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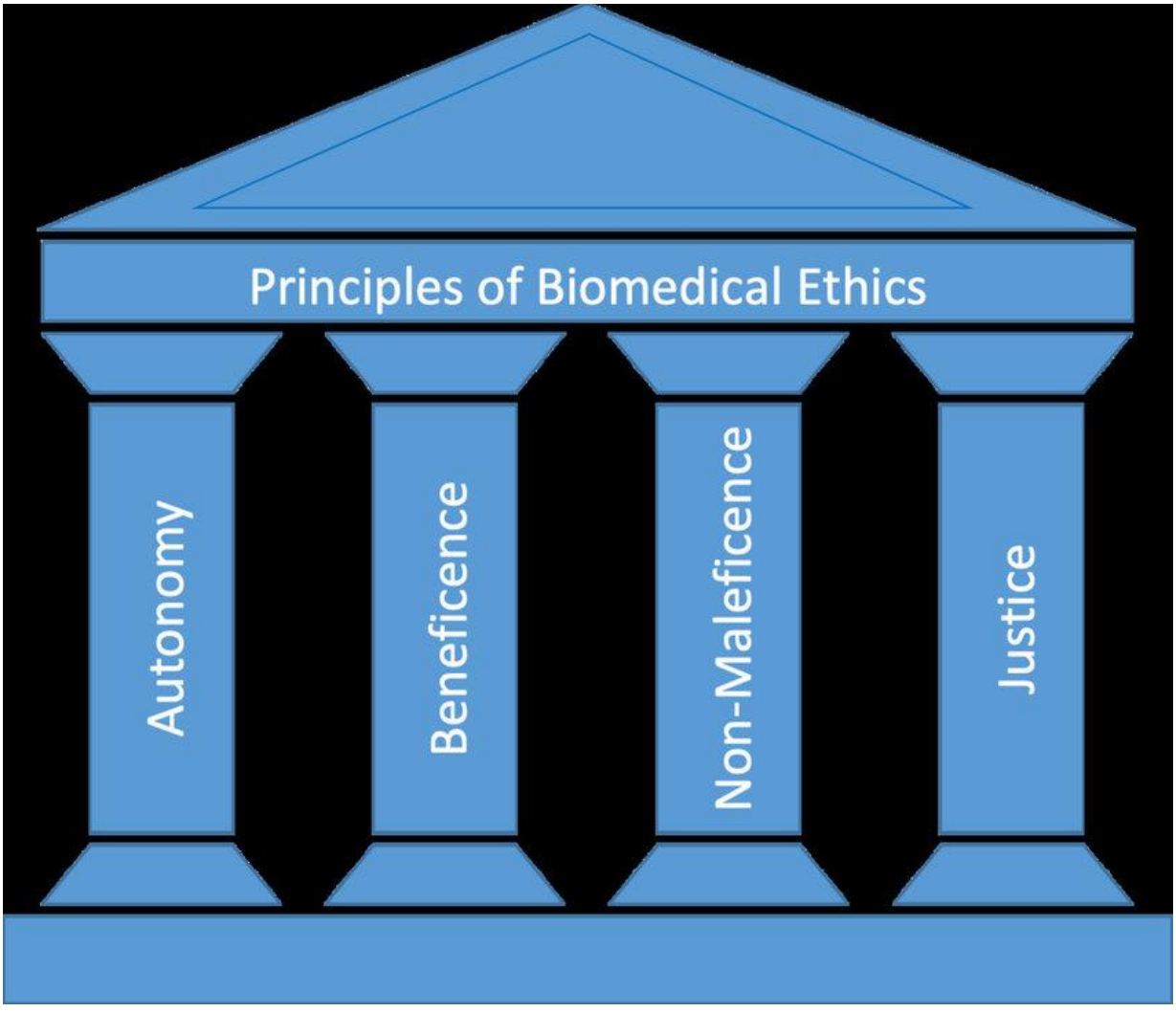
NAAC Accrediatated : ISO Certified 9001-2015, 14001-2015

CODE OF ETHICS



Internal Quality Assurance Cell

Table of Contents

CODE OF ETHICS TO CHECK THE MALPRACTICES AND PLAGIARISM

INTRODUCTION

The prime aim of our institute is to unable staff and students to undertake research projects useful to society, to promote the research culture in the field of Ayurved is the main focus of the research policy of our institute. Hon. Shri. Annasaheb Dange Ayurved Medical College and post Graduate research center, Ashta is committed to promote and maintain high standards of Integrity, honesty and accountability in research and is keen to implant and endorse a culture of trustworthiness and transparency in research. We are trying to allow the academic freedom and innovative thinking.

