



D.A. Pandu Memorial R.V. Dental College & Hospital®

Affiliated to Rajiv
Gandhi University of
Health Sciences,
Bengaluru, Karnataka

Recognised by Dental
Council of India, New Delhi
Accredited by NAAC
with 'A' Grade

Included under Section 2(F)
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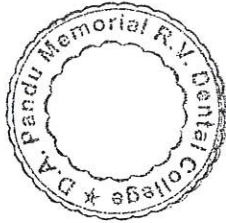
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CERTIFICATE OF INCORPORATION

The Ethical / Institutional Review Board (IRB) Committee of D.A.Pandu Memorial R.V.Dental College was constituted on **26th February 2004** to Review the Research work of Faculty members, students & the institution for scrutiny and Ethical Clearance.

The constitution and the functioning of the IRB is as per ICMR guidelines adopted from time to time.



Prasanna
Principal & Chairman
IQAC

Recd
Filed
11/7/2020

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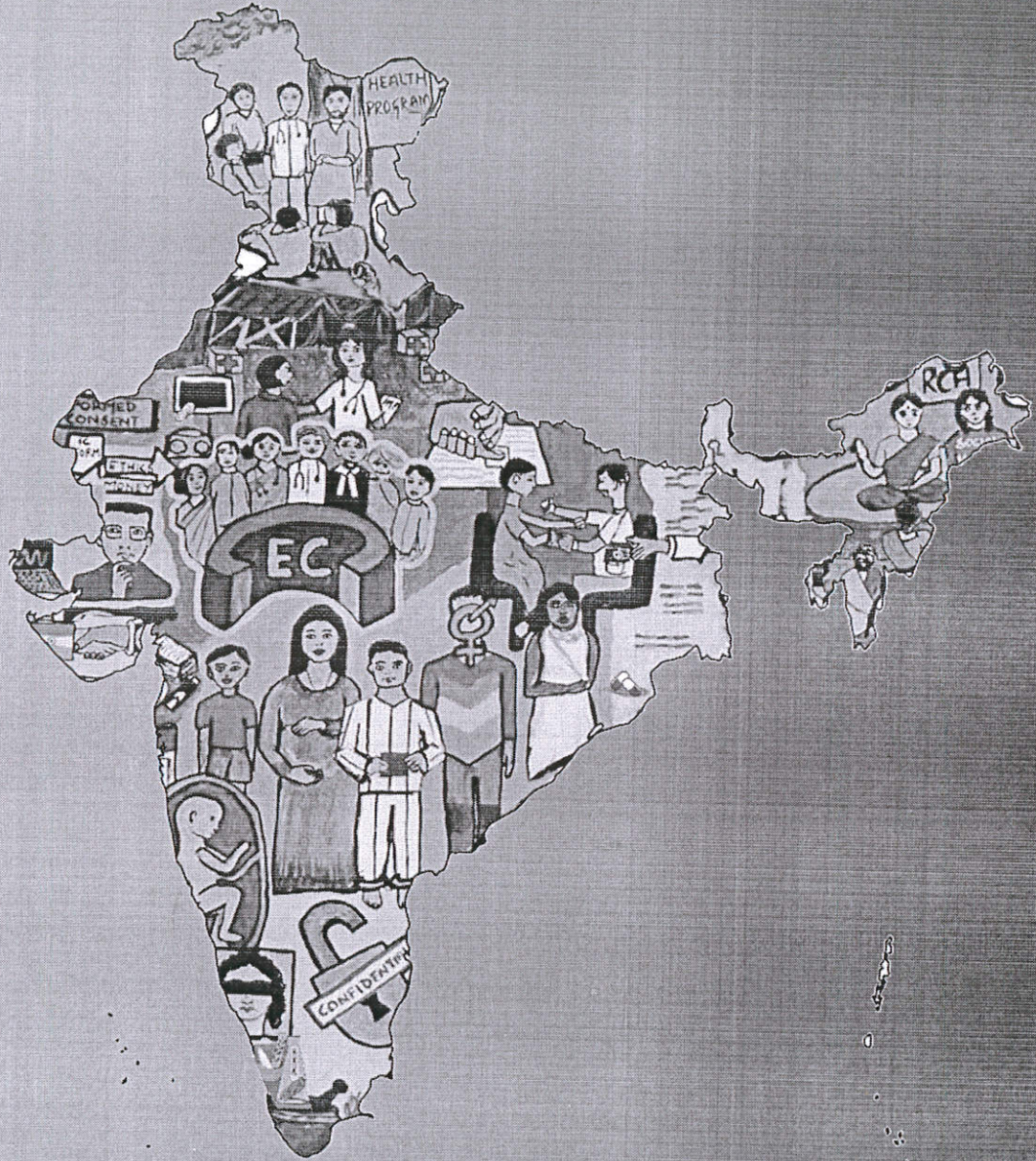
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NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS



