POLICY ON SCIENTIFIC REVIEW AND INSTITUTIONAL ETHICS COMMITTEE (IEC) APPROVAL FOR RESEARCH PROJECTS

The Apollo University

Research Regulations and Policy Committee (RRPC)

1. Policy Title

Policy on Scientific Review and Institutional Ethics Committee (IEC) Approval for Research Projects and Ph.D. Research

2. Purpose

The purpose of this policy is to establish a transparent, systematic, scientifically rigorous and ethically compliant framework for determining when research conducted at The Apollo University requires Institutional Ethics Committee (IEC) review and approval.

The policy establishes a mandatory institutional pathway whereby:

Scientific Committee Review → Scientific Committee Recommendation → Institutional Ethics Committee (IEC) Review → IEC Approval, where applicable

The policy is intended to:

1. Ensure that research submitted for IEC approval is scientifically sound and methodologically appropriate.
2. Ensure that research involving human participants, human biological materials, identifiable human data, animals, or other ethically sensitive areas receives appropriate ethical oversight.
3. Avoid unnecessary submission of projects that do not require IEC review.
4. Establish uniform procedures across all Schools, Departments, Research Centres and Ph.D. programmes.
5. Protect the rights, dignity, safety, privacy and welfare of research participants.
6. Ensure compliance with applicable national regulations, guidelines and institutional requirements.

7. Strengthen the quality, accountability and credibility of research conducted at The Apollo University.
8. Provide clear responsibilities to Principal Investigators (PIs), Ph.D. supervisors, scholars, Scientific Committee members and IEC members.

3. Scope

This policy applies to research undertaken under the name, affiliation, funding or academic supervision of The Apollo University, including:

- Faculty research projects
- Sponsored research projects
- Extramural and intramural research
- Ph.D. research projects
- Postdoctoral research
- Student research projects
- Dissertation and thesis research
- Industry-sponsored research
- Collaborative research projects
- Clinical and translational research
- Research involving human participants
- Research involving human biological specimens
- Research involving identifiable or sensitive human data
- Research involving animals, where applicable
- Research involving vulnerable populations
- Research involving genetic/genomic information
- Research involving health records or clinical information
- Research involving intervention, experimentation or clinical procedures

The policy applies irrespective of whether the project is funded or unfunded.

4. Fundamental Principle

The Apollo University recognizes that scientific validity and ethical acceptability are complementary but distinct requirements.

Accordingly:

4.1 Scientific Review

The Scientific Committee of the University shall determine whether the proposed research is scientifically justified, methodologically appropriate, feasible and capable of answering the proposed research question.

4.2 Ethical Review

The Institutional Ethics Committee (IEC) shall determine whether research requiring ethical oversight is ethically acceptable and complies with applicable ethical principles, regulations and guidelines.

4.3 Sequential Review

Where IEC approval is required, the proposal shall normally follow the sequence:

Researcher/Ph.D. Scholar → Department/School → Scientific Committee → Scientific Recommendation → IEC → IEC Decision → Research Initiation

4.4 No Direct Submission to IEC

A researcher, faculty member or Ph.D. scholar shall not directly submit a research proposal to the IEC for ethical approval without prior review and recommendation by the Scientific Committee of The Apollo University, wherever the project is intended to obtain IEC approval through the University.

5. Important Distinction: Not All Research Requires IEC Approval

IEC approval shall not automatically be required for every research project, faculty project, student project or Ph.D. project.

The requirement for IEC review shall depend on:

- Nature of the research;
- Research participants;
- Use of human biological materials;

- Use of identifiable or sensitive personal/health information;
- Clinical intervention or interaction;
- Potential physical, psychological, social or privacy risks;
- Vulnerability of participants;
- Use of genetic/genomic information;
- Use of archived specimens or clinical records;
- Other ethical considerations identified by the Scientific Committee or competent institutional authority.

Therefore:

All research projects do not require IEC approval. However, all research projects that seek IEC approval from The Apollo University shall first undergo Scientific Committee review and recommendation.

6. Scientific Committee

The Scientific Committee shall serve as the first-level scientific and methodological review mechanism for research proposals intended for IEC consideration.

The Committee shall assess:

1. Scientific rationale.
2. Research question and hypothesis.
3. Review of relevant literature.
4. Objectives.
5. Study design.
6. Methodology.
7. Sampling strategy.
8. Sample size justification, where applicable.
9. Inclusion and exclusion criteria.
10. Statistical methodology.
11. Feasibility.
12. Availability of infrastructure and resources.

