



NARAYANA
MEDICAL COLLEGE

Research Policy

July 2020

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1 Research Policy- Introduction

1.1 Preface

Medical institutions are typically expected to carry out their functions along three pillars- Education, Clinical Care and Research. The Narayana Medical College (NMC) have done well in the areas of Education and Clinical Care. However, there is further scope for improvement in the area of Research. We are conscious of the fact that Research output, among other aspects, can impact the brand, reputation and competitiveness of our institution. This Research Policy is a first step towards creating a research 'ecosystem' in the NMC.

1.2 Applicability

This policy shall be applicable to all the full time faculties, researchers and students at NMC.

1.3 Objective of this policy

The objective of this policy is to create an enabling environment within Narayana Medical Institutions for Research and to state down the guidelines for research and ensure consistent interpretation of the same across NMC. It is envisioned that research at our institution shall be expected to result in:

- Improvement in clinical outcomes.
- Improvement in collaborative research: intra/ inter departmental and cross functional.
- Publications in peer-reviewed refereed journals.
- Presentations in National/ International conferences of repute.
- Generation of Intellectual property with potential for commercialization.
- Research that has an impact on society and feeds into policy making.
- Improvement in the ranking of the institution.
- Creation of a distinct brand and brand positioning for the institution.

1.4 Definitions

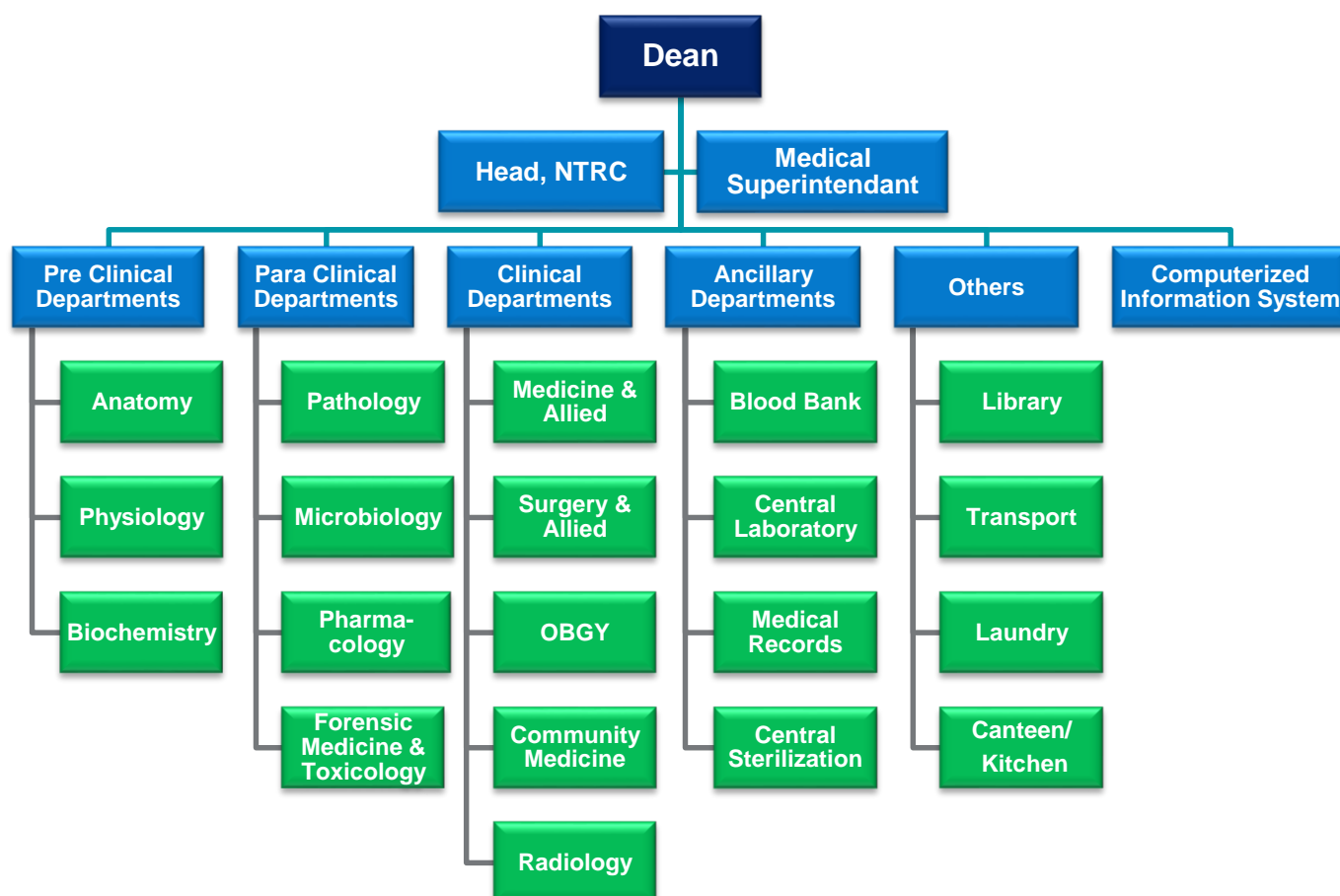
- **Research members** include Full time faculty, Researchers and Students (UG, PG, etc.) of NMC.
- **Sponsored projects** are projects that are funded either through internal or external sources.
 - a. **Intra-mural funds** refer to the funds provided internally by NMC itself.
 - b. **Extra-mural funds** refer to the funds received by NMC from external agencies that includes government, public or private, autonomous bodies, etc.
- **Principal Investigator (PI)** is a faculty of NMC with necessary expertise and competence to lead a research project. Normally the faculty member who submits the project proposal and negotiates with the sponsor and is instrumental in getting the project funding is the PI. Detailed roles and responsibilities of the PI are provided in Annexure III.
- **Co-Investigators or Co-Principal Investigators (Co-PI)** are amongst the working/ retired faculty members of NMC co-opted by the PI to work jointly with him/ her and approved by the funding agency and/ or Dean - NMC. If the PI of a sponsored project retires or leaves Narayana Medical

