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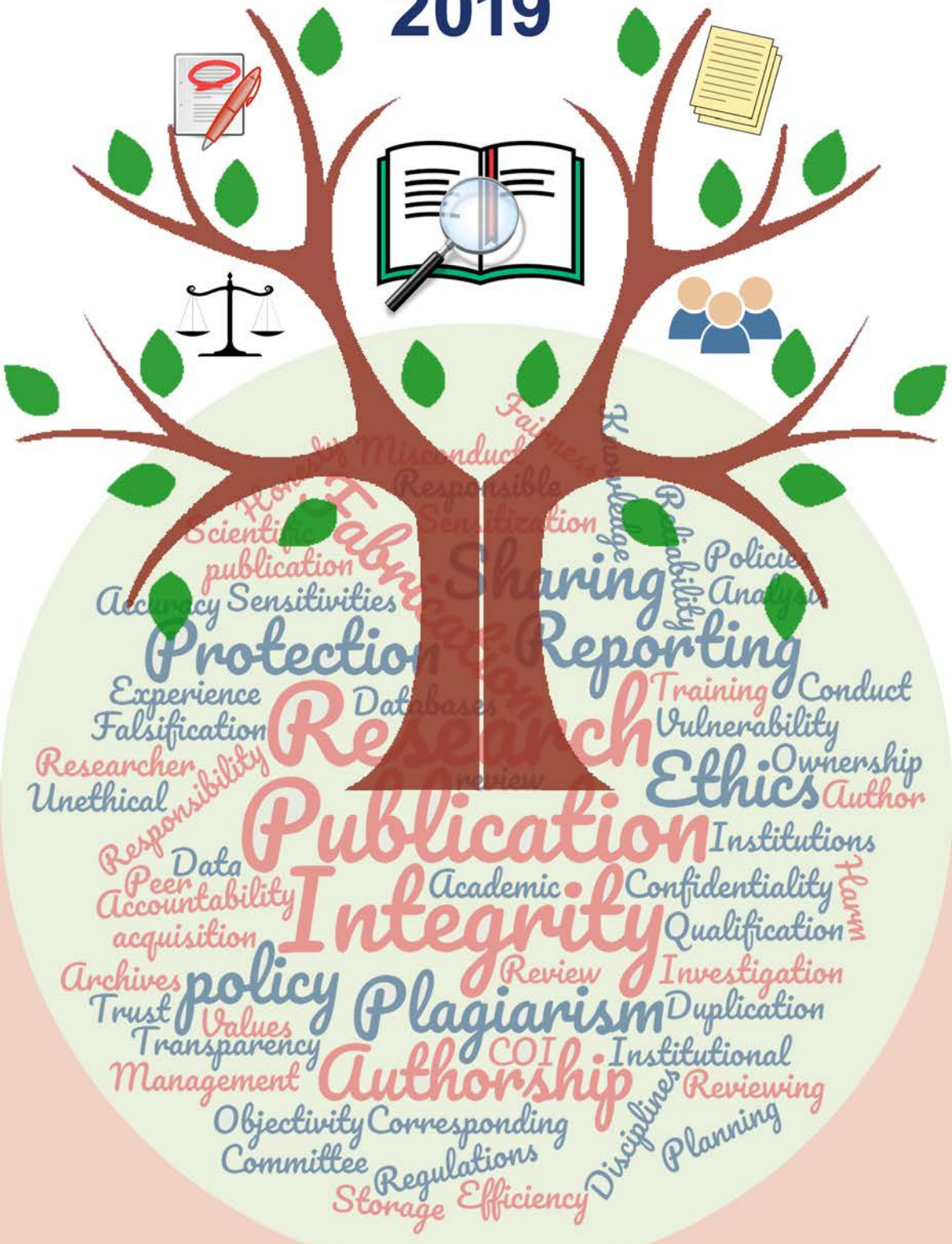
ICMR Policy on Research Integrity and Publication Ethics 2019



ICMR POLICY ON RESEARCH INTEGRITY AND PUBLICATION ETHICS

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.

1. 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.

2. SCOPE:

This policy applies to all ICMR scientific/technical staff and students (regular/contractual) involved in research at ICMR Headquarters or at ICMR Research Institutions, Centres or field units across the country (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.

