**Needs Improvement –** Performance at this level is below the level expected of an employee in the position. Improvement is required in significant dimensions of the job in order to meet the expectations and standards for work quality, quantity and timeliness.
1	**Unsatisfactory –** Performance at this level is unacceptable. The employee often fails to achieve basic requirements of the position and has exhibited little or no improvement in job performance. The employee performing at this level should not be continued in this position; or where extenuating circumstances exist, should be retained only upon significant improvements within a fixed period of time to be defined by the University.

Job Responsibilities:

Date of Joining:
Date of NCG CRO SOP training:

Primary Responsibility:	**Secondary Responsibility:**

Designation (CTA/ CRA)	Project Title (Please specify the start date)	Activities undertaken
Please specify any other activity (if applicable)		

Performance Factors:

Knowledge of work:

Employee:

a) Exceptional
b) Exceeds expectations
c) Meets expectations
d) Needs Improvement
e) Unsatisfactory

Comments (Reason for rating/Examples):

Reviewer Comments:

Planning and Organization:

Employee:

a) Exceptional
b) Exceeds expectations
c) Meets expectations
d) Needs Improvement
e) Unsatisfactory

Comments (Reason for rating/Examples):

Reviewer Comments:

Problem solving/Decision making:

Employee:

a) Exceptional
b) Exceeds expectations
c) Meets expectations
d) Needs Improvement
e) Unsatisfactory

Comments (Reason for rating/Examples):

Reviewer Comments:

Communication:

Employee:

a) Exceptional
b) Exceeds expectations
c) Meets expectations
d) Needs Improvement
e) Unsatisfactory

Comments (Reason for rating/Examples):

Reviewer Comments:

Team work/collaboration:

Employee:

a) Exceptional
b) Exceeds expectations
c) Meets expectations
d) Needs Improvement
e) Unsatisfactory

Comments:

Reviewer Comments:

Attendance and Punctuality:

Employee:

a) Exceptional
b) Exceeds expectations
c) Meets expectations
d) Needs Improvement
e) Unsatisfactory

Comments (Reason for rating/Examples):

Reviewer Comments:

Any additional achievements/participation and presentation in training program/Conferences.

Employee**:**

What is your vision/goals over the next 2 years (not more than 200 words)

Employee**:**

Any other information/achievements which you wish to state, which has not been covered in the above section.

Employee:

Reviewer:

Performance areas which needs improvement:

Employee:

Reviewer:

Plan of action towards improving performance: Employee: Reviewer:	
Training Details: Workshop /Conference attended: Certifications:	
Reviewed By: Name: Signature: Date:	Approved By: Name: Signature: Date:

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Date	Prepared by
1.	Ch 10 V 2.0	V1.0_17-Jan-2018	1.Modification in section 1.0 2.Modification in section 3.0 3.Modification in section 4.0 subsection 4.1.1,4.2.1,4.3.1,4.3.2, 4.5.,4.6.,4.7 4.Modification in section 5.0 5.Modification in Annexure 3.0	V2.0_05-Feb-2020	Mr.Shirsha Chakraborty
2.	Ch 10 V 3.0	V2.0_05-Feb-2020	1.Modification in section 4.3 2.Modification in section 4.7 3.Addition of Sections 4.8 and 4.9 4.Modification in section 6.0: Addition of Annexure 03 and 04	V3.0_10-Feb-2023	Mr.Shirsha Chakraborty

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Title:

Standard Operating Procedure for Regulatory Submission

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
11	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose:

This SOP describes submission of documents of the studies pertaining to NCG for approval to regulatory authorities. This SOP describes the process which ensures that all necessary and applicable forms are prepared for the submission as per the Regulatory requirements.

2.0 Scope:

This SOP is applicable for all studies which are funded/under the purview of NCG and for submission to regulatory authority (DAE approval/DCGI/CTRI) for their approval, if applicable.

3.0 Applicable to Whom:

This SOP applies to all the personnel of the NCG CRO team who are responsible for the conduct of study at NCG.

These include the following:

- Clinical Research Associate (CRA)
- Clinical Trial Assistant (CTA)
- Sponsor Principal Investigator
- Project Manager
- Project In-Charge

4.0 Procedure:

4.1 The regulatory submission of the new trial is the responsibility of the Sponsor Principal Investigator. In case of NCG funded trials, the following regulatory submission/s can be done by the NCG CRO, if requested.

