Sponsored Clinical Trial
Standard Operating Procedures
(SOPs)

आरोग्यम् सुख सम्पदा

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Contents (*Standard Operating Procedures*):

1. Preamble:

Clinical trials are essential for the advancement of medical science and the development of new therapeutic interventions. At the All India Institute of Medical Sciences (AIIMS), Raipur, the conduct of clinical trials must adhere to the highest standards of scientific integrity, participant safety, and ethical responsibility.

All industry-sponsored clinical trials conducted at AIIMS Raipur must comply with national and international ethical guidelines, including those laid down by the **Indian Council of Medical Research (ICMR), Good Clinical Practice (GCP)** guidelines issued by the **Central Drugs Standard Control Organization (CDSCO)**, and international standards such as the **Declaration of Helsinki** and **ICH-GCP**. These trials should also align with India's current public health needs and the prevailing disease burden, ensuring that the research remains relevant and beneficial to society.

AIIMS Raipur, being a premier institute of national importance, is committed to fostering collaborations with the pharmaceutical and biomedical industries to promote evidence-based advancements in medicine. However, such collaborations must be transparent, ethically sound, and scientifically rigorous.

2. Purpose:

The purpose of this document is to provide a structured overview of the institutional process for the **review, approval, and conduct** of **industry-sponsored clinical trials** at AIIMS Raipur. This document serves to guide principal investigators (PIs), co-investigators, and their teams on the procedural requirements and regulatory expectations for initiating and conducting such trials within the institute.

Specifically, this document outlines:

1. The eligibility criteria for the initiation of industry-sponsored clinical trials.
2. The step-by-step process for submission of trial proposals to the **Institute Research Cell (IRC), AIIMS Raipur**.
3. The mechanism of scientific, ethical, and administrative review of proposals.
4. The roles and responsibilities of the investigators, sponsors, and institutional stakeholders.
5. The requirements related to budgeting, contracts, and regulatory compliance.
6. The expectations regarding documentation, monitoring, reporting, and data sharing.

By formalizing these processes, AIIMS Raipur aims to streamline clinical trial operations, safeguard participant welfare, ensure legal and ethical compliance, and promote high-quality research that contributes meaningfully to national and global health.

3. Scope:

3.1 Industry-Sponsored Clinical Trials:

The **Institute Research Cell (IRC)** at AIIMS Raipur will review all proposals for research projects **sponsored by the pharmaceutical, biotechnology, or medical device industry**, which are intended or have the potential to be submitted for regulatory purposes. Approval letter or forwarding letter by the IRC is mandatory before any such proposal can be submitted to the **Institute Ethics Committee (IEC), AIIMS Raipur**.

The scope of review includes but is not limited to trials involving:

1. **New Chemical Entities (NCEs)**, including **biosimilars** and **generic products**.
2. A **new indication** for an already approved drug when submitted with regulatory intent.
3. A **new medical device**, whether diagnostic, therapeutic, or surgical.
4. A **new route of administration** for a previously approved drug.
5. A **new technology** intended for research, patient care, or educational purposes.

All industry-sponsored clinical trials must comply with the:

- **New Drugs and Clinical Trials (Amendment) Rules, 2024**.
- **Medical Devices (Amendment) Rules, 2020**.
- And any subsequent notifications or applicable guidelines issued by the **Central Drugs Standard Control Organization (CDSCO)** or other relevant authorities.

In addition, the **Executive Director, AIIMS Raipur**, may refer any other matter to the IRC for scientific or strategic consideration, even if not falling within the usual purview of the committee.

3.2 Investigator-Initiated Clinical Trials:

All **investigator-initiated clinical trials**, irrespective of funding source, will be reviewed by the Institute Research Cell (IRC) AIIMS Raipur. These trials are typically academic in nature, may or may not involve external funding, and are not intended for direct regulatory submission. However, they must still comply with national and institutional ethical guidelines and must obtain approval from the **Institute Ethics Committee (IEC)** before initiation.

4. Scientific Merits:

The scientific value of a clinical trial is a key determinant of its approval and conduct at AIIMS Raipur. All industry-sponsored trials must demonstrate **clear scientific rationale** and potential to contribute meaningfully to medical knowledge or public health.

Clinical trials should aim to:

1. **Develop and evaluate** new chemical entities (NCEs), novel drug molecules, or biological agents.
2. Investigate **new indications or formulations** of existing therapeutic agents.
3. Study the safety and efficacy of **new vaccines** or preventive biologicals.
4. Assess innovative **medical devices** or diagnostic technologies.
5. Explore **novel drug delivery mechanisms**, routes of administration, or treatment regimens.

Preference will be given to trials that address:

1. **Diseases and health conditions** that are **prevalent in India**, particularly in **Chhattisgarh and central India**, where AIIMS Raipur is situated.
2. **Public health priorities** identified by national and international bodies such as:

- The **Ministry of Health and Family Welfare**, Government of India.
- The **Indian Council of Medical Research (ICMR).**
- The **World Health Organization (WHO).**
- Other reputable global health organizations and regulatory authorities.