In October 2017, the Indian Council of Medical Research issued the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. The purpose of these guidelines is to safeguard the dignity, rights, safety and well-being of the human participants involved in biomedical and health research. These guidelines must be followed by all stakeholders including institutions, ethics committees (ECs), researchers and sponsors/ funding agencies.

This handbook provides a quick reference to all 12 sections of the ICMR National Ethical Guidelines, 2017.

MECHANISM FOR PROMOTION OF RESEARCH

The college provides conducive and reflective academic environment to pursue quality research:-

1. The college encourages undertaking research activities by providing infrastructural facilities as research laboratory and Pharmacy, well maintained Dhanwantari Hospital and learning resources.

2. Institute has established the own

    1. College Research Protocol Committee (CRPC)
    2. Met Unit (MET)
    3. Ethical Committee (IEC)
    4. Research Society Committee (RSCT)
    5. Research Health Education Committee (HSET)

    Based upon the recommendations of the above Research Committee, the Institute provides necessary facilities such as conduction of MET, IMETTT, IPR workshops ,help for completion of MD/MS research work, Ph. D. research work, attending workshops, conferences, seminars and visits to research institutes to participate in various research training programs, research competitions.

3. The institute supports the departments for the organization of State level, National and International level conferences, Seminars and workshops.

4. The institute ensures allocation of considerable amount of budget for the purchase of reference books, advanced instruments, online database,

    e-journals on various subjects across all streams. Research journals and magazines are subscribed as per requirement. This includes online journals.

5. The institute staff members and students take up research projects by participating in state level research project competition, 'Avishkar' organised by the university.

6. The institute encourages the staff to participate in research activities by applying for minor research projects to various agencies like DST, CCRAS, MUHS etc. and major research projects to CCRAS,AYUSH.
7. The institute encourages the staff and students to attend and present their research work at State / National / International levels conferences, seminars and workshops, exhibitions.

8. The institute also provides travel fare assistance and the registration fee as an incentive to the staff members.

CODE OF ETHICS REGARDING RESEARCH

1. Conduct all research activities in harmony with the accepted standards given by MUHS and AYUSH.
2. Ensure the precision of all data that has been collected and /or used in the research work. Only the accurate data, information and research results should be reported.
3. Cite and review every source of information through authentic sources.
4. Properly acknowledge and give due credit to the funding source.
5. Provide necessary assistance to other researchers wherever necessary through CRPC.
6. Maintenance of equipments and material resources carried out regularly.
7. Follow norms regarding bioethics , bio-safety and bio-diversity.
8. Avoid plagiarism, piracy and dishonesty in reporting research results and publications.

9. The www.ijooar.com have been published all research work checked through peer reviewed system and plagiarism.
10. The institute holds final authority to initiate an action against any kind of misconduct in research.

CODE OF ETHICS REGARDING PLAGIARISM

Plagiarism represents unethical scientific behavior which is never accepatable.Proper acknowledgement of the work of others used in a research work must always be given. Further, it is obligatory on part of each author to provide prompt corrections of errors in published work.

DEGREES OF PLAGIARISM

1. Duplication
2. Invalid Source
3. Paraphrasing
4. Secondary Source
5. Replication of research work
6. Misleading attribution
7. Unethical collaboration
8. Complete Plagiarism

Possible nature of Ethical violations are may be such as conflict of interest, dispute about authorship, duplicate submission, fabrication of data or results .

The institution checks the plagiarism of research UG, PG & Ph.D. thesis, dissertations, research articles, Research projects etc on online sources.

PLAGIARISM CHECKER SOFTWARE'S

We Purchased www.turntin.com software for plagiarism check and we renewed it every year

Other free softwares we are using are as follows,

1. Plagiarism checker (https://www.plagiarismsoftware.net)
2. quetext (https://www.quetext.com)
3. Duplichecker (https://www.duplichecker.com)
4. Smalltools (https://www.smallstools.com)

ACTION TAKEN FOR DEFAULTERS

Any violation of the rule and other issue complaints regarding plagiarism attracts disciplinary action to be imposed by Ethical committee within one month from the day of compliance. Depending on type of act and violation of code of ethics suitable penalty or punishment, rework against defaulters shall be recommended by the review committee.