13. Researcher competency and expertise.
14. Risk-benefit considerations from a scientific perspective.
15. Data management plan.
16. Availability of biological materials, equipment and other resources.
17. Research timelines.
18. Whether the proposal requires IEC review.

7. Functions of the Scientific Committee

The Scientific Committee shall:

7.1 Scientific Evaluation

Evaluate the scientific merit and methodological soundness of the research proposal.

7.2 IEC Requirement Assessment

Determine whether the proposed research appears to require IEC review based on the nature of the participants, samples, data, interventions and risks involved.

7.3 Recommendation to IEC

Where IEC review is required, the Scientific Committee shall issue a formal recommendation for submission to the IEC.

7.4 Scientific Revision

The Committee may require modification of:

- Research objectives;
- Methodology;
- Sample size;
- Statistical analysis;
- Research instruments;
- Study procedures;
- Data collection procedures;
- Participant recruitment procedures.

7.5 Documentation

The Scientific Committee shall maintain appropriate records of:

- Proposals reviewed;
- Decisions;
- Recommendations;
- Required modifications;
- Final scientific approval/recommendation.

8. Categories of Research Requiring Consideration for IEC Review

The following categories shall ordinarily be considered for IEC review, subject to applicable regulations and guidelines.

8.1 Research Involving Human Participants

Research involving direct interaction or intervention with human participants, including:

- Clinical studies;
- Interventional studies;
- Surveys involving sensitive information;
- Behavioural studies;
- Psychological studies;
- Physiological studies;
- Health-related research;
- Studies involving vulnerable populations.

8.2 Research Involving Human Biological Materials

Research involving:

- Blood;
- Serum;
- Plasma;
- Urine;
- Saliva;
- Tissue;
- Cells;
- DNA;

- RNA;
- Tumour specimens;
- Biopsy materials;
- Other human biological specimens.

8.3 Research Involving Human Genetic or Genomic Information

Projects involving:

- Genomic sequencing;
- Genetic testing;
- Whole-genome or exome sequencing;
- Genetic profiling;
- Molecular epidemiology;
- Genomic databases;
- Potentially identifiable genetic information.

8.4 Research Using Identifiable Health or Clinical Data

Projects involving:

- Medical records;
- Electronic health records;
- Patient databases;
- Clinical laboratory data;
- Imaging data;
- Genetic information;
- Other identifiable or sensitive health information.

8.5 Research Involving Vulnerable Populations

Additional ethical consideration shall be given to research involving:

- Children;
- Persons lacking decision-making capacity;
- Pregnant women, where applicable;
- Institutionalized populations;
- Economically or socially vulnerable groups;

- Patients in dependent relationships with investigators.

8.6 Research Involving Potentially Significant Risk

Projects involving procedures, interventions or information that may create physical, psychological, social, legal, financial or privacy risks shall be appropriately assessed for ethical review.

9. Research That May Not Require IEC Approval

Research may not require IEC approval where it clearly does not involve human participants, human biological materials, identifiable human data or other ethically sensitive activities.

Examples may include, subject to institutional assessment:

- Purely computational research using publicly available datasets;
- Bioinformatics research using genuinely de-identified/public datasets;
- Mathematical modelling;
- Theoretical research;
- In-silico studies;
- Computational simulations;
- Literature reviews;
- Systematic reviews using published literature;
- Meta-analyses;
- Analysis of publicly available information;
- Certain laboratory studies involving non-human materials;
- Certain educational or curriculum-related studies without human participant research.

However:

The determination that IEC approval is not required shall not be based solely on the researcher's personal assessment.

Where there is uncertainty, the project shall be submitted to the Scientific Committee for determination and documentation.

10. Ph.D. Research and IEC Approval

10.1 General Principle

Not every Ph.D. project at The Apollo University shall require IEC approval.

The requirement shall depend on the nature of the proposed research.

10.2 Ph.D. Projects Requiring IEC Consideration

A Ph.D. project shall normally be considered for IEC review when it involves:

- Human participants;
- Patient recruitment;
- Clinical interventions;
- Human biological samples;
- Patient-derived samples;
- Identifiable health information;
- Genetic/genomic information;
- Sensitive personal information;
- Vulnerable populations;
- Procedures involving potential participant risk.

10.3 Scientific Committee First

Where a Ph.D. project requires IEC approval:

Ph.D. Scholar → Supervisor → Department/School → Scientific Committee → Recommendation → IEC

10.4 No Automatic IEC Requirement

The mere fact that a project is a Ph.D. project shall not by itself create a requirement for IEC approval.

