KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI

(Deemed-to-be-University)
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Accredited 'A' Grade by NAAC (2ⁿᵈ Cycle)   Placed in Category 'A' by MHRD (GoI)

RESEARCH AND INNOVATION POLICY

The University

The KLE ACADEMY OF HIGHER EDUCATION & RESEARCH (KAHER) was established on 13th April, 2006 as per the Ministry of Human Resource Development, Government of India under the recommendation of University Grants Commission. The sponsoring society "The KLE Society" celebrating its centenary was established on 13th of November 1916 by "Seven Dedicated Teachers —The Saptarishis" and has under its wing 250 institutions spread across Karnataka, Maharashtra, Goa, Delhi etc.

In a short span of time the University has firmly established itself as a centre of excellence in terms of medical education, research and health care services at the national and international level. The University offers various undergraduate, postgraduate, post-doctoral, fellowship and certificate programs in the faculties of Medicine, Dentistry, Pharmacy, Ayurveda, Physiotherapy and Nursing.

In terms of infrastructure the University has excellent teaching facility, state of the art teaching hospital and medical research centre having 2400 beds, basic science research centre spread over an area of 10,000sq.ft., Wi-Fi facility all over the campus, digital library and other facilities on par with premier institutes of national and international repute. Facilities like bank, post-office, pharmacy, gym, swimming pool, indoor stadium, cafe, department store, travel booking, etc. are provided in the campus itself. Calendar of events delineating the date of examination schedule and other important curricular events are provided to every student at the beginning of academic session thus enabling the students to plan and pace their studies well in advance.

The Department of Allied Courses was established in 2007. There is expected to be a tremendous demand for allied health professionals in the years to come because of the phenomenal growth in the healthcare industry. In view of this, KAHER offers a range of allied courses in the form of undergraduate, postgraduate, fellowship, diploma, postgraduate diploma and certificate courses.

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1. Preamble :

The KLE Academy of Higher Education and Research (KAHER) is committed to promote and support quality research in an intellectually stimulating and inspirational environment to address the scientific challenges of today and the future.

The enduring excellence in research that KAHER aspires for, is dependent on several attributes that include creativity, rigor, curiosity, persistence as well as on honesty, transparency, responsibility and ability for good communication and collaboration. Thus, intellect and integrity have to go together to maintain the credibility and reputation of the University's Research and repute of individual researchers. Hence it is the responsibility of every staff member and student to uphold the good reputation of the University and, consequently, it is expected that they will conduct research with integrity.

This policy aims to encourage and support research for acquiring, investigating and developing knowledge for the good of society, and to confirm that, all research is conducted in accordance with ethical principles.

2. Purpose of the Policy :

The policy shall serve as a general outline for conduct of all type of research activities of the University.

This policy is in line with University's mission and strategic plans for creating an empowering environment to foster a research culture, provide essential support through research framework and guidelines in order to produce high-quality, relevant and focused research.

It also aims to facilitate the attainment of excellence in research, collaborative activities, and raise awareness regarding good practices in research and innovation all within a meticulous ethical background.

3. Scope of the Research Policy :

The policy will be applicable to all the constituent units of KAHER and applicable to all Faculty of the University, Ph.D. Scholars as well as registered students (undergraduate, postgraduate) who undertake R&I activities, either funded or otherwise within/outside University premises. The research policy pertains to a wider strategic interests of the University including partnerships, collaborations, Clinical trials and MoU's.

4. Objectives :

- To create an empowering environment within KAHER to nurture research culture and to offer requisite support through research framework and guidelines.
- To ensure well-organized and active support system to facilitate faculty and researchers in their research activities.
- Administration of Research and Innovation strategy of the University, Budget, and Coordination Research Excellence Framework.

- To nurture an environment to undertake research that have public health as well as social impact and potential for commercialization.
- Providing a modality of for proper coordination of all research activities of the University and aligning these to the vision and missions of the University and national development goals
- Integrate research activities undertaken by the undergraduate, post-graduate and doctoral students with the research focus of the University in alignment with the national thrust areas;
- Ensure effective dissemination of research activities and achievements of the University both internally and externally and ensure publications in quality journals, indexed in Scopus/Web of Science and/or with impact factor.
- To fostercreate interdisciplinary collaborations and partnerships globally as well as nationally
- Translate new knowledge, innovations, technologies and tools emerging out of research conducted into products and processes for commercialization; Protect Intellectual Property (IP) generated as a result of research conducted
- To ensure that the research activities of the University conform to all applicable rules and regulation as well as to the established standards and norms relating to safe and ethical conduct of research.