STATEMENT OF GENERAL PRINCIPLES

1.1. Every research has some inherent probabilities of harm or risk and thus, protection of research participants and/or communities should be built into the design of the study.

1.2. While conducting biomedical and health research, the four basic principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice must guide research in order to protect the dignity, rights, safety and well-being of research participants.

1.3. ECs must ensure that the research is conducted in accordance with the basic principles.

1.4. The basic principles have been expanded into 12 general principles (Table 1), that are applicable to all biomedical and health research involving human participants or research using their biological material or data.

TABLE 1: GENERAL PRINCIPLES

1. Principle of Essentiality	7. Principle of Professional Competence
2. Principle of Voluntariness	8. Principle of Maximization of Benefit
3. Principle of Non-exploitation	9. Principle of Institutional Arrangements
4. Principle of Social Responsibility	10. Principle of Transparency & Accountability
5. Principle of Ensuring Privacy & Confidentiality	11. Principle of Totality of Responsibility
6. Principle of Risk Minimization	12. Principle of Environmental Protection

GENERAL ETHICAL ISSUES

There are some general issues that must be kept in focus during the conduct of biomedical and health research involving human participants (Table 2).

TABLE 2: GENERAL ETHICAL ISSUES

Benefit–risk assessment	Informed consent process	Privacy and confidentiality
Distributive justice	Payment for participation	Compensation for research related harm
Ancillary care	Conflict of interest	Selection of vulnerable and special groups as research participants
Community engagement	Post-research access and benefit sharing	

2.1. Researchers must protect the dignity, rights, safety and well-being of research participants.

2.2. They should have appropriate qualifications, competence in research methodology andbe compliant towards the scientific, medical, ethical, legal and social requirements of research.

2.3. The researcher, sponsor and EC must conduct a benefit–risk assessment and actively attempt to maximize benefits and minimize risks to participants.

2.4. Benefits to the individual, community or society refer to any sort of favourable outcomeof the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.

2.5. Risk can be categorized as less than minimal risk, minimal risk, minor increase over minimal or low risk and more than minimal or high risk.

2.6. The EC must decide about the type of review required (exempted, expedited, full committee) based on the type of risk involved.

2.7. The researcher must obtain informed consent from the participant/legally acceptable/ authorized representative (LAR) in writing.

2.8. Informed consent documents (participant information sheet and informed consent form) should carry the specified elements in simple, layman's language. These documents should be approved by the EC.

2.9. Oral consent/waiver of consent/re-consent may be obtained under certain conditions, after due approval by the EC.

2.10. Researcher(s) should safeguard the privacy and confidentiality of participants and research-related data from unauthorized access.

2.11. Benefits and burdens of research should be equitably distributed among the participatingindividuals or communities.

2.12. Participants should not be made to pay for research-related expenses incurred beyondroutine clinical care. Reimbursement for expenses incurred can be made in cash or kindor both.

2.13. The researcher must report all serious adverse events (SAEs) to the EC within 24 hoursof knowledge and submit a report on SAE relatedness to research within 14 days.

2.14. Research participants who suffer direct physical, psychological, social, legal or economic harm are entitled to financial compensation or other forms of assistance.

2.15. It is the responsibility of the sponsor (whether a pharmaceutical company,

government or non-governmental organization (NGO), national or international/bilateral/multilateral donor agency/institution) to include insurance coverage or provision for possible compensation for research related injury or harm within the budget.

2.16. In investigator initiated/student research, the investigator/institution where the research is conducted becomes the sponsor and must provide compensation for research-related injury through insurance, corpus funds or grants.

2.17. Free medical care may be offered as ancillary care for non-research-related conditions or incidental findings if it does not amount to undue inducement as determined by EC.

2.18. Policies for declaration and management of financial or non-financial (personal, academic or political) conflict of interest for researchers, EC, institution and sponsor must be implemented by research institutes.

2.19. The selection of vulnerable and special groups needs careful consideration, with provisions for additional safeguards and close monitoring.

2.20. Engaging with the community from the beginning of research till after its completion helps to improve design and conduct of research and ensures greater responsiveness to health needs. However, every individual participant's consent is essential.

2.21. Post-research access and benefit-sharing may be done with individuals, communities and populations, wherever applicable after completion of study.

RESPONSIBLE CONDUCT OF RESEARCH (RCR)

3.1. Major components of RCR are values and policies; planning and conducting research; reviewing and reporting research; responsible authorship and publication aspects.