11. Submission to the Scientific Committee

The Principal Investigator/Ph.D. Scholar shall submit the following, as applicable:

1. Research proposal/protocol.
2. Title of the study.
3. Background and rationale.

4. Research question/hypothesis.
5. Objectives.
6. Literature review.
7. Methodology.
8. Study design.
9. Sample size calculation.
10. Participant recruitment plan.
11. Inclusion and exclusion criteria.
12. Data collection instruments.
13. Statistical analysis plan.
14. Risk-benefit assessment.
15. Data management and confidentiality plan.
16. Funding details.
17. Conflict-of-interest declaration.
18. Investigator qualifications.
19. Information regarding biological samples, if applicable.
20. Draft participant information sheet, where applicable.
21. Draft informed consent form, where applicable.
22. Other documents prescribed by the University.

12. Scientific Committee Decision

The Scientific Committee may issue one of the following decisions:

Category A – Scientifically Approved

The proposal is scientifically satisfactory and may proceed to the next stage.

Category B – Approved with Minor Modifications

The proposal may proceed after incorporating specified minor changes.

Category C – Revision Required

Substantial scientific or methodological modifications are required before further consideration.

Category D – Not Recommended

The proposal lacks sufficient scientific merit, feasibility or methodological justification.

Category E – IEC Not Required

The Committee determines that IEC approval is not required based on the nature of the research.

Category F – IEC Review Recommended

The Committee determines that the proposal should be submitted to the IEC for ethical review.

13. Scientific Committee Recommendation to IEC

For projects requiring IEC review, the Scientific Committee shall forward a formal recommendation to the IEC.

The recommendation shall include:

- Proposal title;
- Principal Investigator;
- Ph.D. scholar, where applicable;
- Supervisor, where applicable;
- Department/School;
- Scientific Committee decision;
- Summary of scientific evaluation;
- Confirmation that required scientific modifications have been addressed;
- Recommendation for IEC consideration;
- Date of Scientific Committee approval;
- Relevant supporting documents.

14. Prohibition on Commencement of Research

Where IEC approval is required:

No recruitment of participants, collection of human biological samples, access to identifiable participant information, or commencement of research procedures shall take place before obtaining the required IEC approval.

Scientific Committee approval alone shall not authorize commencement of research requiring IEC approval.

15. Amendments to Approved Research

Any substantial change to an IEC-approved research protocol shall require appropriate review before implementation.

This may include changes to:

- Research objectives;
- Methodology;
- Participant population;
- Sample size;
- Recruitment strategy;
- Intervention;
- Data collection;
- Biological specimens;
- Consent procedures;
- Principal Investigator;
- Supervisory arrangements;
- Study location;
- Data-sharing arrangements.

The investigator shall not implement substantive protocol changes without obtaining the required approval.

16. Data Privacy and Confidentiality

Researchers shall ensure appropriate safeguards for:

- Participant identity;

- Medical records;
- Genetic information;
- Biological samples;
- Research databases;
- Digital records;
- Audio/video recordings;
- Sensitive personal information.

Access to identifiable information shall be restricted to authorized personnel.

Where data are shared with collaborators, appropriate institutional agreements and data protection measures shall be established.

17. Informed Consent

Where informed consent is required, researchers shall ensure that:

- Participants receive appropriate information;
- Participation is voluntary;
- Adequate opportunity is provided to ask questions;
- Participants understand foreseeable risks and benefits;
- Confidentiality provisions are explained;
- Participants understand their right to withdraw, where applicable;
- Consent is appropriately documented.

Special safeguards shall apply to vulnerable participants.

18. Conflict of Interest

Members of the Scientific Committee shall disclose any actual, potential or perceived conflict of interest.

Conflicts may include:

- Family relationship;
- Financial interest;
- Supervisory relationship;

- Direct involvement in the project;
- Collaborative research relationship;
- Institutional or professional conflict.

A member with a conflict of interest shall recuse themselves from the relevant evaluation and decision-making process.

19. Responsibilities of the Principal Investigator/Supervisor

The PI/Research Supervisor shall be responsible for:

1. Ensuring scientific integrity.
2. Ensuring compliance with this policy.
3. Obtaining Scientific Committee recommendation where required.
4. Obtaining IEC approval where required.
5. Ensuring that research begins only after all necessary approvals.
6. Ensuring appropriate informed consent.
7. Maintaining confidentiality.
8. Maintaining research records.
9. Reporting deviations and adverse events.
10. Obtaining approval for significant amendments.
11. Submitting progress/final reports as required.
12. Ensuring compliance by all research team members.

