RESEARCH INTEGRITY AND PUBLICATION ETHICS (RIPE)

STANDARD OPERATING PROCEDURES

SOP ON RESEARCH INTEGRITY AND PUBLICATION ETHICS

BHOPAL MEMORIAL HOSPITAL AND RESEARCH CENTRE

(As per guidelines of ICMR Policy on Research Integrity and Publication Ethics, 2019)

The quality and credibility of research is dependent on the integrity of the researchers who have a significant social responsibility to abide by the standards prescribed for their professions and by their institutions and also to be guided by the applicable regulations and guidelines. Responsible Conduct of Research (RCR) involves components such as planning and conducting research, reviewing and reporting research, responsible authorship and publication of the research work. The research team should maintain highest standards to uphold the fundamental values of research. The four basic principles of research ethics are autonomy (respect for persons), beneficence (to do good), non-maleficence (to do no harm) and justice (concept of fairness irrespective of caste, creed, region or religion etc.). These principles must be followed for safeguarding the dignity, rights, safety and well-being of research participants and for maintaining the research integrity.

PURPOSE:

To ensure highest professional and ethical standards for biomedical and health research at all stages right from its inception, honesty in conduct of research, obtaining relevant approvals, efficiency, judicious use of resources, ensuring accountability, transparency, declaration and management of Conflict of Interest (COI), justice, reliable data collection, handling, interpretation, integrity in analysis, reporting, publication and translation for the benefit of population. Research must follow applicable guidelines such as ICMR National Ethical Guidelines, Good Clinical/Laboratory Practices (GCP/GLP) and other applicable guidelines and regulations. The policy is intended to also provide procedures to manage allegations of research misconduct to be processed fairly, confidentially, and promptly.

SCOPE:

This policy applies to all BMHRC scientific/technical staff and students (regular/contractual) involved in research at BMHRC or Mini units (irrespective of source of funding). It provides a roadmap to overcome/eliminate any sort of misconduct which may happen at any stage of research and improve the quality for better outcomes.

RESPONSIBILITY:

All stakeholders involved in the conduct, review or reporting of research such as researchers, institutions, scientific review committees and ethics committees must ensure research integrity and quality thereby upholding the reputation, trust of research participants and meaningful translation of research findings for public health benefits while ensuring judicious use of resources.

FRAME WORK:

4.1. **Research Integrity Unit (RIU):** A Research Integrity Unit (RIU) at ICMR Headquarters, New Delhi would facilitate and guide research integrity in ICMR Headquarters and its network of institutions. It would facilitate implementation of responsible conduct of research (RCR) through a designated Research Integrity Officer (RIO) at Institutional/ Divisional level and maintain a designated budget head required for publication fees, plagiarism check etc.

4.2. **ICMR Bioethics Unit (IBU):** ICMR Bioethics Unit will be responsible for development and timely updation of policy on research integrity, misconduct and publication ethics. It will serve as an ethics advisory to suggest mechanisms to ensure conduct of responsible research at ICMR and its network of Institutions.

4.3. **Research Integrity Officer (RIO):** Directors of ICMR Institutions/ Head of Divisions would designate one senior faculty as RIO to facilitate implementation of this policy. RIO would be the contact point for communication between RIU and Division/Institution and provide information to researchers to ensure RCR, prevent research misconduct, and facilitate plagiarism check before publication in peer reviewed indexed journals. RIO would encourage teaching, training, journal clubs and other related activities, would report to Director and provide yearly progress updates (December every year) to RIU. RIO would act to best of his/her ability and would not be directly liable for any unintentional breech discovered later. An alternate senior faculty may be deputed to hold charge if RIO is on long leave or when RIO is an author/has Conflict of Interest (COI). The term for RIO will be for 3 years and can be rotated after tenure. RIO should proactively engage with scientists to avoid any delay and to sort out issues, if any.