3.2. A research office must be set up to facilitate research, manage grants and provide research oversight.

3.3. Institutions must have policies for the protection of participants and should assignresponsibilities to stakeholders.

3.4. Researchers must follow professional codes of conduct and have personal convictionabout ethical requirements.

3.5. The following should be established prior to conducting research:

- Conflict of Interest policies
- Safeguards for data acquisition, management, sharing and ownership
- Policies for handling research misconduct including fabrication, falsification andplagiarism

3.6. Completed research, irrespective of results, must be published in accordance with theguidelines of the International Committee of Medical Journal Editors (ICMJE).

3.7. Clinical studies on human participants should be registered prospectively with the Clinical Trial Registry - India (CTRI). This is mandatory for regulatory trials.

3.8. Issues related to ownership, sharing of materials/data, IPR, joint publications, researchfindings, conflict of interest, commercialization should be addressed in collaborative research.

3.9. The ethical framework of international collaborations should be based on equity and equality. Researchers and EC members should be trained to protect the best interests of the country.

3.10. In multicentre research, common ethics review by a designated EC can help to reduce time for getting ethical approvals from across the sites and improve coordination among participating sites. However, the local EC must look at site specific concerns and monitor research.

ETHICAL REVIEW PROCEDURES

4.1. ECs must safeguard the dignity, rights, safety and well-being of research participants and review research before initiation.

4.2. The EC is responsible for scientific and ethical review of research proposals and shouldhave well defined standard operating procedures (SOPs) for all functions.

4.3. Each member of the EC has a defined role and responsibility. EC members should be trained in protection of human research participants, SOP and Good Clinical Practice (GCP) guidelines, and be conversant with relevant ethical guidelines and regulations.

Composition, affiliations and qualifications given in Table: 3

TABLE 3: COMPOSITION, AFFILIATIONS AND QUALIFICATIONS OF EC MEMBERS

Members of EC	Qualifications
Chairperson/ Vice Chairperson (optional) Non-affiliated	• A well-respected person from any background with prior experience of having served/serving in an EC
Member Secretary/ Alternate Member Secretary (optional) Affiliated	• Should be a staff member of the institution • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills • Should be able to devote adequate time to this activity which should be protected by the institution
Basic Medical Scientist(s) Affiliated/ non-affiliated	• Non-medical or medical person with qualifications in basic medical sciences • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist
Clinician(s) Affiliated/ non-affiliated	• Should be individual/s with recognized medical qualification, expertise and training
Legal expert/s Affiliated/ non-affiliated	• Should have a basic degree in Law from a recognized university, with experience • Desirable: Training in medical law.

Social scientist/ philosopher/ ethicist/theologian Affiliated/ non-affiliated	• Should be an individual with social/behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities
Lay person(s) Non-affiliated	• Literate person who has not pursued a medical science/ healthrelated career in the last 5 years • May be a representative of the community and aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities

4.4. The EC should be multidisciplinary, competent and independent in its functioning with the chairperson and 50% members as non-affiliates.

4.5. The quorum for decision-making should have a minimum of five members, including both medical and non-medical or technical/non-technical members with at least one ofthem as non-affiliated member.

4.6. EC members should be aware of local, social and cultural norms and emerging ethicalissues.

4.7. Larger institutions can have more than one EC while smaller institutions may utilize the services of other institutions under an MoU.

4.8. An EC could have subcommittees with additional members, if necessary, e.g., SAE subcommittee or expedited review committee.

4.9. The institutional head appoints the EC and acts as the appellate authority.

4.10. The EC secretariat should screen proposals for completeness before

categorizing as: exempted from review, expedited review or full committee review.

4.11. The EC reviews every study protocol for ethical issues as given in Table 4:

TABLE 4: ETHICAL ISSUES RELATED TO REVIEWING A PROTOCOL

• Social values	• Scientific design and conduct of study
• Benefit–risk assessment	• Selection and recruitment of participants
• Payment for participation	• Protection of privacy and confidentiality
• Community considerations	• Review of informed consent process
• Disclosure of conflict of interest	• Qualification of researchers and adequacy of study sites
• Plans for medical management and compensation for study related injury	

4.12. The EC monitors progress of ongoing proposals, reviews SAEs, protocol deviations/ violations, new information and final reports.

4.13. An EC office must have space, infrastructure, funds, staff and protected time for the member secretary to coordinate EC functions.