20. Responsibilities of Ph.D. Scholars

Ph.D. scholars undertaking research requiring ethical oversight shall:

- Follow the approved research protocol.
- Work under the supervision of the approved Research Supervisor.
- Obtain all required institutional approvals.
- Not independently commence participant recruitment or sample collection without required approvals.
- Maintain confidentiality.

- Maintain appropriate research records.
- Report protocol deviations.
- Comply with IEC conditions.
- Submit required progress and completion reports.

21. Non-Compliance

Research undertaken without required approvals may be considered a violation of University research regulations.

Depending on the nature and seriousness of the violation, the University may:

- Require suspension of the research;
- Require corrective action;
- Require reporting to the appropriate authority;
- Restrict further research activities;
- Require withdrawal or correction of research outputs;
- Initiate appropriate institutional proceedings.

For Ph.D. research, non-compliance may also be considered under the applicable Ph.D. Regulations and academic/research integrity procedures.

22. Research Publication

Researchers shall ensure that publications arising from ethically reviewed research accurately state the relevant ethical approval information, including the IEC approval reference where appropriate.

Researchers shall not falsely claim IEC approval for research that has not received such approval.

Where a study has been formally determined not to require IEC approval, the relevant institutional determination may be documented and reported where required by the journal, funding agency or collaborating institution.

23. Collaborative and Multicentre Research

For research involving external institutions, hospitals, laboratories or research organizations, investigators shall identify all applicable ethical and institutional approval requirements before commencing the research.

Where multiple institutions are involved, the PI shall ensure appropriate coordination of:

- Scientific approvals;
- IEC approvals;
- Data-sharing arrangements;
- Material Transfer Agreements;
- Institutional permissions;
- Participant consent requirements;
- Confidentiality obligations;
- Publication and authorship requirements.

24. Simplified Approval Pathway

The institutional pathway shall be represented as follows:

A. Research Not Requiring IEC Review

Researcher/Ph.D. Scholar

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Department/School Review

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Scientific Committee

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Scientific Decision

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Research may proceed, subject to other applicable approvals

B. Research Requiring IEC Review

Researcher/Ph.D. Scholar

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Supervisor/Department/School

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Scientific Committee Review

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Scientific Committee Recommendation

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Institutional Ethics Committee (IEC)

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IEC Review and Decision

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IEC Approval

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Research Commencement

25. Key Institutional Rule

For avoidance of doubt, the following rule shall apply throughout The Apollo University:

The requirement for IEC approval shall be determined based on the nature of the proposed research and applicable ethical requirements. However, any research project that requires or seeks IEC approval through The Apollo University shall first undergo scientific review by the University's Scientific Committee and shall be forwarded to the IEC only upon receipt of the Scientific Committee's recommendation.

33. Policy Review

This policy shall be reviewed periodically by the Research Regulations and Policy Committee (RRPC) to ensure continued alignment with:

- Applicable UGC regulations;
- National ethical guidelines;
- ICMR ethical guidance, where applicable;
- Relevant regulatory requirements;
- NEP 2020;
- University Ph.D. Regulations;
- National and international standards for responsible research.

The University may amend this policy whenever required to reflect changes in legislation, regulatory requirements, ethical standards or institutional research practices.

34. Effective Date

This policy shall come into effect from the date of approval by the competent authority of The Apollo University.

Prepared By

S. No.	Name	School/Institute	Designation in RRPC	Signature
1	**Prof. R. Satyanarayana**	School of Health Sciences	Chairperson	
2	**Dr. C. Priyanka**	School of Health Sciences	Member	
3	**Dr. Rupasree Peruru**	Apollo Institute of Pharmaceutical Sciences	Member	
4	**Dr. Praneeth K. R.**	School of Management	Member	
5	**Dr. Shahanaz D.**	School of Management	Member	
6	**Dr. J. Marriam Arockia Dass**	School of Technology	Member	
7	**Dr. Manju A. B.**	School of Technology	Member	
8	**Dr. A. Kabilan**	School of Health Sciences	Convenor	

Recommended Approval Authority

Research Regulations and Policy Committee (RRPC)

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Board of Research Studies (BRS)

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Competent University Authority

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Implementation by all Schools/Departments/Research Centres