Institutions, its Co-Investigator or Co-PI will assume the powers and responsibilities of the PI with the approval of the Dean- NMC.

- A **Research Associate** can be appointed on a sponsored project to carry out the work for fulfilling the objectives of the project, and should have the required qualifications and experience.
 - A research Associate can be an employee of the NMC staffed on a project for a fixed tenure or
 - A research Associate can be appointed on contract on a project for a fixed tenure and may be paid a consolidated salary per month.
 - The method of appointment and terms and conditions shall be as prescribed by the HR department concerned.

1.5 Research Ecosystem at NMC

The Dean – NMC is a key member of the research ecosystem at NMC, as shown below. The detailed responsibilities of the Dean pertaining to research are listed in Annexure III.



2 Policy and Guidelines- Intra mural

2.1 Call for Research Proposals

Every year, the Management will call for Research proposals from the NMC at specified points in the year for intra mural funding.

2.2 Submission of Research Proposals

Research proposals should be submitted as per the format attached at Annexure I to this Policy.

2.3 Process of Shortlisting and Approval

All proposals received shall be studied by a Screening Committee. The composition of the Screening Committee shall be as notified by the Management from time to time. In certain cases, additional external experts may also be co-opted into the Committee or their opinion taken before shortlisting of the proposals. The Screening Committee shall evaluate the proposals on the following indicative parameters:

Cluster	Criteria	Weightage (%)
Alignment	<ul style="list-style-type: none">Is the research proposed to be undertaken in line with the overall research strategy of the NMC?	10%
Significance (Core Aspects)	<ul style="list-style-type: none">Does this research address an important problem?If the aims of the proposal are achieved, how will scientific knowledge or clinical practice be advanced?What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?	15%
Significance (Other Aspects)	<ul style="list-style-type: none">Will the study have an impact on policy, or does it have an ability to be commercialised or will it help improve the brand of the institution?	15%
Innovation	<ul style="list-style-type: none">Are significant aspects of the project based on an innovative or a non-traditional approach or reflects creative thinking?To what degree does the project reflect a unique approach that is new to our Institution or new to the field of study?	10%
Approach	<ul style="list-style-type: none">Are the objectives and plans appropriate for the proposed project?Is the proposed sequence of work appropriate?Does the proposed approach reflect sound knowledge of current theory and practice and awareness of previous or ongoing related research?Does the proposed project flow logically from the findings of the previous stage of study? Does the timetable appear to be readily achievable?	15%

Cluster	Criteria	Weightage (%)
	<ul style="list-style-type: none"> Are the evaluation plans adequate and reasonable? Do evaluation plans facilitate the measurement of project progress and outcomes? Is the team proposed adequate to undertake the research? 	
Budget and cost effectiveness	<ul style="list-style-type: none"> Is the budget request justifiable? Will the total budget be adequate to carry out project activities? Is the proposed project cost-effective? Does it demonstrate a creative use of limited resources, maximize research value per rupee of Narayana Medical Institutions' support, achieve economies of scale, leverage additional funds or have the potential to do so? 	10%
Collaboration	<ul style="list-style-type: none"> What is the extent of collaboration with faculty within and outside the Narayana Medical Institutions? [<i>Note: Collaborations with external faculty and with faculty from other disciplines shall be viewed favourably.</i>] Will the project lead to long-term relationships or cooperative partnerships that are likely to enhance research quality or supplement available resources? 	10%
Institutional Capacity Building	<ul style="list-style-type: none"> Will the project help the institution advance the expertise of current faculty? Are students (UG/ PG/ PhD/ Residents) of the Institution participating in the research? What is their role and will their capacity to undertake research be improved through their participation in the research? 	15%
Overall quality of proposal	<ul style="list-style-type: none"> Is the proposal enhanced by its adherence to instructions (table of contents, organization, pagination, margin and font size, page limitation, appendices, etc.); accuracy of forms; clarity of narrative; well prepared vitae for all key personnel associated with the project; and presentation (if any)? 	5%