4.14. EC documentation should be dated, filed and preserved. Records must be archived for at least 3 years (5 years for regulatory clinical trials) after completion/termination of the study.

4.15. ECs should be registered with the relevant authority and should make efforts to seek recognition or accreditation.

INFORMED CONSENT PROCESS

5.1. Voluntary written informed consent should be obtained in an informed consent document (ICD) from each participant to protect each individual's freedom of choice.

5.2. Informed consent is a continuous process involving three main components:

- Providing relevant information to potential participants
- Ensuring competence and comprehension of the information and
- Voluntariness of participation

TABLE 5: CHARACTERISTICS OF AN ICD

Elements of an ICD	Additional elements (optional)
1. Statement mentioning that it is research	1. Alternative procedures or treatment
2. Purpose and methods	2. Insurance coverage
3. Duration, frequency, methods	3. Possible stigmatizing condition
4. Benefits to participant, community or others	4. Biological material and data, including:
5. Foreseeable risks, discomfort or inconvenience	i) Current and future uses
6. Confidentiality of records	ii) Period of storage and secondary use
7.Payment/reimbursement for participation	iii) Sharing of data and biological materials
8. Treatment and/or compensation for injury	iv) Right to prevent use of biological sample
9. Freedom to participate/withdraw	v) Provisions to safeguard confidentiality
10. Identity of research team and contact	vi) Post-research plan/benefit sharing

persons	
	vii) Publication plan/photographs/pedigrees

5.3. Researchers should only use the EC approved version of the consent form and itstranslation in local languages.

5.4. Informed consent should be voluntary and be signed by the participant after receiving information, understanding it and discussing with family/friends (if required).

5.5. Verbal/oral consent/waiver of consent/reconsent may be obtained only after approval by the EC. Table 6 gives conditions for granting waiver of consent.

TABLE 6: CONDITIONS FOR GRANTING WAIVER OF CONSENT

The EC may grant consent waiver in the following situations:
• **research cannot practically be carried out without the waiver and the waiver is scientifically justified;**
• **retrospective studies, where the participants are de-identified or cannot be contacted;**
• **research on anonymized biological samples/data;**
• **certain types of public health studies/surveillance programmes/programme evaluationstudies;**
• **research on data available in the public domain; or**
• **research during humanitarian emergencies and disasters, when the participant may not be in aposition to give consent. Attempt should be made to obtain the participant's consent at the earliest.**

5.6. Appropriate ICD should be prepared for differently abled participants.

5.7. In case of research involving children, in addition to parental consent, verbal (7-12 years)or simplified written (>12 – 18 years) assent should also be taken from the participant.

5.8. The LAR's consent is required in case a participant is incompetent (medically or legally).

5.9. Electronic/online consent may be obtained for research involving sensitive topics while safeguarding information and data and also if required for regulatory clinical trials.

5.10. Individual consent is important and required, even if the community gives permissionfor participation in a research study.

5.11. In studies using deception a true informed consent may lead to modification and maydefeat the purpose of research. Such research should be carefully reviewed by the EC before implementation. In such instances, an attempt should be made to debrief the participants/communities after completion of the research.

VULNERABILITY

Individuals/ groups/ populations are considered vulnerable if they are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or other reasons. Individuals are considered to be vulnerable if they are:

- Socially, economically or politically disadvantaged and susceptible to exploitation
- Incapable of making a voluntary informed decision for themselves or if their autonomy is compromised temporarily or permanently (e.g., people who are unconscious, differently abled)
- Able to give consent, but their voluntariness or understanding is compromised due to their situational conditions
- Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate, which may lead them to give consent

6.1. Researchers must justify the inclusion/exclusion of a vulnerable population.

6.2. A community representative may be invited to EC meetings to make sure the researchis responsive to their needs and the informed consent process is appropriate.

6.3. Additional precautions should be taken by all stakeholders such as researchers, ECsand sponsors to avoid exploitation of vulnerable participants.

6.4. Informed consent process should be well documented and additional measures adopted if required, such as audiovisual/audio recording of assent/consent/reconsent.

6.5. Research proposals should undergo review in a full committee meeting.

6.6. Protection of privacy and dignity as well as provision of quality health care is requiredin dealing with vulnerable people, especially the minorities.

6.7. Research involving children, in addition, should follow the National Ethical Guidelinesfor Biomedical Research Involving Children, ICMR, 2017.