4.2 The Regulatory Submission can be as follows:

a. Clinical Trial Registry-India (CTRI).
b. Application to Drug Controller General of India (DCGI) (if applicable).
c. Submission of a Clinical Trial for Regulatory Approval in Case of Foreign Collaboration (if applicable).
d. Application for Import License (if applicable)

a. Registration of New Trial at Clinical Trial Registry - India (CTRI):

1. The Clinical Trials Registry - India (CTRI), set up at the National Institute of Medical Statistics, ICMR, New Delhi is a free and online system for registration of all clinical trials being conducted in India (www.ctri.nic.in). Registration of clinical trials in the CTRI is now mandatory, as per notification of the Drugs Controller General (India).

   CTRI website: **http://ctri.nic.in/Clinicaltrials/login.php/**

   Note: The trial should be registered in the CTRI before enrolment of the first participant in the study.

b. Application for new trials to Drug Controller General of India (DCGI) (if applicable):

1. The application for new trials should be done through online portal – SUGAM

   Official website: **www.cdscoonline.gov.in**

   The submission video tutorial available on:
   https://cdscoonline.gov.in/CDSCO/Help_Video

c. Submission of a Clinical Trial for Regulatory Approval in Case of Foreign Collaboration:

1. For Tata Memorial Centre, the circulars dated 1305.5.2021/R&D-II/DAE-6922, DST/INT/HL/2006 would be applicable. The proposal after IEC approval would be approved by Foreign Collaborative Research Sub-committee-ACTREC. Subsequently the proposal would be sent to the DAE with DAE submission checklist (both word format and excel sheet format)

2. A Biological Research Regulatory Approval (BioRRAP) ID would be required. The ID can be generated at **https://biorrap.gov.in/** The details of BioRAPP ID is to be included in the DAE submission.

d. Application for Import License:

The application for import License should be done through online portal – SUGAM

The steps for submitting Import License in SUGAM portal link is as follow:
www.cdscoonline.gov.in

The application manual available on following link:
https://cdscoonline.gov.in/CdscoManuals/Registration%20Guidelines/!SSL!/Multiscreen_HTML5/desktop/First_Topic.htm

Prepared By	Reviewed by	Approved by
Name: Ms. Prachi Kokate Signature: PKokate Date: 21-Feb-2023	Name: Dr. Durga Gadgil Signature: Date: 27 Feb 2023	Name: Dr. C S Pramesh Signature: Date: 28/Feb/2023

5.0 References:

- CTRI: www.ctri.nic.in
- CDSCO : www.cdscoonline.gov.in
- SUGAM : https://cdscoonline.gov.in/CDSCO/homepage
- BioRRAP: https://biorrap.gov.in/

6.0 Annexure: Nil

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Effective date	Prepared by
1.	Ch11/V2.0	V1.0_17 Jan 2018	1.Modification in Section 1.0 2.Modification in Section 2.0 3.Modification in Section 3.0 4.Modification in Section 4.0 5.Modification in Section 5.0 6.Modification in Section 6.0	V2.0_05-Feb-2020	Ms. Lochana Bandekar
2.	Ch11/V3.0	V2.0_05-Feb-2020	1.Modification in Section 2.0 2.Modification in Section 4.0 3.Modification in Section 5.0	V3.0_10-Feb-2023	Ms. Prachi Kokate

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Title:

Standard Operating Procedure for Allocation of responsibilities between Sponsor-Investigator and NCG CRO

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
12	**2.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose:

This SOP describes the responsibilities/tasks assigned to NCG CRO by Sponsor Principal Investigator. Preferably it should be documented in an agreement between NCG CRO and Sponsor Principal Investigator for studies funded/supported by NCG

2.0 Scope:

The SOP would be referred during the planning/preparation of a documentation of roles and responsibilities between NCG CRO and Sponsor Principal Investigator for research related tasks.

3.0 Applicable to Whom:

This SOP applies to NCG CRO team

4.0 Procedure:

4.1. When the Sponsor Principal Investigator approaches the NCG CRO for partial/complete support for a study, the assigned activities would be documented using a Task Ownership Matrix (TOM) (Annexure-01) tool.

4.2. The elements of task ownership matrix can be customised as per the requirements of the Protocol, study conduct and support expected from the CRO.

4.3. The final TOM along with Cost Matrix (Annexure-02) may be signed off by NCG Convener/NCG CRO Project In-charge and Sponsor Principal Investigator (S-PI). Preferably each page can be initialled by the Sponsor Principal Investigator and NCG CRO Project In-charge.

4.4. The terms of TOM and cost matrix would be valid from the date of sign off till the specified duration in TOM and cost matrix.