INDIAN COUNCIL OF MEDICAL RESEARCH

2017

Pragya
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J.P. Nagar I Phase,
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NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS



INDIAN COUNCIL OF MEDICAL RESEARCH
2017

Principals

Principal
D.A.P.M.R.V. Dental College
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INTRODUCTION

The code of conduct for physicians was well laid out in traditional Indian systems of medicine and do no harm was the underlying universal principle besides other principles applicable to the prevalent culture and the class systems of the society. The Indian Council of Medical Research (ICMR) issued the Policy Statement on Ethical Considerations Involved in Research on Human Subjects in 1980.¹ Due to rapid advances in biomedical science and technology, new ethical dimensions emerged which necessitated further updation of these guidelines. Subsequently the Ethical Guidelines for Biomedical Research on Human Subjects was released in 2000,² followed by the revised Ethical Guidelines for Biomedical Research on Human Participants in 2006.³ In the meantime, the Central Drugs Standard Control Organization (CDSCO) also released the Indian Good Clinical Practice Guidelines (2001)⁴ for clinical trials and revised Schedule Y of the Drugs and Cosmetics Act, 1940, in the year 2005⁵ with several amendments in the Rules under Drugs and Cosmetics Act in the year 2013. ICMR and the Department of Biotechnology (DBT) jointly brought out Guidelines for Stem Cell Research and Therapy in 2007 and a further revision in 2013 which is now revised as National Guidelines for Stem Cell Research, 2017.⁶

The Nuremberg Code of 1947⁷ was the first international treatise on the ethics of research involving human beings and highlighted the essentiality of obtaining voluntary consent. In 1964, the World Medical Association formulated guidelines on conducting research on humans, known as the Declaration of Helsinki. This has undergone seven revisions with the latest version being issued in October 2013 at Fortaleza, Brazil.⁸

In 1979, the Belmont Report released by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in the United States of America (USA), for the first time enunciated the three basic ethical principles for research involving human subjects: respect for persons, beneficence and justice.⁹ The Department of Health and Human Services (DHHS), USA, released the Federal Policy for the Protection of Human Subjects as the 'Common Rule' in 1991 (revised in 2017).¹⁰ The International Conference on Harmonization (ICH) brought out the Good Clinical Practice Guidelines E6 (R1) in 1996¹¹ revised as E6 (R2) in 2016.¹² The National Bioethics Advisory Commission, USA (2001),¹³ the Council for International Organizations of Medical Sciences (CIOMS), Geneva (2002 revised in 2016),^{14,15} and the Nuffield Council of Bioethics, United Kingdom (2002)¹⁶ released recommendations/guidelines relevant


to research in developing countries. UNESCO's Universal Declaration on Bioethics and Human Rights (2005)¹⁷ and other international instruments on human rights further defined the Universal Codes of Ethics to be adopted by the member countries. The revised ICMR ethical guidelines have adapted important guidance points from these international guidelines keeping in mind the diverse socio-cultural milieu of our country.