2.4 Funding of Research Projects

- For each Research member, a maximum of only one seed project shall be funded at one time.
- A seed fund of up to Rs.1 Lakh would be provided to initiate the Research. Successful proposals over time will be given additional internal funding and extended support for obtaining funds from external sources as well.
- Due to limited resources, NMC may not support fully all research likely to be undertaken, but it shall allocate the space, facilities, partial funding, and other resources for research programmes based on the scholarly and educational merits of the proposed research.

2.5 Review of Research Projects

All sponsored projects shall be reviewed on a quarterly basis by a Review Committee¹. The composition of the Review Committee shall be notified annually. The review shall be carried out along the parameters defined by the PI in the proposal submitted and any other parameters as may be deemed appropriate by the Review Committee.

¹ Detailed functions of the Review Committee are provided in Annexure III of this Policy.

2.6 Conclusion

All research carried out shall be thoroughly documented during and at the end of the research project. The final publication may be required to be presented to a larger audience and to the Review Committee for wide dissemination. All PIs shall ensure that one copy of the research output is available at the library of the NMC.

3 Policy and Guidelines- Extra mural

NMC actively encourages its Research members to access extra-mural research grants, whether from official government sources, corporate funding, research trusts or from other academic institutions in the form of individual or joint institutional research projects. Such extra-mural grants reflect external recognition of research competence and enhance both the Research member's reputation and the Institutions' research standing and shall therefore be encouraged.

It is recognised that the overall process of seeking external funding and carrying out research shall be as per the guidelines prescribed by the sponsor. However, to ensure that the research carried out meets internal standards, the following guidelines are being put in place:

3.1 Call for Research Proposals

All Research members are encouraged to track calls for research proposals. The NMC also shall track calls for research proposals and disseminate the same to all Research members.

3.2 Submission of Research Proposals

Research proposals shall be submitted as per the guidelines of the sponsor.

3.3 Process of Shortlisting and Approval

- All responses to calls shall be reviewed by a Screening Committee to ensure that they meet internally prescribed standards. Special emphasis shall be provided on 'collaboration' and the 'inclusion of additional faculty/ students' into the research projects.
- The institution shall provide internal support to the Research members in helping them put together the research proposals.
- Each extra mural sponsored research project will have required to be undertaken by at least two faculty members, one of them will be designated as PI. If the designated PI happens to resign from NMC, the other Research member will take over the role of PI, and shall induct one or more Research members into the project. However, the Research member leaving NMC will be encouraged to continue participating in the project for providing academic inputs and content until the completion of the project, so that the quality of research work being carried out is not affected.

3.4 Funding of Research Projects

All funding for research shall be received in the name of Narayana Educational Society only. Internal systems will be put in place to ensure that further fund allocation to the PI is prompt.

3.5 Internal Knowledge Sharing of Research Projects

All Research members shall be encouraged to present their research progress/ findings on a quarterly basis at a formally organised forum for knowledge dissemination. Details about the forum and the frequency of meetings shall be communicated separately.

3.6 Conclusion

All research carried out shall be thoroughly documented during and at the end of the research project. The final publication may be required to be presented to a larger audience and to the Review Committee for wide dissemination. All PIs shall ensure that one copy of the research output is available at the library of the NMC.

4 General guidelines

Additional general guidelines applicable to both intra-mural and extra-mural research projects are details in this section.

4.1 Quality of Research

Quality of research output generated at the Institute is important as it has a direct link on the perception and brand of the institute and of the Research members. We are keen that the research carried out at the institute is of high quality and is quoted, making our Research members sought after.

The institute shall therefore assess the overall institute level research performance on various metrics, as shown below. This assessment shall be carried out for all intra- and extra- mural projects. The metrics provided below are also aligned to the metrics used by global ranking agencies.