5.0 Revision:

5.1. During the study conduct the task owner ship and cost matrix can be revised if applicable. This re-execution will be addendum to existing TOM.

5.2. The changes would have to reviewed and approved by the NCG CRO NCG Convener or delegate/NCG CRO Project In-charge in consultation with Sponsor Principal Investigator.

5.3. Point 4.4 (as described above) would be applicable.

Note: For execution of the responsibilities/activities as outlined in the Task ownership matrix, various trackers can be created by NCG CRO personnel. (for e.g., IEC submission and approval tracker, monitoring tracker etc.)

Prepared By	Reviewed by	Approved by
Name: Ms. Prachi Kokate Signature: Pkokate Date: 21-Feb-2023	Name: Dr. Durga Gadgil Signature: DAgadgil Date: 27 Feb 2023	Name: Dr. C S Pramesh Signature: CS Pramesh Date: 28/Feb/2023

6.0 Annexure:

- Annexure 01 –Task Ownership Matrix template(Ch12-A01-V2.0)
- Annexure02 –Cost Matrix template (Ch12-A02-V2.0)

Task Ownership Matrix template (Ch12-A01-V2.0)

Study Title	
Sponsor Principal Investigator	
Duration of NCG CRO Service	

×: Primary responsibility (×): Supportive

SR. NO.	ACTIVITY	NCG CRO	SPONSOR PRINCIPAL INVESTIGATOR	COMMENTS
A. SITE MANAGEMENT AND MONITORING (Refer to Annexure 02)				
1.	Conduct of site feasibility (Assisting in the development of feasibility questionnaire/conduct of site assessment visit and preparation of visit report)	×	(×)	
2.	Site selection	×	(×)	
3.	Planning and conduct of site initiation visit and preparation of report	×	(×)	
4.	Planning and conduct of routine site monitoring visit, preparation of report and follow up communication	×	(×)	
5.	Planning and conduct of site close out visit report preparation and follow up communication	×	(×)	
6.	Preparation of Monitoring Plan	×	(×)	
7.	Ensuring that the timeline for report preparation and sharing of follow up communication with the site are met	×	(×)	

B. STUDY FILES				
1.	Preparation and maintenance of the Trial Master File	(×)	×	
C. SUBMISSION ANDAPPROVALS				
1.	IEC submission , query response and approval			
2.	CTRI registration and IEC notification			
3.	HMSC (ICMR) submission (if applicable)			
D. STUDY RELATED DOCUMENTS				
1.	Preparation of Protocol and its amendments			
2.	Preparation of Informed Consent and its translations			
3.	Preparation of Case Report Forms			
4.	Preparation of Any other Patient Documents (Patient diary/ questionnaire//Identity cards)			
E. CONTRACT AND FINACE				
1.	Execution of Clinical Trial Agreement with the site			
2.	Site payments			
F. INSURANCE				
1.	Purchase of Insurance			
2.	IEC notification at site			
G. SAMPLE COLLECTION				
1.	Collection, storage and transport of sample (if			

	applicable)			
H. INVESTIGATIONAL PRODUCT MANGEMENT				
1.	Storage of IMP at the Central Pharmacy			
2.	Investigational Product (IP) consignment dispatch to sites from Central Pharmacy			
3.	Maintaining drug inventory Drug destruction and sharing of destruction certificate			
4.	Drug destruction and sharing of destruction certificate			
I. QUALITY ASSURANCE AND AUDITS				
1.	Ensuring data entry timeliness and quality			
2.	Assisting sites with preparation for external audit or inspection (If required)			
J. PHARMACOVIGILANCE				
1.	Preparation of Safety Management Plan			
2.	Reporting of SAEs to Sponsor-Investigator			
3.	Reporting of SAEs to local Ethics Committee			
4.	Reporting of SAEs to the regulatory authority (if applicable)			
5.	Ensuring reporting timelines are met			
6.	Review and tracking of SAEs			
7.	Request for further information on SAEs from sites			
8.	Clinical review of SAEs			
9.	Reporting safety information to Ethics Committee/regulators			
10.	Reporting of SARs and SUSARs			