3. 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.

4. 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 scientist 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/ Head of Division 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 scientist 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.

5. 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 Scientific Advisory Committee (SAC) and EC 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 to ICMR

network of institutions in establishing appropriate policies for declaration and management 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 committee for 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 and consult 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/ Head 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 / Head 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 2-3 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 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/ Head. 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/ Head 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/Head of the Institute/Centre/Division.

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. <u>SENSITIZATION AND TRAINING:</u>

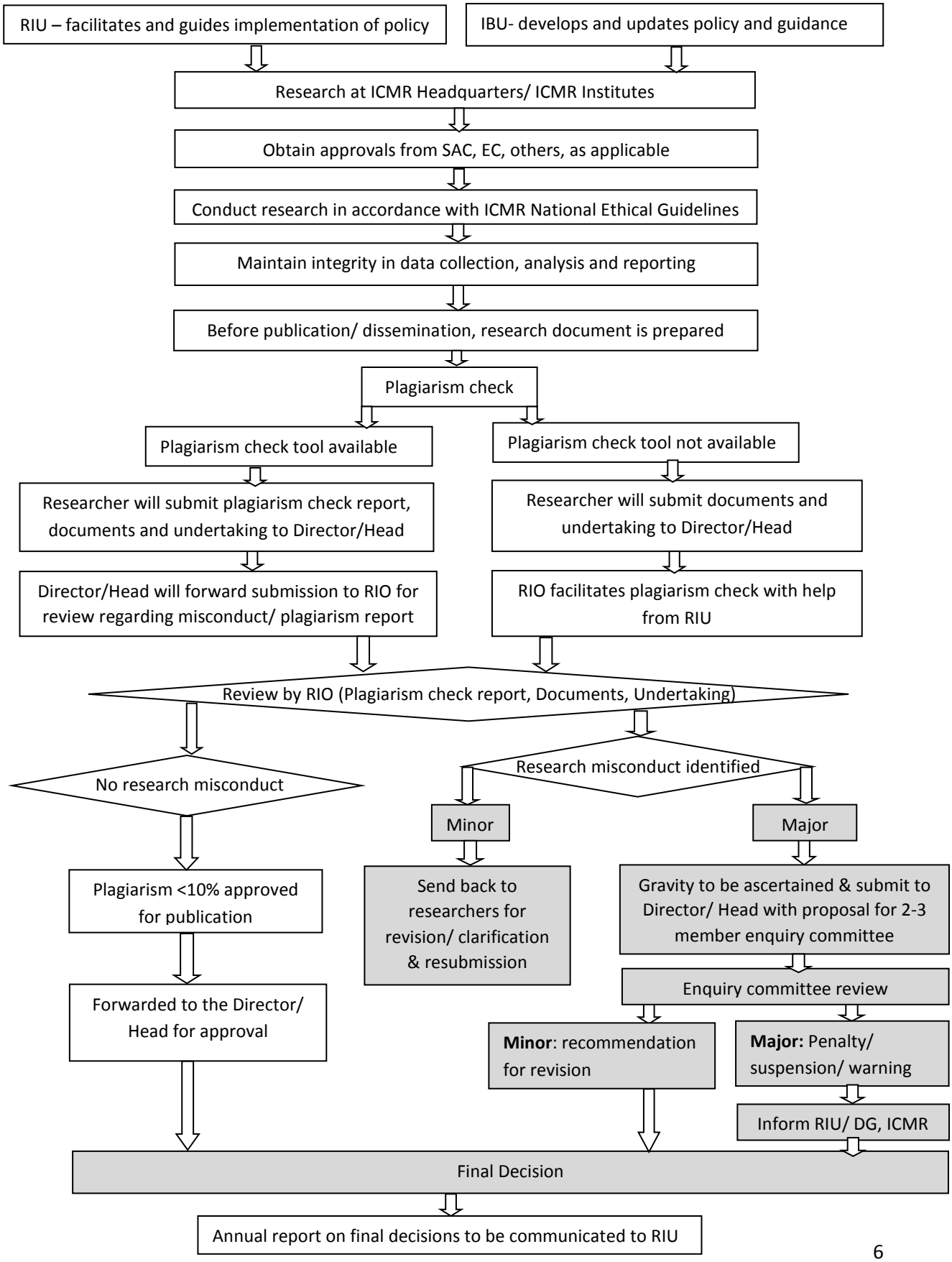
8.1. Needful trainings/workshops should be held periodically for newly recruited/appointed scientific/ research/technical staff as an orientation and induction practice to create awareness towards research integrity. Continued education and training is also necessary to keep researchers apprised of contemporary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