Metric Name	Metric Description
Volume of research	<ul style="list-style-type: none">• No. of on-going projects in the year.• No. of new projects in the year.
Value of research	<ul style="list-style-type: none">• Value of funding received in the year.
Publications	<ul style="list-style-type: none">• No. of projects resulting in a publication in an A, B or C category journal (Refer Annexure II for categorisation of journals).• No. of projects resulting in a presentation in a National/ International conference.• Total number of (i) peer-reviewed papers/ articles published per faculty member (ii) citations per paper. (This will be calculated based on three major sources of publication and citation data worldwide- Web of Science from Thomson Reuters; Scopus from Elsevier and Google Scholar).
Collaboration	<ul style="list-style-type: none">• Total number of projects in collaboration with an internal partner (i.e. Institution or Faculty outside the department of the PI).• Total number of projects in collaboration with an external partner (i.e. Institution or Faculty).
Impact	<ul style="list-style-type: none">• No. of research projects that have had an impact on policy.• Total number of patents/ any other IP (i) applied (ii) approved (iii) commercialized.
Research orientation	<ul style="list-style-type: none">• % of faculty engaged in research projects.

4.2 Incentives for Research

The Research members at NMC shall be incentivised to carry out and publish research. The nature of incentive is aligned to the categorisation of journals and is detailed in Annexure II.

4.3 Intellectual Property (IP) and commercialization

IP shall include patents, copyrights, trademarks, designs, prototype devices, equipment, biological materials, inventions, software created, and other patentable products created.

These forms of IP shall be owned by Narayana Medical Institutions, where:

- They are created with “substantial support” of institute resources and services;
- They are created under a “work for hire” agreement with the institute;
- They are created by staff within the scope of employment;
- They are offered to the institute and the institute accepts them.

4.3.1 Sharing of Revenue

The NMC shall share the revenue from monetization of IP among the Research members. The Net Adjusted Income (to be defined) that accrues through commercialisation will be shared between stakeholders as shown below:

Net Adjusted Income	Inventor	Institution
Up to 5 cr.	20%	80%
Above 5 cr.	20%	80%

4.4 Managing Funds

- The PI shall be responsible for all aspects of the expenses incurred on projects and shall be expected to adhere to the internal processes for claiming/ reporting expenses.
- The Accounts Department will keep a separate account for each research project, identified by a unique project code number, which will be communicated to the PI.
- The Accounts department shall make available to the PI and to the Dean (Research) the details of the income/ expenses incurred on the project on a monthly basis.
- Any expenses incurred over and above the approved budget/ budget head shall be highlighted to the PI and to the dean and shall be approved by the accounts department only after due approvals.
- Any unspent funds, after completion of the project will be handed as per the terms of agreement between the NMC and the funding agencies.

5 Ethics in Research

Research techniques used by the Research members shall not violate established professional ethics, pertaining to the health, safety, privacy, and other personal rights of human beings or to the infliction of injury or pain on animals. NMC shall appoint an Ethics Management Board to validate ethical component of the research projects as per the code of ethics published from time to time. NMC urges the Research members to report any incidents of breach of code to the board as soon as they become aware of such cases. The board will further investigate the matter and take appropriate action.

5.1 Conflict of Interest Relating to Research

A conflict of interest exists where there is a divergence between the individual interests of a researcher and their professional obligation to NMC such that an independent observer might reasonably question whether the professional actions or decisions of that person are influenced by their own interests or are for their own benefit. In the context of research, conflict of interest may compromise a researcher's ethical behaviour and professional judgment in the conduct and reporting of research.

Without limiting the circumstances, the following are examples of areas which can give rise to situations where a conflict of interest may occur:

- Decisions regarding appointment and promotion of research staff.
- Assessment of internal research grant applications and associated funding decisions.
- Decisions regarding suppliers.
- Close personal relationship with another staff member, student, or other person and their involvement in the research project.
- A researcher's affiliation with or financial involvement in any organization with a direct interest in the research or the provision of materials for research.

Research members are expected to declare and manage any real or potential conflicts of interest. Failure to disclose actual or potential conflict of interest may lead to: (a) misconduct or other Disciplinary proceedings against the staff member; (b) action by funding or other Government Agencies; and (c) legal action against NMC or the individuals concerned.

5.2 Misconduct in Research

NMC regards the following practices (indicative list) as research misconduct since they violate the commonly accepted principles and practices of research upheld by the general scholarly community. Such offences are serious and subject to strict disciplinary action.

- Data fabrication, research falsification, plagiarism, abuse of confidentiality, dishonesty in publication, misuse of research funds, etc.

Research misconduct does not include honest error or honest differences in interpretations or judgments of data.