List of Members of the Internal Committee For Research Integrity and Publication Ethics

BHOPAL MEMORIAL HOSPITAL & RESEARCH CENTRE

S. No.	Name	Designation	Affiliation
1	Dr. Sukhpreet Kaur	Chairman	Professor, Dept. of Pathology, BMHRC, Bhopal
2	Dr. Ravindra M.Samartha	Member	Assistant Professor, Dept. of Research , BMHRC, Bhopal
3	Dr. Anjali Sharma	Member	Professor, Dept. of Ophthalmology , BMHRC, Bhopal
4	Dr. Gaurav Acharya	Member	Associate Professor, Dept. of Anaesthesia, BMHRC, Bhopal.
5	Dr. Jyoti Tulsani	Member	Chief Medical Officer, Dept. of ORHC 7 BMHRC ,Bhopal
6	Dr.Shephali Jain	Member	Chief Medical Officer & In-charge Dept. of ORHC 1 BMHRC ,Bhopal
7	Dr. Megha Gautam	Member	Assistant Professor, Dept. of Ophthalmology , BMHRC, Bhopal
8	Dr.Nehal Shah	Member secretary	Physiotherapist, Dept. of Physiotherapy BMHRC, Bhopal.

RESPONSIBLE CONDUCT OF RESEARCH (RCR):

5.1. All biomedical and health research must follow ICMR National Ethical Guidelines and maintain research integrity in the conduct of research while ensuring safety of research participants. Other applicable guidelines and regulations must also be followed and required approvals be obtained before initiating research, such as Ethics Committee (EC), Institutional Animal Ethics Committee (IAEC), Institutional Committee for Stem Cell Research (IC-SCR), Genetic Engineering Approval Committee (GEAC), Review Committee on Genetic Manipulation (RCGM), Health Ministry's Screening Committee (HMSC), Central Drug Standard Control Organization (CDSCO), Institutional Biosafety Committee (IBSC), Atomic Energy Regulatory Board (AERB) etc.

5.2. Researcher/s should obtain approval of Institutional Scientific Committee, Scientific Advisory Committee (SAC) and IEC as per norms and declare COI, if any. Registration with

Clinical Trial Registry-India (CTRI) is mandatory for clinical trials but desirable for other types of research to maintain transparency and accountability.

5.3. Conflict of Interest (COI) both academic and financial may have serious implications and threaten quality of research and its outcomes. ICMR Bioethics Unit would provide needful support toICMRnetwork of institutions in establishing appropriate policies for declaration andmanagement of COI at the level of researchers, EC's as well as institutions.

5.4. Research should be undertaken by persons who are competent with qualifications, having relevant experience/training to collect reliable data, undertake accurate analysis, interpretation and publication.

5.5. Research should undergo peer review in a time bound manner following principles of fairness, honesty and maintaining confidentiality and undertaken by competent reviewers.

5.6. Researchers should be sensitive to societal and cultural values, engage and improve public trust, undertake meaningful research, be accountable to outcomes and take needful steps to protect participants from harm or risks.

5.7. Mentors should lead by example and devote sufficient time to guide and ensure that their trainees (Research Fellows, Associates, Post-doctoral Researchers, students and others) conduct research honestly.

5.8. All raw data should be available and securely kept by the lead investigator that could be presented later (if needed).

5.9. There should be due considerations for data collection and ownership, plan for publication, translation of outcomes and preservation of data for at least 3-5 years after study completion as it may be needed to confirm research findings, establish priority or be re-analysed by other researchers or for monitoring by sponsors or regulators. Present requirement is to maintain research records for 3 years in case of biomedical and health research and 5 years for clinical trials as per regulatory requirements.

5.10. For collaborative research there may be requirement for having appropriate memorandums of understanding (MoU) and material transfer agreements (MTA) in place.

6. REPORTING AND PUBLICATION:

6.1. Completed research irrespective of results must be published and shared on public databases such as CTRI, institute websites or other available relevant platforms.

6.2. Plagiarism or any form of research misconduct is unethical, and this includes self-plagiarism, fabrication, falsification, manipulation of data or images/digital image/use of unreliable or duplicate images, exaggeration on part of results and interpretation, use of wrong statistical tools, gift/ghost authorship etc. Researcher must ensure authenticity of research results before publishing or disseminating information out of the Institution.

6.3. Researchers should follow guidelines of International Committee of Medical Journal Editors (ICMJE), Committee on Publication Ethics (COPE) on publication ethics, research integrity and authorship and ensure substantial intellectual role of all authors who are included in the publication or presentation. The articles should not be submitted to any predatory journal for publication.

6.4. Ghost authorship and gifted authorship are not allowed and contributions of all authors should be clearly identified, collaborations if any, may be declared preferably at the time of project initiation or when the collaboration evolves during conduct of research, with the name and details of collaborators stated.