8.2. RIU, IBU and RIO at ICMR institutes would facilitate initiatives to organise 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.

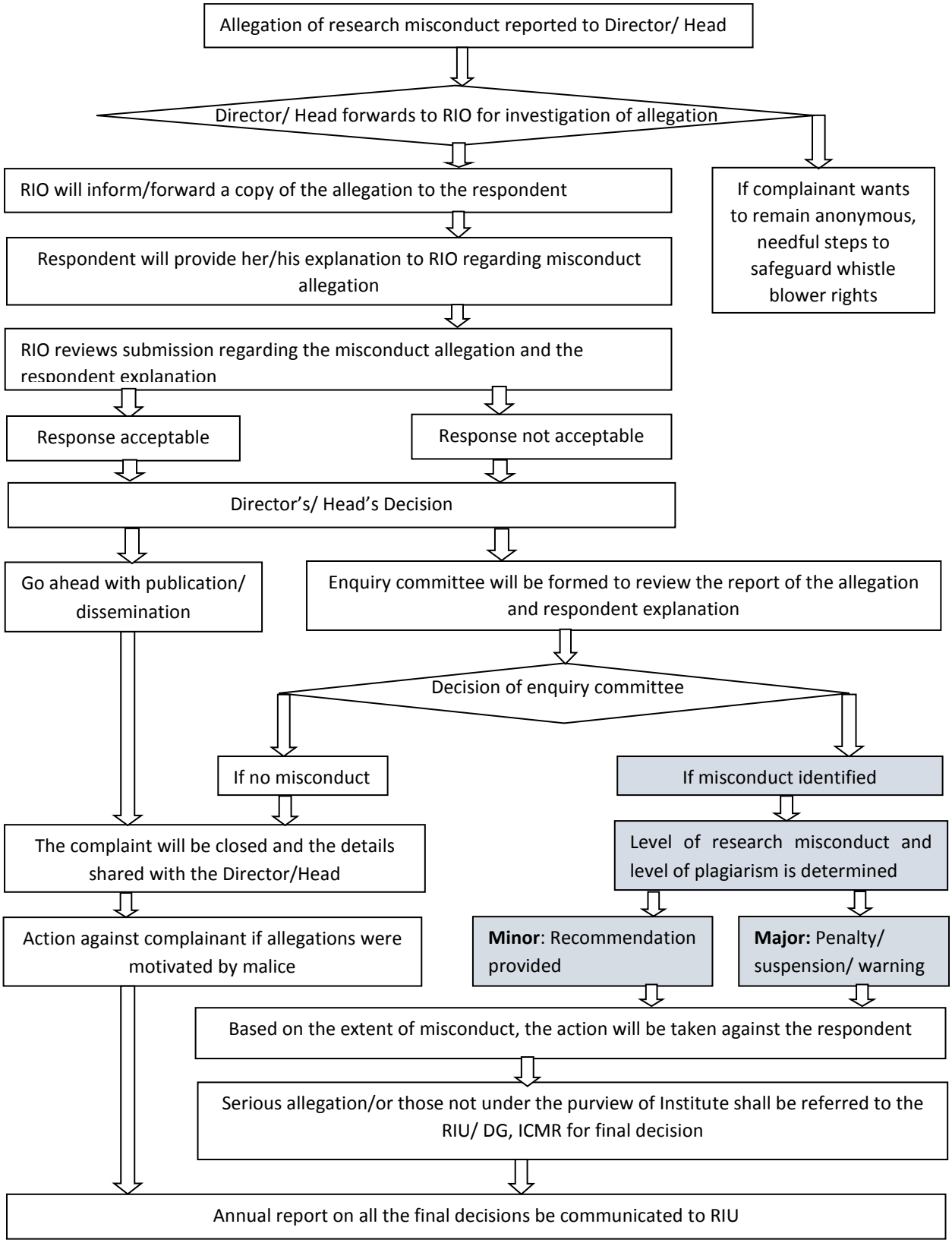
8.3. Any change in the relevant guidelines or regulatory requirements should be brought to the attention by RIU and IBU.