11.	Preparation of periodic and immediate SUSAR reports			
12.	Distribution of periodic and immediate SUSAR reports to investigators			
13.	Preparation of Annual Safety Report (DSUR format)			
14.	Submission of Annual Safety Report to regulators/ethics committee/sites (as required)			
15.	Transmit trial related information to sites from Sponsor Investigator			
16.	Payment of Compensation (in case of death/trial related injury) and medical management of SAEs			
K. DATA MANAGEMENT				
1.	Assisting the sites for resolution of queries			
L. END OF TRIAL				
1.	Communication to CRO			
2.	Collecting site close-out documents			
3.	Communication to local ethics (if required)			
4.	Completing trial close-out documents			
5.	Archiving of trial master file (India) and site materials			
M. STATISTICAL ANALYSIS AND TRIAL REPORT				
1.	Statistical analysis (Interim and final)			
2.	Preparation of trial report			
3.	Review of trial report			
4.	Publications			

N. INVESTIGATOR MEETING				
1.	Investigator meeting (s)-planning and co-ordination; arranging site staff travel; accommodation and reimbursement of expenses			
2.	Preparation of the agenda			
3.	Preparation of the minutes of the meeting			

Sponsor Principal Investigator	**NCG Convener/NCG CRO Project In-charge**
Signature: Name: Date:	Signature: Name: Date:

Cost Matrix Template (Ch12-A02-V2.0)

Study Title	
Sponsor Principal Investigator	
Duration of NCG CRO service	

As per the NCG CRO Revised Proposal dated 27-Jan-22 and Govt. Of India TA DA rules following are the details of the expenditure clauses related to travel:

PARTICULARS	**MODE**	**COSTS**
TRAVEL		
Inner State	Flight- All tickets can be purchased from the authorized travel agents viz. a. Indian Railways Catering and Tourism Co-operation Ltd. (IRCTC) b. M/s Balmer Lawrie & Company Limited	As per actuals

	(BLCL) c. M/s Ashok Travels &Tours (ATT) The travel rules as issued by Government of India from time to time would be applicable.	
Within Maharashtra	Train-AC 2 tier/ AC 3 tier/ chair car (as applicable)	As per actuals
ACCOMMODATION		
Hospital Guest House	-	As per actuals
Hotel	-	Not exceeding Rs.4000/day (including GST)
OTHERS		
Daily allowances(e.g.-meals)	-	750/day

The following costs are as per TMH accounting practices (based on DAE rules):

1. Local travel within Mumbai (Airport-Residence travel):
   Cab: Rs.24/Kilometre
   Auto: Rs.12/Kilometre
   Government transport facility: as per actuals

2. Local travel within the city where the site is located
   a. Airport to Accommodation facility/site-to and fro
      Cab: Rs.24/Kilometre
      Auto: Rs.12/Kilometre
      Government transport facility: as per actuals
   b. Accommodation to site (to and fro): As per actuals, using local conveyance available.

NOTE:

1. For the process of deputation and reimbursement TMC institutional practice will be followed.
2. There is a provision for claiming an advance for travel/ accommodation as per TMC institutional practice.
3. For interstate travel, for sectors where Air India flights are not available, TMC-Director's approval to be taken
4. Claims for air/train travel will be enclosed.
5. Bills /Vouchers will be provided wherever available.

Sponsor Principal Investigator	**NCG Convener/NCG CRO Project In-charge**
Signature: Name: Date:	Signature: Name: Date:

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Date	Prepared by
1.	Ch12/V3.0	V1.0_05-Feb-2020	1. Modification in Section 4.0 2.Modification in Section 5.0 3. Modification in Annexure 01 4. Addition of Annexure 02	V2.0_10-Feb-2023	Ms. Prachi Kokate

NATIONAL CANCER GRID COLLABORATION FOR CANCER CARE	NCG CRO Tata Memorial Hospital, Parel, Mumbai-400012	राष्ट्र की सेवा में परमाणु टी एम सी TMC ATOMS IN THE SERVICE OF THE NATION

Title:

Standard Operating Procedure for Archival of Documents

Chapter Number:	Version Number:	Effective Date:	Valid Up to:
13	**3.0**	**28-Feb-2023**	**27-Feb-2026**

1.0 Purpose

This Standard Operating Procedure (SOP) describes the procedure of archival of documents generated during the conduct of the study for trials that are funded and supported by the National Cancer Grid Contract Research Organization (NCG CRO).

2.0 Scope

This SOP describes the method to archive the documents at TMC, Mumbai.

3.0 Applicable to Whom

This SOP is relevant to the research team within the NCG CRO delegated with a particular study/activity who is responsible to perform the tasks related to archival.

4.0 Procedure

4.1. Archival would be undertaken as per section 4.1, 4.2 and 4.3 in chapter 12 (SOP on Allocation of responsibilities between Sponsor Principal Investigator and NCG CRO) or as per task ownership matrix.