In alignment with institutional vision, trials must ideally fall within the **thrust areas** recognized by AIIMS Raipur, which may include communicable diseases, non-communicable diseases, maternal and child health, neglected tropical diseases, cancer, rare diseases, and emerging infectious threats.

Proposals must be backed by robust preclinical data (where applicable), a well-defined hypothesis, appropriate sample size justification, and scientifically sound methodology to ensure the generation of valid, reproducible, and ethically responsible evidence.

5. Steps in the approval of sponsored clinical trials:

5.1 Confidentiality Disclosure Agreement / Non-Disclosure Agreement (CDA/NDA):

a. A **prospective sponsor** interested in conducting an industry-sponsored clinical trial or research project at **AIIMS Raipur** may approach the **Head of the Department (HOD)** or an individual **faculty member** to discuss the preliminary concept or proposal.

b. Faculty members are permitted to engage in initial discussions with prospective sponsors regarding potential clinical trials. If required, they may **sign a Confidentiality Disclosure Agreement / Non-Disclosure Agreement (CDA/NDA)** to protect proprietary or confidential information shared during these discussions.

1. The signing of a CDA/NDA is considered a **preliminary step** and does **not require formal permission** from the **Institute Research Cell (IRC)**.

2. However, as a good practice, the concerned faculty member should **inform the IRC** about the signing of the CDA/NDA for documentation and institutional transparency.

c. The **signature of the Executive Director or Dean (Research), AIIMS Raipur**, is **not required** for CDA/NDA documents signed at the initial discussion stage.

The **Principal Investigator (PI)** or the faculty signatory shall assume **full responsibility** for adherence to the provisions outlined in the CDA/NDA. It is clarified that the responsibility for managing contracts with SMOs lies solely with the PI. If the PI signs an agreement with an SMO, the institute is not a party to that agreement and bears no responsibility for the SMO's conduct.

In cases where the PI enters into a direct clinical trial agreement (CTA) with a pharmaceutical company and funds are routed through the institute, the PI has the freedom to engage CRCs using project funds. Thus, the SOP places accountability with the PI, who is best positioned to oversee operational partners.

d. The CDA/NDA must be limited to the **confidentiality of shared information only** and **Must Not Impose Any Financial Or Legal Obligations on AIIMS Raipur. Any Binding Commitments Must Be Formalized Through Separate Institutional Agreements Following Due Process.**

5.2 Submission procedure for institute permission:

a. Once the trial protocol is finalized, the **Principal Investigator (PI)** must submit the complete proposal to seek **institute permission** through the **Institute Research Cell (IRC)** via the proper institutional process.

b. The proposal must be prepared in the **prescribed format** (as per annexures attached), along with all relevant **supporting documents and investigator undertakings**.

c. Instead of submitting via email, the **entire proposal (soft copy and scanned documents)** must be routed through the **e-Office system** via the **designated workflow**:

- The file must first be forwarded to the **Associate Dean (Research)**, followed by the **Dean (Research)** for review and onward submission to the **Institute Research Cell (IRC)**.

d. In addition to the digital submission through e-Office, a **hard copy** of the complete proposal — including one additional hard copy of the **Clinical Trial Agreement (CTA)** — must be submitted to the **Office of the Dean (Research), AIIMS Raipur** for official records.

6. Responsibilities of the Principal Investigator (PI):

Eligibility of Investigators:-

The **Principal Investigator (PI)** must:

- Hold a **postgraduate degree** in the relevant specialty.
- Be a **permanent faculty member** of **AIIMS Raipur**.

Roles and Responsibilities:-

a. The PI is **accountable for all aspects** of the clinical trial or project, including:

- Scientific integrity
- Ethical conduct and regulatory compliance
- Patient safety and adverse event reporting
- Timely financial oversight
- Communication with institutional bodies

This includes the **preparation and execution** of the Clinical Trial Agreement (CTA) submission of the proposal to the **Institute Research Cell (IRC)** and **Institute Ethics Committee (IEC)**, and all related correspondence with institute authorities.

b. The PI must ensure that any **investigational drug or device** is administered or used **only by the PI, a co-investigator, or an individual explicitly authorized in writing by the PI**, as described in the approved protocol.

c. The PI may utilize project funds **as per the terms of the agreement**, after obtaining prior approval from the **Dean (Research)/Competent Authority**. An **audited statement of accounts** must be submitted upon study completion.

d. The PI is permitted to **negotiate terms and conditions** of the trial or project on behalf of AIIMS Raipur. It is encouraged that **publication rights remain with the PI**.

e. The PI and co-investigators may attend **Investigator Meetings** related to protocol development or methodology discussions. ***AIIMS Raipur will not bear financial responsibility*** for any trial-related travel or participation expenses. Any meeting that may require the physical attendance of the PI will be funded by the sponsor.

f. The PI is responsible for **registering the trial with the Clinical Trials Registry–India (CTRI)** before initiation.

g. All administrative and clinical **engagements related to the trial** (including staff recruitment, procurement, etc.) must receive **prior approval from the competent authority**.