The socio-cultural ethos in India and its varying standards of healthcare pose unique challenges to the application of universal ethical principles to biomedical and health research. The last decade has seen emerging ethical issues necessitating further revision of the earlier guidelines and preparation of the current National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017. These guidelines have covered some newer areas like public health research, social and behavioural sciences research for health and responsible conduct of research, and research during humanitarian emergencies and disasters while a few other specialized areas like informed consent process, biological materials, biobanking and datasets and vulnerability have been expanded into separate sections.

Scope

These guidelines are applicable to all biomedical, social and behavioural science research for health conducted in India involving human participants, their biological material and data. The purpose of such research should be:

- i. directed towards enhancing knowledge about the human condition while maintaining sensitivity to the Indian cultural, social and natural environment;
- ii. conducted under conditions such that no person or persons become mere means for the betterment of others and that human beings who are participating in any biomedical and/or health research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency; and
- iii. subjected to a regime of evaluation at all stages of the research, such as design, conduct and reporting of the results thereof.


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D.A. PANDU MEMORIAL R.V. DENTAL COLLEGE
J.P. NAGAR, BANGALORE



DAPMRVDC/671 /2020-21

07.12.2020

NOTE

I am pleased to inform that the institution is taking steps to integrate research as one of the primary focus areas. I am attaching herewith the final draft copy of the Institution Research Policy for your kind approval.

The policy will significantly contribute to :

- Recognition and rating of the institution in NIRF, NAAC
- Fulfill the statutory objectives of ICMR and DCI to the highest possible standard.
- Build a much needed ecosystem of Research in the institution.

Prayaga
 PRINCIPAL.

The Hon. Secretary
 RSST

Approved
[Signature]
 9/12/20



2575/20-21
12/12/20

Prayaga

Principal
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To
The Hon. Secretary
RSST

Date: 21.11.20

Sub: Submission of DAPMRVDC Institutional Research Policy for kind approval
Through the Office of Principal for forwarding to the Hon. Secretary

Respected Sir,

We are pleased that the institution is taking steps to integrate research as one of the primary focus areas. The research committee has been working tirelessly in this direction. We are hereby submitting the final draft copy of the Institutional Research Policy.

A Coordinating subcommittee headed by Committee Head, Research Sustenance and Institutional Review Board Committee and represented by departments (Heads of the departments and selected members) drafted this research policy.

This policy will significantly contribute to:

- * Recognition and rating of the institution in NIRF, NAAC
- Fulfil the statutory objectives of ICMR and DCI to the highest possible standard.
- Build a much needed ecosystem of Research in the institution.

If requested we are happy to make a presentation to share the document vision.

Thanking you,



Dr Harikiran AG

Committee Head, Research Sustenance and IRB Committee
Prof and HOD, Dept of Public Health Dentistry



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4/12/20

Annexure:

- Institutional research Policy
- Document History Summary

DAPM RV Dental College and Hospital



Institutional Research policy
Draft Guidelines

Institutional Research Sustenance and Institutional Review Board Committee

DAPMRVDC Institutional Research Policy- Guidelines

Drafted By:

**Coordinating Subcommittee,
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Draft Guidelines

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DAPMRVDC Institutional Research Policy- Guidelines

1. Introduction:

- The DAPMRV Dental College provides financial support to all its faculty for research and training in research and research ethics to promote teaching and research in emerging areas in medical/dental sciences.
- Before submitting the proposals under the scheme, the faculties are requested to follow the guidelines of the institutional funding. Non-compliance of the guidelines will lead to rejection of the proposal.

2. Objective:

- To promote excellence in research in faculty by supporting research programs.

3. Budget:

- A budgetary head to be allocated.
- The institution may allocate minimum Rs 10 Lakh for the research. The budgetary allocation to be increased by a factor of 20% per year.
- The budget may be utilized for training of faculty in research, research ethics and/or facilitating research grants to faculty, To develop support mechanisms for PhD students & guiding faculty, appropriate administrative support, resource person consultancy, research related exploratory partnerships/visits to centers of excellence for knowledge sharing/exchange and any other activity towards realizing the objective.