5. Custodian of Policy
- The implementation and updating of Research Policy shall be carried out by Director of Research, KLE Academy of Higher Education. The Research Policy will function under the Research Coordination Committee headed by the Vice Chancellor, KAHER and administrative committee, to contribute and recommend in matters related to research within KAHER.
- The Principals and Deans of the various constituent colleges are responsible for the conduct of the research that is undertaken in their Institutions. They will ensure that all researchers are applying to the ethics review procedures for research activities that involve human participants, personal data or human tissue, in line with the University's Ethics Policy, governing the research involving human participants, personal data and human tissue. They will also be responsible for ensuring that all staff and students engaging in research are familiar with the content of the Policy and that appropriate training and guidance is made available.

6. Composition of the Research Coordination Committee (RCC)
- Vice chancellor – Chairperson
- Director, Research – Member Secretary
- Deans of Various Constituent Units
- Eminent experts from outside the University.

The RCC will meet thrice a year to review research progress, offer critical comments and suggest remedial processes to augment the research activities of the University. The 'Term' of the RCC, once constituted, will be for a period of Three (3) years after which the same membersmay be continued for another term.

7. Institution objectives & Research priorities
- KLE Academy of Higher education and Research (KAHER) envisions as one of the TOP TWENTY FIVE Medical and Allied Sciences Universities in the Asian Region by contributing to high quality Education, Healthcare, and Biomedical Translational Research and Institutional Social Responsibility service to the Society.
- The University aims to enhance the research profile of the University by effective dissemination of research activities and achievements of the University at all levels to maximize the impact and recognition of research done at KAHER at national and international levels. It also purposes to advance and facilitate interdisciplinary and multidisciplinary relationships by connecting with other research institutions and industries.

- The research should be consistent with the strategic interests of the University. It should will focus on the development of research and analytical skills, identification of social needs and its solutions regarding social, behavioral, financial and health problems of the people in the region,must improve the health outcomes of the community both local and global.
- Maintain and enhance the quality of research undertaken byCreating transparent, effective and efficient systems for maximizing research outputs;
- Translate new knowledge, innovations, technologies and tools emerging out of research conducted at Amity into products and processes for commercialization or for societal benefit; Protect Intellectual Property (IP) generated as a result of research conducted
- Encourage and facilitate research collaborations within different Institutes of the University along with reputed Institutes, Universities and Research Organizations both in India and abroad
- Ensure effective dissemination of research activities and achievements of the University both internally and externally

8. Identification of Thrust areas of Research
The Research projects undertaken should preferably fall under the thrust areas of the university/institute.

9. Research management:
The overall management of research activities will be coordinated by Directorate of Research, KLE Academy of Higher Education under direct supervision of Vice Chancellor. Research Coordination Committee and administrative committee shall be responsible for overall functioning of research activities within the University. Each Institution research activities will be coordinated by individual head of institutions and their committees thereof.

10. General Guidelines
Undertaking Research :

Faculty : Faculty members of KLE Academy of Higher Education and research departments are expected to undertake research, leading to quality publications, presentations in National/International conferences of repute, generation of Intellectual property with potential for commercialization, socially useful outcome and other similar research activity. Research output will be considered one of the criteria for faculty recruitment and promotion along with other academic responsibilities. All faculty should know the contents of the policy, follow the guidelines and apply for ethical approval to be reviewed and approved by the Institutional ethics Comittee

Postgraduates : The postgraduates as part of their program must undertake dissertation work and other research projects in their respective disciplines. Their projects are reviewed by the scientific and Ethical committees at the constituent unit level.

Research Scholars/Ph.D Scholars : A Ph.D. dissertation is the first indicator of a researcher's ability to produce good quality research. KAHER believes in producing high quality research through their Ph.D Program. The candidates are recruited after a stringent two step elimination procedure involving a written examination and Interview. A sepearte Scientific and Ethical Review committee for the PhD program oversees the scientific quality, innovation and progress of the Scholars.