h. Upon completion of the trial, the PI must:

- Submit a **final study report** to the sponsor, as outlined in the CTA.
- Share a copy of this report with the IRC/IEC, routed through the **Head of Department** and the **Dean (Research)**.

i. The PI must ensure participant safety throughout the study. A **Safety Management Plan** should ideally be developed during the study setup phase, clearly outlining roles and responsibilities related to ongoing safety oversight. The **sponsor** remains responsible for continuous safety evaluation of the investigational product or intervention.

j. The PI is responsible for **promptly reporting any Adverse Events (AEs) and Serious Adverse Events (SAEs)** to the **IEC**, **sponsor**, and **regulatory authority**, as per applicable guidelines.

k. The PI must ensure that the trial is conducted in full compliance with **ethical guidelines**, and **obtain prior approval** from the IEC before initiating any sponsored clinical trial.

7. Clinical Trial Agreement (CTA):

Before initiating any clinical trial, the **sponsor** and the **Principal Investigator (PI)** must enter into a legally binding agreement. A **tripartite agreement** involving the **Sponsor, the PI, and the Executive Director (ED)** (on behalf of **AIIMS Raipur**) must be executed prior to trial commencement. This agreement may take the form of a **Clinical Trial Agreement (CTA).**

Note: The PI should carefully review the agreement and is encouraged to **negotiate relevant clauses** with the sponsor before initial submission to the Institute Research Cell (IRC).

The agreement must include, but is not limited to, the following clauses:

a. **Contact details** of the sponsor, PI, and designated institutional authorities.

b. **Obligations and responsibilities** of the sponsor and the investigator(s), clearly defined.

c. **Funding details**, payment schedule, and total sanctioned budget, breakup by financial head. The receipt acknowledgment must be submitted to the IRC and accounts section using standard format provided.[Annexure 1] This clause applies primarily to PI-led clinical trials with direct contracts with pharmaceutical companies, and not to SMO-managed trials.

d. Summary of the **study protocol**, including subject enrolment, conduct, handling of biological samples, data ownership, and documentation of study records.

e. **Study duration** and the **validity period** of the agreement.

f. **Disclosures** as mandated by applicable laws and institutional policies.

g. A **statement of compliance** with Indian laws governing clinical trials (including New Drugs and Clinical Trials Rules, 2019/2024 amendments).

h. **Confidentiality clauses**, including NDA/CDA where applicable.

i. **Monitoring mechanisms**, including undertakings by the PI on:

- Participant safety.
- Adverse Event (AE) and Serious Adverse Event (SAE) reporting.
- Ethical conduct of the trial.

j. Provisions for **inspection and audits** by the sponsor, regulatory bodies, or institutional authorities.

k. Clauses related to **inventions, patents, intellectual property (IP) rights**, and **publication rights**.

l. **Clinical trial insurance**: The sponsor or its authorized representative must provide **insurance coverage** for any subject injury or death resulting from trial participation. (Minimum insurance fee calculation will be 10 times the PI fee).

m. **Indemnity and liability**:

- The sponsor must **indemnify the investigators and study staff** for any professional liability arising out of trial conduct.
- Alternatively, the PI and the team must maintain an **Errors & Omissions (E&O) policy**.
- *In cases of breach of confidentiality or misuse of patient data, the **sponsor shall be held liable**.*
- Compensation decisions by the **IEC–CT SAE Committee** of AIIMS Raipur in accordance with the NDCT Act, and will apply even to trials such as nutraceutical studies that do not fall under CDSCO.

n. **Dispute resolution**: An **arbitration clause** must be included to address disputes between parties.

o. **Jurisdiction clause**: All disputes shall be governed under the **laws of India**, and the parties shall consent to the **exclusive jurisdiction of courts located at Raipur, Chhattisgarh**.

p. If **biological specimens** are to be transported outside AIIMS Raipur:

- A written **assurance** must be provided that specimens will be used **only for the purposes specified in the study protocol**.
- **Residual samples** must be **disposed of responsibly** after study completion. If future use is intended, clearly specify the reconsenting process to be followed.
- A joint **undertaking** by the PI and sponsor must be submitted to this effect.

q. The PI must submit a **signed copy of the final CTA**, along with all required undertakings, to the **Dean (Research) Office, AIIMS Raipur**, for official records.

r. For multicentric studies, details of other participating sites and any comments or conditional approvals from IRC and IEC should be provided.

s. Publications and authorship guidelines:

- The name of the principal investigator (PI) must be mandatorily included in any publication that involves data generated from the clinical trial conducted at AIIMS, Raipur.(as applicable)
- The PI's name must appear in any publication using data generated from AIIMS Raipur
- PI should negotiate for inclusion of results/data from our institute in any publication, and that the institute must be duly acknowledged in all publications arising from the trial. The PI may consider authorship in any position (not necessarily first author) for academic citation purposes.
- Names of Co-Principal Investigator (Co-PI) and contributing team members may also be included based on their level of contribution, in line with authorship criteria.
- The institute name (AIIMS, Raipur) must be clearly mentioned in the acknowledgement section of all such publications and presentations.