4. General Guidelines:

- Research grant is open to *faculty members only*. The project may be undertaken by either an individual faculty as an independent researcher or a group of faculty [more than one faculty].
- The institution has sanctioned a research grant for this financial year.
- All institutional research grants will be funded under 2 categories:
 - a. Minor Research Project [Rs 2,00,000/-]: projects of duration one year or less.
 - b. Major Research Project [Rs 3,00,000/-]: projects of duration of two years.

5. MINOR PROJECTS:

5.1 General Guidelines:

- 5.1.1 A project may be undertaken by either an individual faculty or a team of faculty of the same department. In case a project is undertaken by a team of faculty, one of the faculties will function as a Principal Investigator (PI) and he/she will be responsible for all matters pertaining to the project.
- 5.1.2 A working faculty can apply as PI only in one project at any given time.
- 5.1.3 The project, which is offered and accepted, first, must be completed before application of another project.

DAPMRVDC Institutional Research Policy- Guidelines

- 5.1.4 The project should have obtained IRB clearance before the start of the study.*
- 5.1.5 On completion of the project, the PI should publish one paper in a reputed journal and/or paper presentation in conferences.
- 5.1.6 The investigators may avail special casual leave or duty leave for field work or collection of data as per institutional/ICMR/UGC/DCI guidelines.
- 5.1.7 The effective date of implementation of the project will be mentioned in approval cum sanction letter.

Note:

*The IRB committee of the institution will have members in accordance with ICMR guidelines. The IRB committee will also initiate the process to be registered with apex bodies like ICMR. Sufficient time will be provided for presentation and discussion for proper evaluation of the research proposal.

5.2 Nature of Assistance:

5.2.1 Allocation of grants

Research Grant open to all faculty members irrespective of their department

- Research grant is *open to all* faculty members *only* from the institution.

5.2.2 The amount of money allotted for each research project may depend on the following:

A] Number of projects accepted.

B] The maximum amount allotted will also depend on the strength of the project.

5.2.3 The grant amount may be utilized for the following:

- Honorarium for the investigators[PI & Co-PI] – 20-30% of the total project cost
- Books and journals*
- Equipment*
- Contingency⁺
- Chemicals and consumables
- Field visits
- Presentation in conferences/Publication

Note:

* The equipment and books and journals acquired by the PI under a major research project must be deposited to the institution or in the central library after the completion of the project which will be the institutional property.

+ Contingency includes spares for apparatus, stationery, telephone, internet, computation, printing & postage. Expenditure towards the biostatistician and audit fee may also be claimed under contingency head.

5.3 Procedure for applying

- The college teachers who wish to avail financial assistance for minor research project should submit their research proposal in the proforma as per Annexure I on or before the final submission date.
- Any applications received after the submission date will not be entertained.

5.4 Procedure for Approval

- The project should have obtained IRB clearance after which the PIs will be invited to make presentations before the expert committee.
- The decision will be taken by the expert committee and recommended to the principal for approval.

5.5 Procedure for the release of the Grants

5.5.1. 40 - 80% of the total grant amount will be released to the PI at the time of acceptance.

5.5.2. The remaining grant will be released upon submission of following documents:

- a. Copy of final report of project along with soft copy
- b. Consolidated item wise detailed audited statement of expenditure
- c. Details of paper presentation or publication
- d. Unutilized grant if any should be refunded immediately
- e. In case of any balance grant not claimed within 1 year from the date of completion of the project the same will lapse and no representation will be entertained on this behalf.
- f. If a principal investigator fails to complete a project within the stipulated time he/she has to refund the entire amount sanctioned. For any extension in tenure approval of research committee is required.
- g. In case the PI leaves the institution before completion, he/she has to select the PI from the existing co investigators or refund the entire amount funded. The project is non transferable to investigators not included in the accepted proposal.