11. Ethics in Research:
The ethical conduct of research is essential for those working in all disciplines, particularly for researchers in medicine and life sciences. Research should avoid causing harm, distress, anxiety, pain or any other negative feeling to participants.

11.1: For Human Participants :

The University follows Ethical Guidelines for Biomedical Research on Human Participants of ICMR as are available at: http://icmr.nic.in/ethical guidelines.pdf.

The University shall adhere to all the instructions given in the above said guidelines and their amendments to be made from time to time in future also by ICMR regarding human ethics in research. University is also committed to follows Standard Operating Procedures (SOP) of IECs as per ICMR as available at: http://icmr.nic.in/ethics_SOP.pdf

Clinical trials to be undertaken by the Institutes under KAHER will also comply with the requirements of the New Clinical Trails Rules 2019.

11.2: Animal Ethics policy :

The University follows Guidelines mentioned by CPCSEA, New Delhi on Animal Experimentation, Breeding and Laboratory Animal Facility as are available at: http ://cpcsea.nic.in/writereaddata/user files / file/sop cpcsea inner page.pdf

The University shall adhere to all the instructions given in the above said guidelines and their amendments to be made from time to time in future also by CPCSEA. Similarly, the University is also committed to follow the below placed Act for ensuring the guidelines and provisions therein for prevention of cruelty to animals: The Prevention of Cruelty to Animals Act 1960 (59 Of 1960)

link : www.awbi.org

11.3: Committees to Oversee Research :
1. Institutional Ethics Committee :
The university has in Place the Institutional Ethics Committee as per New Clinical Trial Rules 2019 and ICMR Guidelines which reviews the ethics of all medical research involving human participants, tissue and data also and monitor the ethics review measures in the constituent colleges including faculty research, Industry Sponsored Clinical Trial, Collaborative research etc. It will also dynamically promote the knowledge and awareness of research ethics and the policy thereof by conducting training and other academic events. The committee can offer advice on any research ethical matters that are referred to the committee and look into matters of research misconduct within the University. It will ensure recognition of the IEC by recognized bodies. The details of the Composition and Function is attached.
2. Ph.D. Ethics Committee for Human Research :
All research proposals by research scholars registered for PhD under all faculties (full time and part time) shall be scrutinized by this committee. The committee shall scrutinize applications for ethical approval for the research proposal, inspect and update the research scholar's regarding approval or recommend changes if need be. The research scholars are expected to address the concerns raised by the committee. The Committee provides guidance to all Faculties/Departments/constituent colleges.
The details of the Composition and Function is attached.
3. University Animal Ethics Committee :
This committee fFunctions as per the guidelines of Committee for Purpose of Control and Supervision of Experiments on Animals. (CPCSEA) and provide avenues and directions towards participation in animal research in all constituent colleges.
4. Ethics Committees for Individual Constituent Units : All the constituent Units also have their Ethics committees that monitor the Postgraduate Research undertaken in the Individual Constituent Units.

11.4 :Responsible conduct of Research :
The responsible conduct of research (RCR) involves the following major components : values, policies, planning and conducting research, reviewing and reporting research and responsible authorship and publication.

11.5: Responsibilities of the Researcher :
- Honesty and integrity as an investigator
- Minimal possible risk to participants and to themselves
- Respect for other people, their values and their cultures.
- Think through ethics issues for the particular   project – minimize harms, choose populations fairly, develop respectful procedures
- Submit protocol to IEC, submit annual reviews to IRB, submit changes to IRB, submit adverse or unanticipated events to IRB
- Maintain records (with IRB, with subjects)
- The university expects that these principles are taken into consideration from the beginning, and throughout project's lifetime.
- Research projects shall be designed with a specific outline which may include a data management plan and define the project's operational procedure and timelines;
- An explicit statement on how the project can benefit the society shall be mentioned wherever appropriate.
- Any risks to people and/or animals and/or the environment and/or to cultural should be recognized wherever probable, and actions should be taken to manage/ minimize risks,
- Potential or real conflicts of interest should be declared and addressed adequately,
- In collaborative R&I, an initial arrangement shall be made as to the roles and responsibilities of researchers involved in a R&I project.The strategy for communications, transparent criteria for publication strategy, authorship, acknowledgements and intellectual property rights (IP rights) shall be explicitly agreed upon by all involved.