8. Institute Research Cell (IRC) Approval:

The **Institute Research Cell (IRC)** at **AIIMS Raipur** is responsible for scientific and procedural oversight of all **industry-sponsored clinical trials** prior to their submission to the Institute Ethics Committee–Clinical Trials (IEC-CT).

Constitution of IRC:

The IRC shall be **appointed by the Executive Director, AIIMS Raipur**, from among the **faculty members** of the Institute. While constituting the committee, an effort shall be made to include a **diverse set of competencies**, including but not limited to:

- Clinical trial methodology.
- Medical, surgical, and pediatric disciplines.
- Public health.
- Pharmacology and biostatistics.
- Legal and regulatory affairs (as applicable).

Role of IRC:

The IRC will ensure that all proposed studies:

- Are in compliance with **Good Clinical Practice (GCP)** guidelines.
- Uphold **participant rights, safety, and well-being.**
- Follow **scientific merit and institutional priorities.**
- Are ethically sound and logistically feasible
- Have clearly outlined **risk mitigation** and **data integrity** plans.

Inclusion of Subject Experts:

The **Dean Research** may **co-opt up to two subject experts**, as needed for project-specific evaluation. These experts may be drawn from within or **outside AIIMS Raipur** to ensure proper scientific and technical review. All such appointments must be made in **consultation with the Executive Director**.

9. Conduct of Institute Research Cell (IRC) Meetings:

a. Calling of Meetings

- The **Dean Research** shall determine the **date and time** of each meeting.
- The **Member-Secretary** will be responsible for **circulating meeting details** (agenda, date, and time) to all IRC members well in advance.
- The IRC will **convene approximately every one and half monthly**, or on any other date deemed suitable based on member availability and volume of submissions.
- Meetings will be convened **only if proposals requiring IRC evaluation are available**, such as clinical trials involving **new drugs, new indications, biosimilars, or new medical devices**.
- A meeting shall be considered valid if a **quorum of at least 50% of IRC members from various disciplines** is present.

b. Minutes of the Meeting:

- The **Member-Secretary** will prepare the **draft minutes** of each IRC meeting and circulate them to all members for review and comments.
- After incorporating any suggestions or corrections, the **final minutes** shall be:
- **Approved by the Dean Research.**
- **Forwarded to the Executive Director, AIIMS Raipur**, for administrative endorsement and action on the committee's recommendations.

10. Other Regulatory Approvals and Requirements:

a. Ethics Committee Approval (IEC–CT):

- The **Institute Ethics Committee (IEC), AIIMS Raipur**, will review and approve clinical trial proposals **only after approval from the Institute Research Cell (IRC)**.
- The **study protocol**, **informed consent documents**, and other supporting materials must be submitted to the IEC–CT for ethical clearance **prior to trial initiation**.
- The **Principal Investigator (PI)** and the study team must ensure compliance with all institutional ethical norms and national regulatory guidelines.
- The PI and co-investigators must submit **six-monthly progress reports** to the IEC–CT.
- Any **Serious Adverse Event (SAE)** must be reported to the **IEC–CT SAE Subcommittee** within **24 hours** of occurrence.

b. Registration with Clinical Trials Registry–India (CTRI):

- It is mandatory to **register all clinical trials** with the **Clinical Trials Registry of India (CTRI)** before enrolment of the first participant.
- **AIIMS Raipur** must be clearly listed as the **site of study** in the registration record.

c. Drug Controller General of India (DCGI) Approval:

- The **sponsor** must obtain regulatory clearance from the **Drug Controller General of India (DCGI)** for the investigational product, protocol, and site approval.
- A copy of the DCGI approval letter must be submitted to the Institute **prior to trial commencement** for regulatory compliance.

d. Health Ministry Screening Committee (HMSC) Approval (if applicable):

- For **multinational clinical trials** or studies involving **international funding**, prior approval from the **Health Ministry Screening Committee (HMSC), Government of India**, is required.
- The sponsor or PI must ensure this clearance is obtained **where applicable**.

e. Foreign Collaboration Approvals:

- For research studies in **life sciences involving foreign collaboration** (human, animal, plant, or environmental research), approvals must follow the **guidance document issued by the Government of India** and any **subsequent amendments** or policies. [Annexure 3a,3b,3c].
- A copy of such approvals must be submitted to the **Dean (Research) Office** and maintained with the study file.

11. Policy on Laboratory Tests Involving Biological Samples:

a. In-house Testing Preferred.