5.6. Monitoring and evaluation

5.6.1 A report summarizing the progress of the research should be submitted to the research committee at 6 month interval

5.6.2 Final Report to be submitted at the end of one year.

6. MAJOR PROJECTS

6.1 General Guidelines:

6.1.1 A project may be undertaken by either an individual faculty or a team of faculty of any department of the institution. In case a project is undertaken by a team of faculty, one of the faculties will function as a Principal Investigator (PI) and he/she will be responsible for all matters pertaining to the project.



DAPMRVDC Institutional Research Policy- Guidelines

- 6.1.2 A working faculty can apply as PI only in one project at any given time.
- 6.1.3 The project, which is offered and accepted, first, must be completed before application of another project.
- 6.1.4 The project should have obtained IRB clearance before the start of the study.*
- 6.1.5 On completion of the project, the PI should publish a minimum of one paper in a reputed journal and paper presentation in conferences.
- 6.1.6 The investigators may avail special casual leave or duty leave for field work or collection of data in accordance with the rules of institution/DCI/ICMR/UGC.
- 6.1.7 The effective date of implementation of the project will be mentioned in approval cum sanction letter.

Note:

*The IRB committee of the institution will have members in accordance with ICMR guidelines. The IRB committee will also initiate the process to be registered with apex bodies like ICMR. Sufficient time will be provided for presentation and discussion for proper evaluation of the research proposal.

6.2 Nature of Assistance:

The grant amount may be utilized for the following:

Recurring:

- Contingency⁺
- Chemicals and consumables
- Field visit
- Hiring services

Non recurring:

- Honorarium for the investigators[PI & Co-PI] – 20-30% of the total project cost
- Books and journals*
- Equipment*
- Presentation in conferences/Publication

Note:

* The equipment and books and journals acquired by the PI under a major research project must be deposited to the institution or in the central library after the completion of the project which will be the institutional property.

+ Contingency includes spares for apparatus, stationery, telephone, internet, computation, printing & postage. Expenditure towards the biostatistician and audit fee may also be claimed under contingency head.



6.3 Procedure for applying

- The college teachers who wish to avail financial assistance for major research project should submit their research proposal in the proforma as per Annexure II on or before the final submission date.
- Any applications received after the submission date will not be entertained.

6.4 Procedure for Approval

- The project should have obtained IRB clearance after which the PIs will be invited to make presentations before the expert committee.
- The final decision will be taken by the expert committee and the allocation of grants will be based on the same.
- The effective date of implementation of the project will be mentioned in approval cum sanction letter.

6.5 Procedure for the release of the Grants

6.5.1. First installment - 100% of the non recurring grant amount will be released to the PI at the time of acceptance. 50% of the total recurring grant approved by the research committee will be released to the PI.

6.5.2. Second installment - On receipt of the annual progress report statement of expenditure and utilization of first installment of grant, 40% of the total recurring grant will be released as second installment

6.5.3 Third installment - The remaining 10% of the grant will be released upon submission of following documents:

- a. Copy of final report of project along with soft copy
- b. Consolidated item wise detailed audited statement of expenditure
- c. Details of paper presentation and publication
- d. Unutilized grant if any should be refunded immediately
- e. In case of any balance grant not claimed within 1 year from the date of completion of the project the same will lapse and no representation will be entertained on this behalf.
- f. If a principal investigator fails to complete a project within the stipulated time he/she has to refund the entire amount sanctioned. For any extension in tenure approval of research committee is required.
- g. In case the PI leaves the institution before completion, he/she has to select the PI from the existing co investigators or refund the entire amount funded. The project is non transferable to investigators not included in the accepted proposal.

6.6. Monitoring and evaluation


6.6.1 A report summarizing the progress of the research should be submitted to the research committee at yearly intervals. Final Report should be submitted at the end of two years.

DAPM RV Dental College
Institutional Research Policy

Document History Summary

• Coordinating committee Formed	December 2015
• No of meetings and discussions of coordinating committee	December 2015 – January 2016
• Number of oral discussions with Principal (Former principal and present principal) held and the revision of policy	
• First submission of draft Policy to Office of principal	9.3.2016
• Second submission of draft policy after revisions	17.3.2016
• Third submission of the institutional Research policy	20.10.2020




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