12. Research Promotion :
The university has several schemes under which financial assistance is being given to undertake and promote Research and Innovation activities :
- Capacity Building:KAHER provides financial assistance to conductConference, Seminars, workshops, Symposia and CME's on Research Methodology, Good Clinical Practice, Good Laboratory Practice, Publication and Peer review, Grant writing, IPR and Patenting, awareness of academic misconduct like plagiarism for promoting and improving the quality of research
- Seed money Faculty for Research:KAHER provide seed grants for faculty on a competitive basis based on the prior research experience and the quality of the proposed research project.
- Financial Support to attend State/National/International conference for faculty and Students
- Grants for Cash Incentives for prize winning presentation at National/International Level
- Financial assistance towards publication of Scientific Proceedings of Conference/CME in the form of Book.
- Financial grants for Publication of Books or Contribution of Chapter to textbooks
- Grant of cash Incentives for Patents
- Financial Grants for Publications in Scopus, Web of Science and Pubmed Journals.
- Scholarships and Contingency for Ph.D. Scholars

Additionally, KAHER encourages its Faculty by constituting several Research awards which include :
- Best PhD Thesis
- Best Postgraduate Dissertation award
- Cash award or Incentive for publication of Textbook or Reference Book
- Best Scientist award
- Best Young scientist Award
- Cash Incentive for Faculty who have received financial grant from external funding agencies
- Incentives for UG, PG students and Scientists to undertake Research activities

The details of the Finacial assistance schemes and Research awards is attached as an Annexure.

13. Specific Research Endeavors :

13.1: Clinical Trials :

• Clinical trials must be conducted with a high standard of quality that assures the research question is answered in a reliable, valid, and unbiased manner, and that the rights and welfare of human subjects are protected.

• All clinical trials must be registered in the Clinical Trial Registry of India as mandated by CDSCO as on 15 June 2009 for clinical trials that are registered under the Drugs and Cosmetics Act and its Rules. All clinical trials, as a part of postgraduate, doctoral thesis or sponsored research being conducted in the University must be registered in the Clinical Trials Registry–India, linked to WHO registry.

• Trial registration should involve providing information regarding the study, investigators, Sites, sponsor, ethics committees, regulatory clearances, disease/condition, types of study, methodologies, outcomes, etc.

• The SMO coordinates the Clinical trials conducted in KAHER and the detailed SOP are attached.

13.2 : Research Collaborations :

• Researchers are increasingly collaborating with colleagues who have the expertise and/or for resources needed to carry out particular research. This could be inter-departmental/ inter-institutional or international and also multi center involving public and/or private research centers and agencies.

• Collaborative R&I ranges from international projects, potentially involving institutions from countries both in the developing and developed world, to mid-range collaborations involving several institutions within one country, through to projects involving two researchers from different disciplines. Collaboration includes R&I projects between researchers from different disciplines in the University, and R&I projects between the University and other institutions in India and/or in other countries.

• The main ethical issues surrounding collaborations pertain to sharing techniques, ownership of materials and data, IPRs, joint publications, managing research findings, managing COI and commercializing research outcomes. All these issues must be addressed by collaborating Institutes/investigators through a contract or MOU.

• Researchers should familiarize themselves with all aspects including local, national and international requirements for research collaboration including necessary approvals, memorandums of understanding (MoUs) and material transfer agreements (MTA) and EC approval of collaborating institutes.

• The IEC and the SMO Coordinate the Research Collaborations at KAHER.

13.3: Conflict of Interest :

• Conflict of interest (COI) is a set of conditions in which professional judgment concerning a primary interest such as patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest such as financial gain or non-financial (personal, academic or political)considerations have the potential to compromise, or are perceived as compromising the exercise of professional judgment. COI can be at the level of researchers, EC members, institutions or sponsors and the types that can occur in research include conflicts of commitment, conflicts of conscience, and institutional conflicts of interest which vary from each other.