All **laboratory investigations** required for a clinical trial should **preferably be performed at AIIMS Raipur**, using institutional laboratory infrastructure and personnel, to maintain quality control, data integrity, and institutional compliance.

b. Sending Samples to External Laboratories (Within India):

In cases where:

- A specific test **cannot be performed at AIIMS Raipur**, or
- **Uniformity of laboratory methodology** is required for multi-centre studies, Biological samples may be sent to an **external accredited laboratory**. In such cases:
- The **sponsor or designated laboratory** must submit a written **undertaking** stating that:
- The samples will be used **only for the tests outlined in the approved study protocol**.
- **Residual samples** will be **disposed of appropriately** and **not retained** after study completion.
- No part of the sample will be used for purposes beyond the approved study without explicit written permission from the PI and AIIMS Raipur authorities.
- A separate Memorandum of Understanding (MoU) must be signed between the PI and the designated external laboratory after due approval from the Dean research.

c. Sending Samples Outside India (International Transfer):

If biological samples are proposed to be **exported outside India**:

- The **sponsor** must provide a written assurance that all transfers will comply with the applicable **Government of India regulations**, particularly:
- The guidelines issued by the **Ministry of Health and Family Welfare**, Government of India, vide **O.M. No. L-19015/53/97-IH (Pt.) dated 19th November 1997**, and
- Any **subsequent updates or amendments** to international sample transfer policies.
- Necessary **ethical and regulatory permissions** must be obtained, including:
- Institutional Ethics Committee (IEC) approval for sample transfer.
- Health Ministry Screening Committee (HMSC) approval, if applicable.

12. Policy on Receiving and Utilizing Funds for Sponsored Clinical Trials:

a. Funding Proposal and Charges:

- The **Principal Investigator (PI)** must submit a **detailed budget proposal**, including:
- **Head-wise projected expenditure** (staff, consumables, services, etc.).
- **Institutional overhead charges.**
- **Compensation plan** for study participants, as per regulatory guidelines
- All funding should be addressed to:

"The Executive Director, AIIMS Raipur"

b. Receipt of Funds:

- Prior to the initiation of the project, the **sponsor must transfer the sanctioned project funds** to the official account of AIIMS Raipur.
- The **payment should be made via electronic transfer** to the following account:

Account Name: Research Grant Account, AIIMS Raipur
Bank Name: Bank of India (BOI)
Branch: Tatibandh Branch, Raipur
Account Number: 936310110005302
IFSC Code: BKID0009363
Account Type: Savings Account
PAN: AACAA7875J
GSTIN: 22AACAA7875J2ZL

- A **cancelled cheque** of the institutional account will be provided as **Annexure [2]** for verification and transfer purposes.
- **TDS Exemption:** AIIMS Raipur is a 100% centrally funded Autonomous Body under the Ministry of Health & Family Welfare, Government of India. The Institute is registered under Sections 12AA and 80G of the Income Tax Act. It functions as a not-for-profit organization. Accordingly, AIIMS Raipur is eligible for exemption from deduction of tax at source. The Institute shall issue TDS Exemption Certificates upon receipt of the requisite documents, in accordance with the applicable provisions of the Income Tax Act and the relevant guidelines issued by the Central Board of Direct Taxes.
- An advance payment for 3 months should be transferred after approval from the IEC for the smooth running of the project.
- Payment to the IEC is handled separately. The account number and terms of payment are to be shared directly by the IEC office. However for the sponsor's convenience and to prevent any confusion the IEC account details are as follows.
- **Account Name:** AIIMS Raipur (OPD Registration)
  Bank Name: Bank of India (BOI)
  Branch: Tatibandh Branch, Raipur
  Account Number: 936320110000024
  IFSC Code: BKID0009363
  Account Type: Savings Account

c. **Utilization of Funds:**

Upon confirmation of fund receipt, the PI may **initiate expenditure** only after obtaining **prior approval from the competent authority** for the following purposes:

i. Recruitment of Project Staff:

- The PI may appoint staff as per sanctioned posts in the project proposal.
- Appointments must follow **AIIMS Raipur recruitment norms** and require **approval of the Executive Director or Dean (Research)**.
- There will be no legal binding or relation of Employee and Employer between the project staff and no claim for any additional emoluments, perquisites, privileges, continuation of project services in any other ongoing project and regularization of service against the regular sanctioned posts shall be entertained.

ii. Management of Interest Earned on Trial Funds:

a. For Government sponsored trials: Interest accrued on Government Sponsored Trials shall be refunded or adjusted in accordance with the terms and conditions prescribed by the respective funding agency.

b. **For Private/Industry sponsored trials:** No calculation, adjustment, or accounting of interest shall be undertaken, and the funds shall be managed purely as per the budgetary estimates of the Clinical Trial Agreement and institutional rules.

iii. Purchase of Consumables/Equipment:

- Expenditure for laboratory supplies, kits, study-related materials, and minor equipment is permitted.
- All purchases must comply with the **General Financial Rules (GFR)** and **AIIMS Raipur procurement policies.**
- Management of Fixed Assets Procured Under the Project: The ownership and disposition of fixed assets procured from project funds shall be governed by the provisions of the applicable CTA or the sponsor's stipulated terms. AIIMS Raipur shall function solely as the custodian of such assets during the tenure of the project. Upon completion of the trial, all assets shall be returned, transferred, or otherwise disposed of in accordance with the terms and conditions prescribed by the funding agency. In cases where no such terms exist in the CTA and no claim is submitted by the sponsor on or before 31st March of the financial year immediately succeeding one year after project completion, the assets shall be retained by the concerned Department/Research Cell for continued use in research activities of the Institute.