Annexure I: Research Proposal Format

PART I: GENERAL INFORMATION

Eligibility: Faculty, Researchers and Students of NMC

Total Budget: Up to INR 10,00,000 per project

Total Duration: 2 years

1. Title
2. Investigators
 - a. Principal Investigator
 - Name:
 - Date of Birth:
 - Designation:
 - Department:
 - Telephone:
 - E-mail:
 - Number of funded research projects being handled at present:
 - b. Co-Investigators (The number of co-investigators is not restricted. Please include information of all Co-Investigators)
 - Name:
 - Date of Birth:
 - Designation:
 - Department:
 - Telephone:
 - E-mail:
 - Number of funded research projects being handled at present:
3. Project Summary (maximum 500 words).

Signature of Principal Investigator:

Date:

Signature of Co-Investigator(s)

Date:

Signature of Head of the Department:

Date:

PART II: TECHNICAL DETAILS OF PROJECT

(The total pages should be within ten A4 papers in 1.5 space, Font - Times New Roman; size 11)

1. Introduction
 - a. Origin of the proposal.
 - b. Objectives including the premise or hypothesis to be addressed.
 - c. Review of literature.
2. Current status of research and development in the subject.
 - a. International Status.
 - b. National status.
3. Relevance and importance of the project for Andhra Pradesh, Nellore and NMC.
4. Preliminary work done if any.
5. Detailed methodology including study design and outcome measures.
6. Detailed Work Plan: please include study design, participant selection, intervening or investigative procedure if any, data collection and analysis, outcomes and milestone schedules etc.

Note: The project shall be reviewed on a quarterly basis in line with the outcomes and milestones mentioned in the research proposal.

7. Proposed Budget with justification under the following categories:

Sl.	Categories	1 st Year (A)	2 nd Year (B)
1	Professional fee (i.e. Manpower cost): provide cost split of permanent employees and contracted staff.		
2	Equipment cost		
3	Consumables and Reagents		
4	Cost of data collection/ conduction of surveys		
5	Cost of travel and communication		
6	Miscellaneous costs (Printing, stationary, Typing etc.)		
7	Cost of converting projects to publications		
8	Any other (specify)		
9	Total		
10	Grand Total (A+B)		

8. Facilities and resources available within the institution for pursuing the project.

Note: The selection panel may contact the PI/ Co-PI in case of any clarifications with respect to the research proposal. The participants may be required to make a presentation to the panel during the selection process.

PART III: Details of Investigators

Please include updated CVs including Publications and honors/ awards of the PI and Co-PI.

Annexure II: Incentive Scheme

NMC shall incentivise its Research members for their research output. This incentive is being provided in order to encourage existing Research members to benchmark their research output with the best in the world and also to encourage non-Researchers to explore research as an extension of their clinical work.

Incentives for Publication

As a first step, the Incentives are being linked to the quality of the Journal that the research work is published in. Typically, the impact factor of the Journal is a reflection of the quality of the Journal and therefore, the Journals are being classified into four categories, A, B, C and D as detailed below based on the PubMed impact factor. The incentives are linked to the category of Journal published in.

The incentives, payable for successful publication are as listed below:

Type of journal	Impact Factor	Incentive amount (Rs.)
Class – A	< 20	25,000
Class – B	10-20	20,000
Class – C	5-10	10,000
Class - D	0-5	5,000

Note:

- These incentives are for a publication by the research team. If the multiple authors include persons not members of NMC, the amount awarded to the NMC's Research member is equivalent to his/her share only.
- Award shall be given only after the paper is published.
- Affiliation must mention NMC for the credit.

Incentives for Conferences (Indicative – TBD)

NMC Research members are encouraged to present their research papers in national/ international level seminars/ conferences. The following guidelines are applicable for conferences:

- Expenses towards registration fee, participation fee, Visa fee and TA/ DA (as per Institution approved rates) shall be paid to individuals for presenting a paper in National and International Conferences (Refereed). The above expenses shall be paid subject to the review and recommendation of the Screening Committee. The Committee shall consider the past research work of the applicant (where applicable) or demonstrated sustained interest towards research in the case of applicants with limited research experience, while evaluating the applications for Conferences.
- The Research member would be treated on official duty for the duration of the seminar/ conference plus journey days, for availing of this facility.

For attending any conference, Research member has to seek prior approval from Dean.

Annexure III: Roles & Responsibilities

Principal Investigator:

- The PI will, at his/ her discretion, co-opt the names of other faculty members as Co-PIs or Co-Investigators with their consent.
- The PI will prepare the research project proposal in conformity with the rules, regulations and statutes of the funding institution and according to the policy of Narayana Medical Institutions for sponsored projects.
- All proposals for sponsored research shall be submitted to the sponsors through the Dean (Research).
- The PI shall be responsible for getting the project work completed satisfactorily within the sanctioned amount of research grant and project duration.
- The PI is responsible for the completion, accuracy, and timeliness of all reports required by the sponsor.
- The PI is responsible for ensuring that all financial aspects of the project are done in a timely manner so the financial reports can be submitted as required by the sponsor.
- The PI shall write to the sponsor for timely release of funds with a copy to the Dean.
- In consultation with the Dean, the PI shall ensure compliance with all applicable financial and administrative regulations and NMC and procedures.
- In consultation with the Dean office, the PI shall approve final payment to subcontractors.