• Regulatory Aspects: Research being conducted in alliance with industries/ commercial companies will strongly review the possible COI between scientific responsibilities of researchers and business interests at the beginning. The Standard Operating procedure of Institutional Ethics committee and Site management Office will be strictly adhered to that will help the Self-regulatory processes to monitor, prevent and resolve conflicts of interest.

- The investigators shall declare conflicts of interest (financial interests, consulting fees or honorarium per participant, intellectual property rights from patents, copyrights and royalties from such rights, etc.) in the application submitted to IEC for review. IEC members would declare the conflict of Interest before the review of the proposal and recuse from the deliberations and decision making on the specific proposal.
- A declaration of a conflict of interest, with a brief written record of that declaration, will suffice in most situations. Sometimes, may require modification of the project's plan.

13.4: Research Data Management :
KAHER regards the effective management of the data generated by research projects as an essential part of good research and innovation practice. It has the following steps undertaken for data management :
- Exploiting the impact of data-intensive research
- Assurance of research integrity
- Enhanced data protection and storage and minimizing the risk of data loss
- Enablement of data sharing and collaboration
- Open access principle to publicly-funded research outputs
- Compliance with the requirements of research funders.
- The primary responsibility for effective research data management during the course of research projects lies with Principal Investigators. However, all researchers, including postgraduate and undergraduate students undertaking research, have a personal responsibility to manage effectively the data they create.
- All research proposals for funded research shall include a data management plan. This will help to ensure that research data management is be considered at every stage of a research project, from the initial proposal and research costing, through to provision for long-term data curation.
- Data protection and storage is important and once collected, data must be properly protected, as it may be needed at a later stage to confirm research findings, establish priority, or be re-analyzed by other researchers. Responsible data handling begins with proper storage and protection from accidental damage, loss or theft.
- Care should be taken to reduce the risk of fire, flood and other catastrophic events. Computer files should be backed-up and the back-up data saved in a secure place at a site that is different from the original data storage site.

Data sharing is important as research data is valuable and needs to be shared, but deciding when and with whom to share may raise difficult questions. Once a researcher has published the results of an experiment, it is generally expected that all the information about that experiment, including the final data, should be freely available for other researchers to check and use. Data should be shared or placed in a public domain in a de-identified/anonymized form, unless required otherwise, for which applicable permissions/re-consent should be sought unless obtained beforehand.

13.5: Publications :

Responsible Authorship and Publication :

- Completed research must be published and shared on public databases such as CTRI, institute websites or other available relevant platforms.
- Plagiarism or any form of research misconduct is unethical and will be strictly avoided The research misconduct 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.
- 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.
- 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.
- 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
- To ensure research output towards the most significant, highly cited publications within similar fields of disciplines, KLE Academy of Higher Education has collaborated with leading research data bases with indexing agencies viz; like Scopus (Elsevier) and expects the authors to publish in highly prestigious and externally peer-reviewed publications (preferably Journals indexed in Scopus, PubMed, Web of Science and UGC-Care list), wherever possible, to ensure opportunities for dissemination of our research are maximized. The articles should not be submitted to any predatory journal for publication.
- All sources, materials and methods used to obtain and analyze research data should be explained clearly in the publication. Any potential or real conflicts of interest should be declared in the publication
- The Research data and results should be checked rigorously for their integrity before being published and/or communicated with the public. Before publication or dissemination, the researcher/corresponding author should submit the final draft along with details of authorship and plagiarism check report to the Publication Review committee for approval where it will be reviewed regarding misconduct before giving approval (15 days)
- The research documents with acceptable level of plagiarism ($\leq$10%) or without identified misconduct shall be permitted for before publication/dissemination.

13.6: Patents and IPR :

Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. IP is protected in law by (patents, copyright, trademarks, and technology etc.) Intellectual Property Rights (IPRs), enable individual to earn recognition or financial benefit from what they invent or create. KAHER has a well-defined IPR Policy applicable to the faculty, staff, graduate students, post-doctoral fellows, and non-employees (including visiting faculty, affiliate and adjunct faculty, industrial personnel, fellows, etc.) who participate in research projects in the University. All potential inventors who participate in a sponsored research project and/ or make use of University-sponsored resources should abide by this policy and should accept the principles of ownership of IP as stated in this policy unless an exception is approved in writing by the University. A IPR cell in place to manage all IPR related issues.