iv. Service-related Expenditure:

- Funds may be utilized for:
- **Calibration and maintenance of trial-specific equipment.**
- **Insurance** (including professional liability or errors & omissions).
- **Printing of study materials, labelling, couriering of samples, etc.**
- **Miscellaneous expenses/other expenses only with prior approval from the sponsor.**

⚠ **Not Permitted**

- Trial funds **must not be used** for:
- **Travel, lodging, or accommodation** of the PI or study staff.
- **Honoraria or personal benefits.**
- **Unapproved or unrelated institutional activities**

v. Treatment of Unspent Balances:

a. For Government sponsored trials: Any unspent balance after deduction of Overhead Charges, PI/Co-PI fees or any other dues or liabilities arising from the trial, shall be dealt with in accordance with the provisions of the applicable CTA or the sponsor's stated terms.

b. For Private/Industry-sponsored trials: Any unspent balance, after deduction of overhead charges, PI/Co-PI fees, and any other dues or liabilities arising from the trial, shall be dealt with in accordance with the provisions of the applicable CTA or the sponsor's stated terms. In cases where no such terms are specified in the CTA, and where the sponsor does not submit a claim on or before 31st March of the financial year immediately succeeding one year after project completion, the remaining balance shall be treated as institutional overhead.

vi. Re-appropriation of Funds: Re-appropriation of funds between approved budget heads will be permitted for smooth conduct of trial up to a limit prescribed by the Competent Authority of AIIMS Raipur. Such re-appropriation shall be undertaken only with prior approval of the Competent Authority, subject to justification provided by the Principal Investigator and adherence to the applicable provisions of the GFR.

d. Fund Utilization Reporting:

- The **PI must submit a detailed financial utilization report** annually, along with the **annual progress report** of the study to the **Institute Ethics Committee (IEC).**
- A **final audited statement of accounts** must be submitted upon **study closure**, with appropriate sign-off from the **Dean (Research)** and the **Executive Director.**
- Annual report and SOE should be submitted as per norms in prescribed format. A receipt and payment account should be prepared annually for all the project.
- Final settlement of the Accounts will be done only after receiving the receipt of the following.

1. Full and final utilization certificate
2. Full and final audited statement of expenditure
3. A list of all equipment's procured from the project funds along with their cost, date of installation and suggestions for the disposal of the same.

13. Institute Fee (Institute Overhead Charges):

a. Pharmaceutical/Private Company-Sponsored Projects:

- For industry-sponsored research projects supported by pharmaceutical companies, CROs, or private agencies, the **Institute Overhead Fee will be 10%** of the total project budget shall be charged.

b. National or State Government-Sponsored Projects:

- For projects funded by **governmental funding agencies** (e.g., **ICMR, DBT, DST, CSIR, DHR, State Health Departments**):
- The **institute overhead charges will follow the norms and ceilings prescribed by the respective funding agency.**
- Treatment of PI/Co-PI fees: Any amount earmarked under the heads PI Fees, Co-PI Fees, honorarium, professional fee, or any similar remuneration specified in the Clinical Trial Agreement (CTA) shall be treated as "Institutional User Charges" of AIIMS Raipur. Such amounts shall not accrue to the Principal Investigator, Co-Investigator, or any faculty member in a personal capacity and shall be credited to the designated institutional head of account in accordance with applicable financial and administrative rules.

14. Insurance and Indemnity Provisions:

- The **Clinical Trial Agreement (CTA)** must clearly outline:
- The **sponsor's liability** for all **study participants** in the event of **anticipated or unforeseen injuries, illnesses, adverse events, or death** related to the clinical trial.
- The details of **insurance coverage** provided for participants as per the current **regulatory requirements** of CDSCO and applicable national guidelines.
- The **sponsor is required to provide**:
- An **insurance policy** covering **all enrolled participants**, ensuring timely compensation for any study-related harm.
- An **indemnity contract** covering the **Institute** and the **Institute Ethics Committee (IEC)**, beyond participant insurance, to protect institutional interests from litigation or liability arising from the conduct of the trial.
- The finalized **CTA** must be:
- **Vetted by the Institute's Legal Cell** to ensure all legal obligations, indemnity clauses, and risk-sharing responsibilities are clearly articulated and compliant with Indian laws.
- **Reviewed by the Finance/Accounts Department** to confirm the financial provisions related to insurance, compensation, and indemnities are appropriately budgeted and in accordance with institutional financial policies.
- To prevent the misuse of "**deficient care**" arguments by the sponsor in denying compensation to patients:
- The **sponsor must submit a written undertaking** affirming that:
- The **reports and recommendations of the Institute's SAE Committee** and the **Institute Patient Safety Committee/Patient Care Review Committee** will be **final and binding** with regard to the determination of patient injury or trial-related harm.
- The sponsor will comply with the **compensation and remediation measures** as per these reports **without dispute**.