Dean

- Manage and administer the Research Policy.
- Set up the process of scrutiny and approvals of intra-mural research proposals.
- Approve research funding for intra-mural research projects.
- Ensure timely review of all projects (Intra mural and extra mural).
- Assist protection of intellectual property rights.
- Provide training courses on writing proposals and publishing papers.
- Create awareness to the Research members on international funding opportunities arising through any collaboration.
- Establish ethics in research and ensure zero tolerance for breach of code.
- Establish KPIs and evaluate them periodically.

Research Advisory Committee (RAC) –

RAC was formed mainly to frame guidelines pertaining to the conduct of students and faculty research projects. RAC members meet once in 3 months The composition of RAC is as follows:

Chair Person	Dr. Surya Prakasa Rao, Dean, NMC
Convenor & SPOC	Dr. V. Krishna Chaitanya, Professor of ENT
Members	
S.No	Name & Designation
1	Dr. Sivakumar Vijayaraghavalu, Prof. of Genetics and Head NTRC
2	Dr. Sampath Kumar NS, Prof. & Head – Neurology
3	Dr. Jyothi C, Prof. of Social and Preventive Medicine
4	Dr. Ramalingam K, Prof. of Biochemistry
5	Dr. Shanthi V, Prof of Pathology

- ❖ The term of membership of all the members, other than the Dean, is restricted to two years
- ❖ All the members of RAC are nominated by the Dean
- ❖ The RAC meets at least once in 3 months in an academic year.
- ❖ One-third of the RAC members form the quorum.

Functions of RAC:

- ❖ To technically scrutinize the project proposals applied by the faculty and students. Experts from the respective departments will be co-opted depending on the project proposal
- ❖ To prepare a perspective of research and major thrust areas for research, if any, in the disciplines under its purview
- ❖ To review the status of the research project periodically in each department.
- ❖ To suggest the priority areas of research in each department considering the expertise and facilities available
- ❖ To frame regulations for research conduct
- ❖ To promote inter-disciplinary research programmes between different disciplines and institutions
- ❖ To evaluate institutional research projects for funding by national/international agencies

Institutional Ethics Committee (IEC)

IEC has been constituted with an aim to provide public assurance of protection, reviewing and approving the clinical trial protocol, the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at NMC under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR and its requirements.

Role of IEC

- ❖ IEC reviews and approves the different types of clinical study protocols involving human participants in order to safeguard the dignity, rights, safety and well-being of all actual and potential research participants. The goal of research, however important, should never be permitted to override the health and wellbeing of the research subjects.
- ❖ The IEC takes care that all the cardinal principles of research ethics viz., Autonomy, Beneficence, Non-maleficence and Justice are taken care in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden, benefit and provisions for appropriate compensations wherever required
- ❖ IEC reviews the clinical study proposal prior to start of the study and monitor the research progress through-out the till its completion.
- ❖ The committee will also examine compliance with regulatory requirements, applicable guidelines and laws. The mandate of the IEC will be to review all study protocols involving human subjects to be conducted at Institute, irrespective of the funding agency.

Composition of IEC

Ethics committee will be multidisciplinary and multi-sectorial in composition. It is in compliance with ICMR Guidelines, Schedule Y and ICH-GCP Guidelines with the applicable laws and regulations. IEC has members representing both

Ethics committee will have members representing both the genders at least one lady member.

- ❖ Chairperson will be from outside the Institution
- ❖ The Member Secretary is from the Institution.

- ❖ The board will not consist entirely of members of single profession.
- ❖ One member can satisfy more than one of the membership requirements for the committee.
- ❖ Current IEC member list is as follows -