14. Research Misconduct :

Research misconduct will involve fabrication, falsification and plagiarism of data, that are serious issues both nationally and internationally.

The University has adopted the definitions of research misconduct set out by UNIVERSITY GRANTS COMMISSION (PROMOTION OF ACADEMIC INTEGRITY AND PREVENTION OF PLAGIARISM IN HIGHER EDUCATIONAL INSTITUTIONS) REGULATIONS, 2018

Policy on Research Misconduct :

The University considers any allegation of research misconduct to be a matter of great concern and will investigate any such allegation fully. Given its reputation and status, the University has a responsibility to the research community and to the public at large. Research misconduct, if suspected, will be investigated. If facts are not presented accurately, Institution will investigate all allegations of misconduct as present or future participants' lives may be endangered. Such investigations will be done in a timely, fair and transparent manner and the results will be made available in the public domain wherever appropriate.

The university has constituted an Institutional Academic integrity Panel (IAIP) for the individual constituent Units of the University that will submit its recommendations to the University Academic Integrity Panel (UAIP). A detailed Plagiarism Policy is also in place.

15.Review of the Policy:

This policy will be reviewed every three years for inclusion of latest developments and revisions as per National and International Guidelines.

16. References :

1. National Ethical Guidelines for biomedical and health research involving human particpants – Indian council of medical research 2017-
https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
2. National Ethical Guidelines for biomedical and health research involving human particpants – Indian council of medical research 2018-
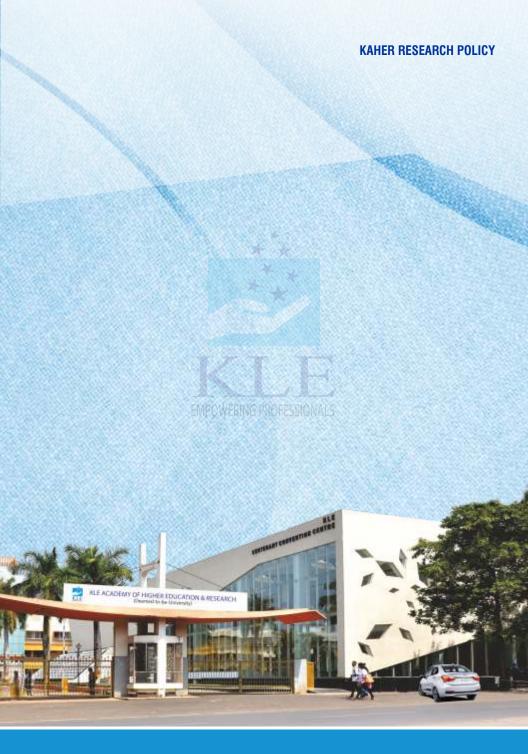https://naitik.gov.in/DHR/resources/app_srv/DHR/global/pdf/downloads/Handbook_on_ICMR_Ethical_Guidelines.pdf
3. ICMR Policy on research Integrity and Publication ethics (2019) :
https://www.icmr.nic.in/sites/default/files/upload_documents/ICMR_policy_ripe.pdf
4. National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During COVID-19 Pandemic guidelines
2020,https://www.icmr.gov.in/pdf/covid/techdoc/EC_Guidance_COVID19_06052020.pdf
5. COPE Guidelines- Good Publication Practices (2000):
https://publicationethics.org/files/u7141/1999pdf13.pdf
6. COPE Guidelines- How to handle authorship issues for new researchers 2018:
https://doi.org/10.24318/cope.2018.1.1
7. The US Office of Research Integrity, Introduction to the responsible conduct of research (2007)
8. WHO Code of conduct for responsible research (2017): https://www.who.int/about/ethics/code-of-conduct-responsible-research.pdf
9. UGC Guidelines for "Promoting and Improving the Quality of Research in Indain Universities" (2019): https://www.ugc.ac.in/pdfnews/5816125_Promoting-and-Improving.pdf
10.The UK Research Integrity Office, Code of Practice for Research: promoting good practice and preventing misconduct (2009) : https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf

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