15. Data Safety Monitoring Board (DSMB):

- The **sponsor** is responsible for constituting an **independent Data Safety Monitoring Board (DSMB)** for clinical trials where:
- Long-term safety is a concern.
- High-risk populations or interventions are involved.
- Interim efficacy evaluations are anticipated.
- The DSMB shall:
- Periodically assess **safety data**, **trial conduct**, and **efficacy endpoints.**
- Make recommendations on whether the study should **continue unchanged**, be **modified**, or be **terminated early** based on safety or efficacy signals.
- The sponsor must:
- Share the ***constitution of the DSMB***, *its* ***charter of responsibilities***, *and* ***meeting schedule*** *with the* **Principal Investigator (PI)** and the **Dean (Research), AIIMS Raipur.**
- Clearly define the **DSMB's reporting structure**, decision-making authority, and the **criteria for early stopping or protocol amendments.**

16. Reporting of Serious Adverse Events (SAEs):

a. Immediate Reporting:

- Any **Serious Adverse Event (SAE)** must be reported by the **Principal Investigator (PI)** to:
- The **Institute Ethics Committee–Clinical Trials (IEC–CT).**
- The **trial sponsor.**
- This report must be submitted **within 24 hours of the SAE's occurrence** using the prescribed format.

b. Final Report:

- Within **14 calendar days** of the SAE, a **detailed final report** must be submitted jointly by the **PI and sponsor** to the following:
- **SAE Subcommittee of the IEC.**
- **Central Drugs Standard Control Organization (CDSCO)/DCGI.**
- **Head of the Institution (Executive Director, AIIMS Raipur).**

c. SAE Subcommittee Responsibilities:

- An **SAE Subcommittee** will function under the **IEC of AIIMS Raipur**. Its mandate includes:
- **Causality assessment** (whether the SAE is related to the investigational product or study procedures).
- **Recommending compensation**, if the injury is related to trial participation, as per regulatory and institutional norms.
- **Reporting the SAE** to the **Drug Controller General of India (DCGI)** within **30 days of occurrence**, with intimation to the IEC.
- **Recommending continuation, modification, or termination** of the trial in case of risk outweighing benefit.
- If the SAE is found to result from protocol violations or poor safety management, the committee may recommend:
- Immediate suspension of recruitment.
- Amendment of study protocol.
- Complete withdrawal of the trial approval.

17. Policy on Document Archiving, Handover of Trial Records, and Asset Management:

To ensure regulatory compliance, institutional accountability, and long-term data and asset security, the following policies will govern the **archiving, handover, and management of records and equipment** related to sponsored clinical trials at **AIIMS Raipur**:

a. Central Archival of Regulatory Documents:

- All **regulatory and administrative documents** related to a clinical trial must be submitted by the **Principal Investigator (PI)** to the **Dean (Research) Office**.
- The Dean's Office will maintain these records in a **dedicated master file** for each study.

b. Investigator's Record Retention:

- The PI will maintain study-specific documents, including:
- Case report forms (CRFs).
- Participant clinical data.
- Informed consent forms (ICFs).
- Adverse event documentation and communications.
- The PI is responsible for ensuring the **completeness and integrity** of these documents.

c. Change in PI or Long-Term Absence:

- If the PI **resigns**, **retires**, or is **absent for more than 3 months**, a **Co-PI** or designated representative must take charge of the study and documentation, with oversight by the **Dean (Research) Office**.
- A formal **handover of records** must be completed.

d. No Dues Clearance:

- A **No-Dues Certificate** for *PI* relieving from *AIIMS Raipur shall* be issued **only after**:
- The Dean (Research) Office verifies document handover.
- All reports and financial statements are settled.

e. Retention for Legal and Ethical Claims:

- The Dean (Research) Office will retain **duplicate copies** of all essential records (e.g., consent forms, AE logs, safety reports) to:
- Address legal claims.
- Support institutional memory.
- Respond to audits and regulatory queries.

f. Archival Duration:

- Records will be retained per:
- The **New Drugs and Clinical Trials (Amendment) Rules, 2024.**
- The **Medical Devices (Amendment) Rules, 2020.**
- Other applicable national/international regulations and the terms of the **CTA.**

g. Post-Study Document Archiving System (Future Provision):

- A **central post-study document archival system** is **yet to be initiated** at AIIMS Raipur.
- Once implemented, the system will:
- Provide secure storage of **original trial documents.**
- Be available to PIs and sponsors for future reference or regulatory audits.
- An **annual archival fee** will be **levied on the sponsor** to maintain this system, and:
- This ***fee must be included as a line item in the Clinical Trial Agreement (CTA.***
- Sponsors will be informed once the system is in place, and fees will be billed accordingly.

h. Assets Policy:

- **Ownership**: All **assets and equipment** procured under the trial budget will remain the **property of the sponsor/funding agency** during the study period.
- At study closure, ownership transfer to the Institute (if applicable) shall be decided mutually and documented.
- **Maintenance and Liability**:
- The **PI and sponsor** will be responsible for **maintenance, calibration, repair, and safety** of equipment during the study.
- Any **malfunction or injury** caused by such equipment shall be **the responsibility of the PI and sponsor**, and appropriate **compensation or remedial measures** must be ensured.