S. No.	Name & Designation	Degree	Affiliation	Current Residential Address, Telephone/Mobile No. & e-mail ID	Affiliated with NMC (Yes/No)
1	Dr. J. N. Naidu; Chair Person	MD (Biochemistry)	Not affiliated to any organization	15-54/1D, Padmavathi Nagar, MR Palli, Tirupathi (urban), Chittoor 517502, Andhra Pradesh (AP) +91 9885675591; drjnnaidu@gmail.com	No
2	Dr. V. Krishna Chaitanya; Member Secretary	MS (ENT)	NMC, Nellore 524003, AP	No 76 Staff Quarters, NMC, Nellore, AP, +91 8008086119; drvkc17@gmail.com	Yes
3	Dr. C. Kumar; Scientific Member	MD (Community Medicine)	-do-	No 76 Staff Quarters, NMC, Nellore, AP, +91 9849106293; chintakumar1974@gmail.com	Yes
4	Dr. K. Jithendra; Basic Medical Scientist	MD Microbiology	-do-	103, Sai Balaji Enclave, 4 th line Harnadhapuram, Nellore, AP, India. +919885576221; jithendra3@gmail.com	Yes
5	Dr. V. Surya Prakasa Rao; Member Clinician	MD (Community Medicine)	-do-	No F – 63, Staff Quarters, NMC, Nellore, A.P., India. +919422193852; dean@narayanamedicalcollege.com	Yes
6	Dr. G. Kiran Kumar; Member Clinician	MS (Ophthalmology)	-do-	Door No 24-7-147, Flat No 402, Lotus Apartment, Magunta Layout, Nellore 524003, A.P. India. +91 9440573467; drkiran9459@gmail.com	Yes
7	Dr. K. Ramalingam; Member	PhD (Biochemistry)	-do-	No 306, Serene Woods Apartments, ISKON city, Nellore 524004, A.P. India. +919490166078; ramclinbio@gmail.com	Yes
8	Dr. S.C. Thasleema; Member	Ph.D. (Statistics)	Not affiliated to any organization	No. 28/3/426, Aravinda Nagar, Mypadu Road, Nellore 524002, A.P. India. +91 9393045706; sethasleema@gmail.com	No
9	Mr. P. Vijaya Kumara Reddy; Legal Expert	B.A., B.L.	Advocate – Private practitioner	16-2-583; Srinivasa Agraharam Minibypass Road, Nellore 524002; A.P. India. +919849527270; pvkreddy20@yahoo.in	No
10	Mr. Prabhakar Rao; Lay Person	B.Sc. (Agriculture)	Not affiliated to any organization	401, Dream homes apartment 5 th lane, Ramji Nagar, Nellore, A.P. +91 9849878168; rprao1943@gmail.com	No
11	Mrs. P. R. Nalini; Social Scientist	M.A (Psychology)	Nalinipelluru Psychology Center Nellore, Andhra Pradesh	203, A block, Pavani Majestic, Near Childrens park, Nellore 524002, AP - +91 7893086770; nalinipelluru.psychologist@gmail.com	No
12	Mrs. J. Jeyashri; Member	M.Com	Not affiliated to any organization	No 2 Gangai Amman Koil street, Big Natham, Chengalpet, +919677287528; jeyashri24@gmail.com	No

Authority Under which IEC is Constituted

The Dean, NMC will be the authorized person to construct IEC and appoint its Chairman.

The Chairman of the IEC, in consultation with institutional management and recommendations from the current IEC members will appoint all the members of IEC based on the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

Membership Requirement

- ❖ The normal term for IEC members including chairman will be for 2 years. At the end of two years the committee will be reconstituted and 50% of existing members will be replaced
- ❖ During the term, chairman can disqualify any member if the contribution is not adequate and, or there is long term non-availability.
- ❖ Member can tender resignation form IEC after giving at least one-month advance notice with proper reasons to do so.
- ❖ Chairman can replace the member of IEC as and when required with proper reasons.
- ❖ Each member is required to sign the declaration and confidentiality agreement regarding IEC activities. All members should maintain absolute confidentiality of all discussions during the meeting. The members of the IEC should declare conflict of interest.

Quorum Requirement

- ❖ Minimum 5 members are required to compose the quorum without which a decision regarding the research should not be taken. Chairperson and Member secretary should also be present for review of each protocol along with these 5 members
- ❖ No quorum should consist entirely of members of one profession.
- ❖ Quorum will include at least one representative from the following group:
- ❖ One basic medical scientist (preferably one pharmacologist)
- ❖ One clinician
- ❖ One legal expert
- ❖ One social scientist/ representative of non-government organization /philosopher /ethicist/theologian or a similar person
- ❖ One lay person from the community
- ❖ For expedited review, minimum of 3 members are required of which one will be expert in the area of research proposal.
- ❖ All decisions will be taken in meetings and not by circulation of project proposals

Application Procedures

- ❖ No study will be initiated without obtaining a written approval / permission by the IEC. The IEC is responsible for reviewing the clinical trial documents within reasonable time
- ❖ The PI will submit an application in a prescribed application form (given below)
- ❖ Application will be submitted to the office of the member secretary, IEC on any working day.
- ❖ All the proposals and documents will be submitted in English and regional languages. It should be submitted not less than 7 days prior to scheduled date of IEC meeting.
- ❖ Twelve (12) copies of study proposal (with all documents) will be submitted along with application form duly signed and dated by the investigator (s).
- ❖ On receipt, the applications will be acknowledged including the completeness of application by the IEC office
- ❖ Every application will have to be routed through the concerned Head of the Department to the IEC.
- ❖ In case of sponsor initiated trials one-time application fee of rupees twenty-five thousand only (Rs. 25,000/-) for regular IEC review meeting and 35,000 Rs. for expedited review of the study protocol will be paid to IEC by the PI/sponsor

Documentation Requirements

The PI has to submit an application in this format.