4.2. Storage and archival

4.2.1. The documents would be archived after the final closeout visit of all the participating site has been done for the study/Sponsor Principal Investigator confirms that all study related activities are completed and responsibility of the NCG CRO ceases. The documents that are identified for archival and approved by the Project Manager (PM)/Project In-charge (P-In) need to be:

- Recorded in the archival inventory (Annexure 1).

- Packed and sealed in labeled boxes (Annexure 2).

4.2.2. The archived boxes should be stored in an appropriate room or locked cupboard which is safely access controlled.

4.2.3. Details of the archiving location should be recorded in a register maintained at the NCG CRO office.

The register would record the following details:

- Name of the study.
- Short Title of the study.
- Name of the PI/Sponsor Principal Investigator
- Date to be archived until (15 years from the date of archival).
- Location of archival

4.2.4. Whenever a document needs to be retrieved post archival, the details of the same should be recorded in the above register. Retrieval may be carried out by the P-I/PM/CRA/CTA with approval and documented authorizationby email from the Sponsor Principal Investigator/NCG Convener.

The register would record the following details (Annexure 3):

- Name of the person requesting retrieval of the document.
- Date of request.
- Details of the document required.
- Purpose of retrieving the document.
- Details of the authorizing authority: Name, Signature and date of the Project Manager/Project In-charge.
- Date returned to archive.
- Name, Signature and date of the person returning the document/s to the archival facility.

4.3.Retention Policy

The documents should be archived for 15 years from archival date or till such time the Sponsor Principal Investigator authorizes that the documents are no longer required.

4.3. Destruction of study related documents:

The archived documents would be destroyed and documented as per the TMC Institutional policy/CTA (as applicable).

Prepared By	Reviewed by	Approved by
Name: Ms. Prachi Kokate Signature: Pkokate Date: 21-Feb-2023	Name: Dr. Durga Gadgil Signature: Date: 27 Feb 2023	Name: Dr. C S Pramesh Signature: Date: 28/Feb/2023

5.0 Reference

- NDCT Rules, 2019
- Appendix V-CDSCO guideline: Essential Documents.
- ICH Guidelines for Good Clinical Practice (E6 R2) section 4.9 – Records and Reports.
- ICH Guidelines for Good Clinical Practice (E6 R2) section 5.22 – Clinical Trial/Study Reports.
- 21 CFR 312.57 – Record Keeping and Retention.
- 21 CFR 312.58 - Inspection of Sponsor Records and Reports.

6.0 Annexure

- Annexure 1: Archival Inventory template (Ch14 –A01-V3.0)
- Annexure 2: Archiving Box Labels template (Ch14 –A02-V3.0)
- Annexure 3: Template for Details In The Register For Retrieving Documents Post Archival (Ch14 –A03-V3.0)

Archival Inventory Template (Ch13 –A01-V3.0)

STUDY NUMBER	
STUDY TITLE	
STUDY SHORT TITLE	
SPONSOR PRINCIPAL INVESTIGATOR's NAME	
DATE OF ARCHIVAL	
ARCHIVAL UPTO	
CONTENTS OF BOX (__ OF __)	

Archiving Box Label Template (Ch13 –A02-V3.0)

STUDY NUMBER	
STUDY SHORT TITLE	
SPONSOR PRINCIPAL INVESTIGATOR's NAME	
DATE OF ARCHIVAL	
ARCHIVAL UPTO	
CONTENTS OF BOX (__ OF __)	

Template for Details In The Register For Retrieving Documents Post Archival (Ch14–A03-V3.0)

NO	DOCUMENT RETRIEVAL REQUEST				DOCUMENT RETRIEVAL		DOCUMENT FILING		
	Name of the person requesting	Date	Document details	Purpose	Name of the person retrieving	Signature and date	Date returned to archive	Name of the person filing the document	Signature and date

History of Change

Sr. No.	SOP Code	Previous version_Date	Changes in the current version	New version_Effective date	Prepared by
1	Ch 13/V2.0	V1.0_15-Jan-2018	1.Modification in Title 2.Modification in section 1.0 3. Modification in section 2.0 4. Modification in section 3.0 5. Modifications in section 4.0 subsections 4.1, 4.2 and 4.3 6. Modifications in section 5.0 7. Modification in section 6.0	V2.0_05-Feb-2020	Mr. Shirsha Chakraborty
2.	Ch13/V3.0	V2.0_05-Feb-2020	1.Modification in section 4.0 2. Modification in Annexure 01 and 02	V3.0_10-Feb-2023	Ms. Prachi Kokate