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Ethics Committee Registration No.: ECR/714/Inst/CT/2015/RR-21
NECRBHR (DHR)No.: EC/NEW/INST/2022/CG/0075

Circular No.: IEC/AIIMS-RPR/2026/5766

Date: 26.02.2026

CIRCULAR

Subject: Guidance on conduct of academic and investigator-initiated clinical trials at AIIMS Raipur

The Institutional Ethics Committee (IEC), AIIMS Raipur, wishes to inform all faculty members and academic guides that issues pertaining to the conduct of **academic / investigator-initiated clinical trials**, including **resident thesis-linked randomized controlled trials**, were deliberated in detail by a Subcommittee and subsequently by the Full Board of the IEC.

These deliberations were undertaken in the context of statutory requirements under the **ICMR National Ethical Guidelines, NDCTR 2019, and ICH-GCP**, particularly with regard to **participant safety, SAE reporting, and compensation**, in trials conducted without external sponsorship.

Based on these discussions, the following guidance is issued for information and compliance:

1. Applicability of Regulations

Academic and investigator-initiated clinical trials are subject to all applicable ethical and regulatory provisions, including SAE reporting and compensation, irrespective of funding status.

2. Responsibility in Unfunded Academic Trials

In the absence of an external sponsor, the Principal Investigator functions as Sponsor-Investigator and is responsible for ensuring adequate risk assessment, SAE reporting, and management, under IEC oversight.

3. Risk Categorisation

All academic clinical trials must be categorised by the PI as less than minimal risk, minimal risk, or higher risk, with justification provided at the time of submission.

4. Eligibility of Academic Trials

Ordinarily, only trials assessed as minimal risk, preferably involving standard-of-care interventions, may be considered for approval as academic studies.

5. SAE Management Plan

A clear and feasible SAE management plan, including provisions for immediate medical care and regulatory reporting, must be submitted by the PI for all academic clinical trials.

6. Compensation Mechanism

The PI must declare and earmark any feasible mechanism or resources available for SAE management and compensation, where applicable.

7. Role of Guides and Heads of Department

For thesis-based trials, the Guide and Head of Department must explicitly endorse the risk assessment and SAE management plan.

8. Mandatory Declarations

Submission of a clinical trial declaration and SAE management statement by the PI shall be mandatory for all academic clinical trials without external sponsorship.

These measures are intended to ensure participant safety, regulatory compliance, and protection of investigators and the institution. Detailed procedural requirements shall be incorporated into IEC SOPs and application formats.

Faculty members are requested to take note of the above while planning and submitting academic clinical trial proposals.

By order of the Institutional Ethics Committee
AIIMS Raipur



Chairperson, IEC
AIIMS Raipur

Chairman

Institute Ethics Committee
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Frequently Asked Questions (FAQ)

Academic / Investigator-Initiated Clinical Trials at AIIMS Raipur

Q1. What is meant by an “academic” or “investigator-initiated” clinical trial?

An academic or investigator-initiated clinical trial is a study initiated by a faculty member or conducted as part of a resident’s thesis **without external commercial sponsorship** and not intended for regulatory approval of a new drug or device.

Q2. Do regulatory rules apply to academic clinical trials?

Yes. **All clinical trials**, including academic and thesis-based trials, are governed by applicable provisions of:

- ICMR National Ethical Guidelines
- NDCTR 2019
- ICH-GCP

Regulatory obligations are based on the **nature of the study**, not on whether it is funded or unfunded.

Q3. If the study compares two standard-of-care (SOC) treatments, is it exempt from SAE reporting or compensation?

No.

While SOC comparisons may be **lower risk**, they are **not automatically exempt** from:

- SAE reporting requirements, or
- Compensation obligations if a causal relationship with the trial is established.

Each study is assessed **case by case** based on risk and causality.

Q4. Can the Participant Information Sheet (PIS) state that “no compensation will be provided”?

No.

Such statements **do not override statutory or ethical obligations** and should be avoided. Participants cannot waive their rights to safety, SAE reporting, or compensation under applicable regulations.

Q5. Who is responsible for SAE management in unfunded academic trials?

In the absence of an external sponsor:

- The **Principal Investigator acts as Sponsor-Investigator**, and
- Is responsible for ensuring **planning, reporting, and coordination of SAE management**, under IEC oversight.

Immediate medical care for SAEs must be ensured at **no cost to the participant**, with institutional facilitation.

Q6. Are residents or postgraduate students personally liable for compensation?

No.

Residents and PG students are not personally or financially liable for SAE management or compensation.

Responsibility lies with the **Principal Investigator, Guide, and Institution**, as applicable.

Q7. Is insurance mandatory for academic clinical trials?

Insurance is:

- **Mandatory** for sponsored clinical trials and BA/BE studies.
- **Not automatically mandatory** for academic trials.

However, the IEC may require insurance for academic trials **based on risk assessment**, nature of intervention, and participant vulnerability.

Q8. What types of academic clinical trials are more likely to be approved?

Academic trials that are:

- **Less than minimal or minimal risk**, and
- Involve **standard-of-care interventions**, are more likely to be considered for approval.

High-risk studies, novel interventions, or non-SOC comparisons **without a clear SAE and compensation mechanism** are generally discouraged.

Q9. What is meant by “risk categorisation,” and who does it?

Risk categorisation refers to classifying the study as:

- Less than minimal risk
- Minimal risk
- Higher risk

The **Principal Investigator must perform and justify this assessment** at the time of submission. The IEC reviews and may modify this categorisation.

Q10. What happens if an SAE occurs and the participant dies?

- The SAE must be **reported within prescribed timelines**.
- The IEC conducts a **causality assessment**.
- If the death is found to be **related or possibly related** to the trial, compensation may be recommended **irrespective of funding status or SOC nature**.

Q11. AIIMS Raipur does not currently have a compensation corpus. What does the PI need to do?

For unfunded academic trials, the PI must:

- **Declare a feasible SAE management and compensation plan**, and
- **Earmark any available resources or mechanisms**, if applicable, at the time of submission.

This declaration is mandatory and subject to IEC review.

Q12. What is the role of the Guide and Head of Department in thesis-based trials?

For student-based or thesis-linked clinical trials:

- The **Guide and Head of Department must endorse** the risk assessment and SAE management plan.
- Their recommendation is required for ethical and administrative approval.

Q13. Will these requirements discourage academic research?

No.

These measures are intended to:

- Protect research participants
- Protect faculty and residents
- Ensure regulatory compliance
- Strengthen the credibility and sustainability of academic research at AIIMS Raipur

Q14. Where can investigators seek clarification before submitting a proposal?

Investigators are encouraged to:

- Consult the **IEC Secretariat**

- Seek **pre-submission guidance** for academic clinical trials involving interventions or randomisation

Early consultation is strongly recommended.

Q15. Will these requirements be included in IEC SOPs and application forms?

Yes.

These positions will be:

- Incorporated into **IEC SOPs**,
- Reflected in **Form 2 / clinical trial checklists**, and
- Used during **review, monitoring, and audit** of academic clinical trials.

Closing Note

These FAQs are intended to promote **ethical, safe, and regulator-compliant academic research**, while safeguarding investigators, trainees, and the institution.