PI Name:

Short title of the study:

List of documents to be submitted along with application for the IEC review

Following documents should be submitted for review of Institutional Ethics Committee as per the **“SCHEDULE Y”**

- 1 Project submission application form duly filled
- 2 Letter to Member Secretary/ Chairperson

- 3 IEC application Fee
- 4 Summary of protocol (in not more than 500 words)
- 5 Protocol
- 6 Amendments to protocol
- 7 Informed consent document in English
- 8 Informed consent documents in Regional languages
- 9 Back translations of Informed consent documents
- 10 Back translation certificate
- 11 Amendments to the informed consent document
- 12 Case Record Form
- 13 Subject recruitment procedures: advertisement, notices
- 14 Patient instruction card, identity card, diary etc.
- 15 Patient/ Subject Questionnaire/s
- 16 Investigator Brochure
- 17 Insurance policy
- 18 Investigator's undertaking to DCG(I)
- 19 DCG(I) approval
- 20 Investigator's agreement with sponsor
- 21 FDA marketing/manufacturing license for herbal formulations/ nutraceuticals
- 22 Health Ministry Screening Committee (HMSC) approval in case the study involves collaboration with any foreign laboratory/clinic/institution
- 23 Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations. Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy
- 24 Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis
- 25 Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions
- 26 Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study co-coordinator)
- 27 Ethics Committee clearance of other centers
- 28 Delegation of responsibility of the study team members - Sample Format Enclosed)
- 29 Document Receipt Form.
- 30 Current Status of Ongoing Studies conducted by principal investigator
- 31 Documentation of CTRI registration/ any other WHO platform registry (whenever applicable)
- 32 GCP training certificates of PI and Co-PI
- 33 Statement on conflict of interest
- 34 Any other Documents submitted

Institutional Animal Ethics Committee (IAEC)

IAEC of NMC, has been constituted to supervise and evaluate all aspects of the animal care and use program in the institution under Rule 5(a) of the breeding and Experiment on Animals (Control and Supervision) rules 1998 as per the CPCSEA (Committee for the Purpose of Control and Supervision of Experiments on Animals) norms. It ensures quality and consistent ethical review mechanism for biomedical research in animal for all research proposals submitted to the committee. It is also responsible for reviewing various regulatory forms as indicated by CPCSEA, inspecting animal facilities and uphold 3R's principles of (Replacement, Reduction and Refinement) ensuring adherence to CPCSEA guidelines. IAEC approval is required prior starting a pre-clinical research study.

Role of IAEC

- Review proposed use of animals in research and require any modifications necessary for approval

or withhold approval prior to use of animals

- Approve research involving animals which conform to the various guidelines for use of animals in research
- Review periodically the Institute's animal facility
- Review and investigate legitimate concerns involving the care and use of animals during research
- Ensure that all personnel involved in animal care and use are appropriately qualified to perform their duties and conduct proposed activities

Application procedure:

- All proposals should be submitted in the prescribed application form, copies of which will be available from the Member Secretary.
- All relevant documents with check list should be enclosed with application form.
- Fifteen copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator and Co-investigators/Collaborators should be forwarded by the Head of the Department to the IAEC. Sixteen additional copies for proposals for experiment on large animals will be required for forwarding it to CPCSEA.
- A fee of Rs 20,000/- will be charged for extra-mural sponsored project.
- The Member Secretary will acknowledge the receipt and indicate any lacunae. Missing information should be supplied within two weeks.

Current IAEC member's list

S.No	Name of Member	Position in IAEC	Designation	Scientific Background
1.	Dr. V. Surya Prakasa Rao	Chairman & Biological Scientist	Dean, NMC	M.D.(Community Medicine)
2.	Dr. Sivakumar Vijayaraghavalu	Member- Secretary & Biological Scientist	Professor & Head, NTRC	Ph.D. (Cancer Biology)
3.	Dr. R.Venkataiah	Veterinarian	Veterinary Doctor	B.V.Sc
4.	Mr. M. Vasanth Kumar	Biological Scientist	Assistant Professor, NTRC	M.Pharm.(Pharmacognosy)
5.	Mr. V. Bhopal Chandra	Biological Scientist	Tutor, Department of Pharmacology, NMC	M.Sc., (Pharmacology),