18. Submission of Reports:

The **Principal Investigator (PI)** is responsible for ensuring timely submission of study-related reports to institutional authorities, sponsors, and regulatory bodies as per the following schedule:

1. Annual Progress Report and **Audited Statement of Accounts.**

- Must be submitted **within three months** of the **completion of each financial year** during the course of the trial.
- To be routed through the **Dean (Research)** and **Accounts Section**.

2. Final Project Completion Report with Audited Accounts.

- Must be submitted **within three months** of the **trial closure**, in accordance with the Institute–Sponsor Agreement (ISA) or Clinical Trial Agreement (CTA).

19. Closure of the Study:

At the time of study closure, the **Principal Investigator** shall:

- Submit the **Project Completion Report** and a **Final Audited Statement of Accounts.**
- This must be done **within four months** of the trial's conclusion.
- The report is to be forwarded through:
- The **Head of Department**.
- The **Dean (Research)**,
- And the **Accounts Section**,
- To the ***Executive Director, AIIMS Raipur***, *for formal closure and record.*

20. Dispute Resolution:

In the event of a **dispute** or disagreement arising in relation to any aspect of a sponsored clinical trial:

- The matter shall be referred to the **Executive Director, AIIMS Raipur.**
- Whose decision shall be **final and binding** on all parties involved.

21. Legal Jurisdiction and Governing Law:

- The **CTA** shall be governed and interpreted in accordance with the **laws of India**.
- Both the sponsor and the institute consent to the **exclusive jurisdiction of the Courts at Raipur, Chhattisgarh** for any legal proceedings arising out of the agreement.

22. Timelines:

The following are the **approximate timelines** for key activities related to the processing and approval of sponsored clinical trials by the **Institute Research Cell (IRC)** at **AIIMS Raipur**. These may vary depending on the complexity of the study, completeness of documentation, and institutional scheduling constraints:

Activity	Timeline (Working Days)
Acknowledgement of submission by IRC (via eOffice route)	Within 3 working days
Preliminary screening of documents for completeness	Within 5 working days of receipt
Communication of deficiencies, if any	Within 7 working days of screening
Resubmission by PI after addressing deficiencies	Within 7–10 working days
Technical review by Institute Research Cell	Within 10–15 working days post-clearance
IRC Meeting for detailed discussion and recommendation	First Thursday of every month (or as scheduled)
Minutes of IRC meeting finalized and submitted to Executive Director	Within 7 working days post-meeting
Final approval and communication to PI after Director's endorsement	Within 10 working days of IRC recommendation
Submission to Institute Ethics Committee (IEC-CT)	Immediately after IRC clearance
IEC Review and Approval (subject to IEC schedule)	As per IEC monthly meeting timeline
Submission to DCGI *(if applicable)*	*To be done by Sponsor after IEC clearance*
Trial Registration in CTRI	To be completed before trial initiation by PI

Note: Timelines are **indicative** and may be adjusted in exceptional circumstances. All submissions must follow the **designated eOffice route** through the **Associate Dean (Research)** and **Dean (Research)** for procedural transparency and institutional tracking.

Serial No	Contents of the Title	Subtitle (Key Focus)	Included in CTA (Yes/No)	Section	Page No	Line No
1	Basic contents of CTA	**a.** Contact details b. Roles & responsibilities c. Funding & budget; d. Study protocol summary e. Study duration & validity; f. Mandatory disclosures; g. Compliance with Indian law; h. Confidentiality clauses i. Monitoring mechanisms j. Inspection & audit provisions; k. IP rights & publication rights; l. Clinical trial insurance m. Biological specimen transfer rules; n. Multicentric site details & conditional approvals; o. Publication & authorship rules				
2	Other Regulatory Approvals and Requirements	IEC approval, CTRI registration, DCGI clearance, HMSC, foreign collaboration				
3	Policy on Laboratory Tests Involving Biological Samples	In-house testing, external labs, international transfer				
4	Policy on Receiving and Utilizing Funds	Budgeting, sanctioned heads, permissible expenditure, utilization reporting				
5	Institute Fee (Institute Overhead Charges)					
6	Insurance and Indemnity Provisions	Participant insurance, sponsor liability, indemnity contract, legal vetting				
7	Data Safety Monitoring Board (DSMB)	Independent safety oversight, constitution, responsibilities, reporting				
8	Reporting of Serious Adverse Events (SAEs)	Immediate reporting (24h), detailed final report, IEC SAE committee role				
9	Policy on Document Archiving, Handover of Trial Records, and Asset Management	Archival, PI handover, retention duration, asset ownership & maintenance				
10	Submission of Reports	Annual progress & audited accounts, final project report				
11	Closure of the Study	Project completion report, audited accounts, routing process				
12	Dispute Resolution	Referral to Executive Director, binding resolution				
13	Legal Jurisdiction and Governing Law	Indian law applicability, Raipur court jurisdiction				