9. FLOW CHARTS

9.1: Review of research documents and handling research misconduct before publication/ dissemination at Institutional level:



9.2: Handling Misconduct Allegations against researchers:



Supplementary material
on
ICMR Policy on Research Integrity and Publication Ethics



Annexure I

Research Integrity Undertaking by the Lead Investigator

I, Dr/ Mr/ Mrs……., designated as ……..…… in …… (Name of Institute/ Division) give an undertaking for the document entitled ……. Here by, as a lead investigator of this work, on behalf of all the authors, I would like to certify that:

Tick if applicable:

- ☐ All authors have contributed sufficiently to qualify for authorship and are not involved into any research misconduct.
- ☐ SAC/scientific approval was obtained for the study.
- ☐ EC/IAEC approval was obtained, informed consent taken and study followed ICMR National Ethical Guidelines and other applicable guidelines and regulations.
- ☐ Conflict of Interests were declared / not declared to EC.
- ☐ All authors have read, accepted and provide their consent for this publication/ presentation.
- ☐ I shall not submit the paper to any predatory journal. The name of the journal to which paper being submitted is……
- ☐ I shall be responsible for any legal issues related to misconduct, plagiarism and violation of the copyright act related to this particular work.
- ☐ All raw data for the figures/tables presented in the manuscript are available with me and kept securely and can be provided if required.
- ☐ We have disclosed/acknowledged the financial support received for carrying out the study.
- ☐ Plagiarism Checker Available: ☐ Yes ☐ No
  - ☐ If yes, the content of this research document is original and own work, and is free from plagiarism. I have checked the research document through an approved Plagiarism detection tool provided/approved by the institute. Name of Tool used …… (Enclose Report)
  - ☐ If no, the RIO is requested to get the plagiarism check done through RIU.
- ☐ Any other information ……

Sl. No	Contributing Authors Name, Designation and Affiliation	Area of contribution
1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____

Lead Investigator/ researcher Name and Signature:
Date:

Annexure II

Definitions:

- **Accountability:** The obligation to account for activities, accept responsibility and disclose results in a transparent manner.
- **Fabrication**: The intentional act of making-up data or results and recording or reporting them.
- **Falsification**: Manipulating research materials, equipment or processes, or changing or omitting/ suppressing data or results without scientific or statistical justification or inaccurate representation.
- **Plagiarism**: The "wrongful appropriation" and "stealing and publication" of another paper or another author's "language, thoughts, ideas, or expressions" and the representation of them as one's own original work or duplicating one's own publication. World Association of Medical Editors (WAME) identifies plagiarism as a condition where six consecutive words are copied or seven to eleven words are overlapping set of 30 letters.
- **Professional competence**: The broad professional knowledge, attitude and skills required in order to work in a specialized area or profession.
- **Research document:** Any research manuscript, research paper, conference paper, oral presentation, case studies, abstract, monographs, books, dissemination report, scientific articles, magazines, newspaper or any other scientific document (such as Ph.D/MD/M.Sc Dissertation/ thesis or any other) that is to be disseminated outside the institute.
- **Research integrity**: An active adherence to the ethical principles and professional standards essential for the responsible conduct of research.
- **Research misconduct:** Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- **Transparency:** An intentional openness, communication and accountability operating in such a way that it is easy for others to see what actions are performed.
- **Lead Investigator:** The scientist/researcher who is in charge of a research document; usually prepares and carries out the research, sometimes analyses the data and reports the results of the work done. Lead investigator may not be PI but who takes responsibility/authority/lead for the publication/dissemination.
- **Image/Digital Manipulation:** It is the process of alterations, enhancements, transforming, misrepresenting images or photographs by using softwares/ airbrushing/ tools or techniques/ digital tools for editing/duplication etc.