6.5. Role of all authors should be clearly identified/justified. Authorship should be duly given to all those who have substantially scientifically contributed to the research and may include permanent as well as contractual/ temporary staff.

6.6. RIO in consultation with RIU should make sure that their respective Institute, Centre or Division is provided with access to anti-plagiarism software.

6.7. Before publication or dissemination, the researcher/corresponding author should submit the final draft along with details of authorship, undertaking (Annexure I) and plagiarism check report to the Director/Head for approval and the Director will forward this to RIO for needful review regarding misconduct before giving approval (15 days).

6.8. Researcher is also required to submit continuing review/ annual report (Common form

for EC review- Annexure 3) and/or final report (Common form for EC review - annexure 12) to ethics committeefor review. Available at: http://ethics.ncdirindia.org/Common forms for Ethics Committee.aspx

6.9.RIO has the responsibility to maintain confidentiality of the draft article submitted by a researcher.

6.10. The researcher in consultation with RIO should assess patentability of the research outcome andconsult IPR Unit at ICMR before publication, if applicable.

6.11. The research documents with acceptable level of plagiarism (<10%) or without identified misconduct shall be forwarded by RIO to Director for approval before publication/dissemination.

7. REPORTING AND REVIEW OF RESEARCH MISCONDUCT AND ALLEGATIONS:

7.1. The allegations regarding research misconduct can be reported directly to Director/ Head with proper evidence and justification. Complainant can reveal her/his details or can request to anonymise identity but provide description of misconduct along with supporting documents. The below mentioned process may be followed for responding to allegations/research misconduct: 7.1.1. Director will inform/forward a copy of allegation to the respondent who will be given an opportunity to provide explanation within a limited time period (15 days).

7.1.2. In case of suspected research misconduct or allegation, Director may inform RIO to constitute a 2 to 3 member enquiry committee (one external) to evaluate misconduct/ allegation and explanation by respondent to investigate credibility of evidence, extent/nature of misconduct, personnel involved and intentions to suggest further course of action, including punitive/ disciplinary action.

7.1.3. For investigation, committee will be given access to inspect any reports, data, manuscripts or any other material considered relevant to the inquiry.

- If misconduct has not happened, complaint will be closed and details shared with the Director.
- If misconduct has happened, the level of misconduct and level of plagiarism will be determined.

7.1.4. The enquiry committee would take final decision through broad consensus or majority vote. It would suggest needful action based on seriousness of research misconduct such as issue warning, suspend research, and suggest penalty or other action. The enquiry should be time bound and completed within a period of 3 months from date of receiving the complaint.

7.1.5. Report of enquiry committee will be shared with Director. Based on the extent of misconduct, action will be taken by Director.

7.1.6. The charge of misconduct has serious implications for all the stakeholders involved. Therefore, investigation should be kept confidential to safeguard the rights of concerned parties. Appropriate steps may be required to protect the whistle blower from victimization by others. Handling the allegation of misconduct should be customised and be dealt with on a case to case basis. Every effort should be made to safeguard interests of the complainant and respondent.

7.1.7. If it is established that allegations were motivated by malice, Director will formulate appropriate course of action against the individual/s involved.

7.1.8. All the above reports or action taken in context to research integrity should be reported to the RIU by the RIO through the Director of the Institute.

7.1.9. Any major issue/s that is not under purview of the Institute can be referred to Research Integrity Unit (RIU) at ICMR Headquarters, New Delhi for further investigation/decision (1 month).

7.1.10. The Director General, ICMR shall be the final authority to decide on disputed/ dubious/ unacceptable research or publication.

8. SENSITIZATION AND TRAINING:

8.1. Needful trainings/workshops should be held periodically for newly recruited/appointed scientific/ research/technical staff as an orientation and induction practice to create awareness towards research integrity. Continued education and training is also necessary to keep researchers apprised of contemporary issues related to research integrity and publication ethics.

8.2. RIU, IBU and RIO at ICMR institutes would facilitate initiatives to organize training programs on regular basis for bringing awareness and updating the skills/knowledge of the researchers regarding the research integrity and RCR. This includes holding regular journal clubs, workshops and invited lectures to facilitate discussion, generate awareness and sensitize researchers at the institute level.

8.3. Any change in the relevant guidelines or regulatory requirements should be brought to the attention by RIU and IBU.