Annexure III

Guidelines for avoiding Plagiarism:

- "Acknowledgment" is the ethically right manner of crediting someone else's work. In case of verbatim text is being taken from another source, it must be enclosed in quotation marks and by providing citation to indicate its origin.
- Upon utilisation of someone else's work, the essence of the work must be reframed in her/his own words in a summarised version by providing appropriate citation.
- Manipulating references is considered malpractice and is unacceptable. References used in a paper should only be those that are directly related to its contents and in a required style.

Types of Plagiarism:

- **Direct Plagiarism:** This includes the complete or partial direct copying or word by word copying of a someone's work without acknowledging the original author.
- **Self-Plagiarism:** A situation where the person duplicates his previous works or sentences used in a new project or new publications. This is also considered an unethical practice in case of publication in journals
- **Mosaic Plagiarism**: Copying of idea and general structure of the concept of someone by changing the phrases and words like using synonyms and without quoting.
- **Accidental Plagiarism:** When the author neglects or forget to cite the original source or refer to a wrong source or unintentionally paraphrases someone's idea by using similar words, groups of words, and/or sentence structure without attribution.
- **Redundant publications ('salami' publications):** This refers to publishing many very similar manuscripts/reports based on the same experiments and same work design.

Annexure IV

PREDATORY JOURNALS: Worldwide there is an increase in deceptive publications in predatory journals which are usually online and offer the incentive of immediate/overnight publications/free/or at low cost. Due to the academic pressure to publish or perish many researchers take this short cut route and the number of such predatory journals is increasing exponentially. Most of the academic and research organizations give considerable weight to number of research publications in a year while assessing them for promotions. In India, ICMR, UGC and other agencies have recommended academic as well as scientific community to avoid publication in predatory journals and conferences.

- The Consortium for Academic and Research Ethics (UGC-CARE) has listed legitimate and good quality journals and also reported about the increase in number of publications in these journals within a very short span of time without valid peer review and editorial board in last consecutive years. By doing so, these journals are accepting poor quality scientific research without any peer review and charging payment fees for publication. A 'UGC- CARE Reference List of Quality Journals' across various disciplines was posted at https://ugccare.unipune.ac.in/site/website/index.aspx
- UGC has released in a public notice on Academic Integrity dated 14th June 2019 stated that "*Any publication in predatory/dubious journals or presentations in predatory/dubious conferences should not be considered for academic credit for selection, confirmation, promotion, performance appraisal, award of scholarship or academic degrees or credits in any form. Vice Chancellors, selection committees, research supervisors/guides and such other experts involved in academic evaluation/assessment are hereby advised that they must ensure that their decisions are primarily based on quality of research work and not merely on number of publications*".
- It is often not easy to identify predatory journals as they name themselves and present themselves in a highly reputed manner. It is important for researchers to identify non-predatory journals for publishing research. Relevant agencies must also plan action against predatory journals.
- There is a need to further discuss ways to separate out academic assessments required for promotions or career progression from number of publications in the year.
- At present an updated database listing of predatory journals is not available. ICMR Scientists and ICMR network of Institutes to remain vigilant and may report from time to time the names and web links of predatory journals to RIU as they come across any. RIO's can consult researchers to prepare a list of such journals in their areas of research and provide this to RIU for creating a central register which can be updated based on inputs from ICMR institutes.

Annexure V

List of relevant National and International guidelines

Sl. No	Institute / Organization	Document
International		
1.	Office of Research Integrity (ORI)	• First attempts to tackle scientific misconduct and dishonesty were made in the U.S. in 1992 by launching the "Office of Research Integrity (ORI)". Available at: https://ori.hhs.gov/ori-policy-plagiarism
2.	Committee on Publication Ethics (COPE)	• COPE developed Guidelines on Good Publication Practice and most of the journals use COPE guidelines to address issues related to publication ethics. Available at: https://publicationethics.org/files/u7141/1999pdf13.pdf
3.	International Committee for Medical Journal Editors (ICMJE)	• ICMJE developed recommendations to review best practice and ethical standards in the conduct and reporting of research and other material published in medical journals. Available at: http://www.icmje.org/icmje-recommendations.pdf
4.	CONSORT	• CONSORT, encompasses various initiatives to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs). Available at: Schulz et al., CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials BMC Medicine 2010, 8:18
5.	National Institutes of Health (NIH)	• NIH Policies and Procedures for Promoting Scientific Integrity (2012) • Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH (2016) • A Guide to the handling of research misconduct Allegations: Available at: https://www.nih.gov/sites/default/files/about-nih/nih-director/testimonies/nih-policies-procedures-promoting-scientific-integrity-2012.pdf
National		
1.	University Grants Commission (UGC) Regulations for promotion of academic integrity and prevention of plagiarism in Higher Educational Institutions (HEI)	• In India, in 2018, UGC took an initiative to coordinate and determine the standards of HEI by promotion of academic integrity and prevention of plagiarism in HEI. • It is applicable to all the students, faculty, researchers and staff of all HEI in the country. • It explains the curbing plagiarism and levels of plagiarism, detection/reporting/handling of Plagiarism, penalties in case of plagiarism in submission of thesis, dissertations, academic and research publications Available at: https://www.ugc.ac.in/pdfnews/7771545_academic-integrity-Regulation2018.pdf
2.	Department of Biotechnology (DBT) Statement on the handling of allegations of research misconduct	• This policy statement is intended to address situations where research integrity may be compromised. • It provided clear guidelines for responsibilities of the organizations in receipt of funds, Principles for investigation by organizations of allegations of research misconduct and involvement of DBT in dealing with the allegations etc. Available at: http://dbtindia.gov.in/sites/default/files/DBTresearch-misconduct13042016.pdf
3.	ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017	• ICMR National Ethical Guidelines 2017 provides a separate chapter on Responsible Conduct of Research (RCR) highlighting values of research, need for policies for addressing research misconduct and to have a governance mechanism to monitor research objectivity, data capture, disclosure of Conflict of Interest and Conflict of Commitment. Available at: https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

Annexure VI

References:

*This document is drafted based on the

1. ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants 2017. Available at: https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
2. Department of Biotechnology (DBT) Statement on the handling of allegations of research misconduct. Available at: http://dbtindia.gov.in/sites/default/files/DBTresearch-misconduct13042016.pdf
3. University Grants Commission (UGC) Regulations for promotion of academic integrity and prevention of plagiarism in Higher Educational Institutions (HEI). Available at: https://www.ugc.ac.in/pdfnews/7771545_academic-integrity-Regulation2018.pdf
4. Research Misconduct Policy- NARI –ICMR
5. Raising Awareness about Misconduct in Research and Investigation into the same at NCBS. Available at https://www.ncbs.res.in/sites/default/files/policies/research_misconduct.pdf

Additional Readings:

1. UGC-CARE. Public Notice on Academic Integrity. Reference No. F.1-1/2018 (Journals/CARE) dated 14th June 2019: Available at: https://www.ugc.ac.in/pdfnews/6315352_UGC-Public-Notice-CARE.pdf
2. Nicholas H. Steneck. Introduction to the Responsible Conduct of Research. Office of Research Integrity. 2007. Available at: https://ori.hhs.gov/sites/default/files/rcrintro.pdf
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Annexure VII

LIST OF MEMBERS

The draft "ICMR Policy on Research Integrity and Publication Ethics" has been prepared by the following committee:

1	**Prof. Balram Bhargava** Secretary DHR and DG, ICMR, New Delhi	**Chairperson**
2	**Dr. R. Gangakhedkar** Scientist 'G' & Head, Division of Epidemiology and Communicable Diseases (ECD), ICMR, New Delhi	**Member**
3	**Dr. N. C. Jain** Scientist 'G' & Head, Division of Human Resource Planning and Development (HRD), ICMR, New Delhi	**Member**
4	**Dr. Roli Mathur** Scientist 'E' & Head, ICMR Bioethics Unit, NCDIR, Bengaluru	**Member Secretary**

The policy was prepared by the above committee and revised based on inputs received from Divisions of ICMR Headquarters and ICMR Institutes.

This policy document is to ensure highest professional and ethical standards for biomedical and health research at all stages right from inception,conduct, review, reporting and publication



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