6.8. Due approvals are needed from competent authorities before entering tribal areas.

6.9. Research involving cognitively impaired individuals or those with mental illness mustbe done carefully, especially if there is risk to themselves, to others or suicidal ideation.

6.10. The EC should carry out the benefit–risk analysis and examine risk minimization strategies.

THE BIOMEDICAL AND HEALTH RESEARCHRELATED CLAUSES EXTRACTED FROM NEW DRUGS AND CLINICAL TRIALS RULES-2019

The following are all relevant clauses extracted from New Drugs & Clinical Trials Rules- 2019 whichare having reference to ICMR National Ethical Guidelines.

Preliminary

Biomedical and health research means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioural); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial as defined in New Drugs & Clinical Trials Rules- 2019

Clinical Trial in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,-

- clinical or;
- pharmacological including pharmacodynamics, pharmacokinetics or;
- adverse effects,

Ethics Committee means, for the purpose of, -

(i) clinical trial, Ethics Committee, constituted under rule 7 and registered under rule 8;

(ii) biomedical and health research, Ethics Committee, constituted under rule 16 and registeredunder rule 17;

ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH

Ethics Committee for biomedical and health research: Any institution or organization which intends to conduct biomedical and health research shall be required to have an Ethics Committee to review and oversee the conduct of such research as detailed in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

CONSTITUTION OF ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH.

1. The Ethics Committee referred to in rule 15, relating to biomedical and health research shall be constituted in accordance with the National Ethical Guidelines for Biomedical and Health

Research Involving Human Participants as may be specified by the Indian Council of Medical Research from timeto time and shall function in accordance with said guidelines.

2. The Ethics Committee referred to in sub-rule (1), shall review the work of the biomedical and healthresearch centre before initiation and oversee throughout the duration of the biomedical and health research as per National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.
3. An institution or organisation or any person shall conduct any biomedical and health research withthe approval of the Ethics Committee for biomedical and health research registered under rule 17.
4. Any biomedical and health research shall be conducted in accordance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants as may be specified by the Indian Council of Medical Research from time to time.
5. Institutions desirous of conducting biomedical and health research as well as clinical trials or bioavailability or bioequivalence study shall require obtaining registration from specified authorities as provided in rule 8 and rule 17.

REGISTRATION OF ETHICS COMMITTEE RELATED TO BIOMEDICAL AND HEALTH RESEARCH.

1. An Ethics Committee constituted under rule 16, shall be required to register with the authority designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research under these rules for which an application shall be made in Form CT-01 to the said authority.
2. The application referred to in sub-rule (1) shall be accompanied with the information and documents as specified in Table 1 of the Third Schedule.
3. On receipt of application in Form CT-01 under sub-rule (1), the authority designated under sub- rule (1) shall grant provisional registration which shall remain valid for a period of two years.
4. After the grant of provisional registration under sub-rule (3), the authority designated under

sub- rule (1) shall scrutinise the documents and information furnished with the application, and if satisfied that the requirements of these rules have been complied with, grant final registration to Ethics Committee in Form CT-03; or if not satisfied, reject the application, for reasons to be recorded in writing and the final registration in Form CT-03 shall supersede the provisionalregistration granted under sub-rule (3).

5. An applicant who is aggrieved by the decision of the authority designated under sub-rule (1), mayfile an appeal within sixty working days from the date of receipt of such rejection before the Central Government in the Ministry of Health and Family Welfare, and the Central Government, may, aftersuch enquiry as is considered necessary in the facts and circumstances of the case, and after givingan opportunity of being heard to the appellant, dispose of the appeal within a period of sixty working days.
6. The Ethics Committee shall make an application for renewal of registration in Form CT-01 along with documents as specified in sub-rule (2) at least ninety days prior to the date of the expiry of itsfinal registration: Provided that if the application for renewal of registration is received by the authority designated under sub-rule (1), ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on the application: Provided further that fresh set of documents shall not be required to be furnished, if there are nochanges in such documents furnished at the time of grant of final registration, and if the applicantrenders a certificate to that effect indicating that there is no change.
7. The authority designated under sub-rule (1) shall after scrutiny of information furnished with the application and after such further enquiry, as considered necessary and on being satisfied that therequirements of these rules have been complied with, renew the registration of Ethics Committeein Form CT-03, or if not reject the application, for reasons to be recorded in writing.
8. The authority shall take a decision under sub-rule (7) within a period of forty-five working days, from the date of application made under sub-rule (1).
9. The registration granted in Form CT-03 shall remain valid for a period of five years from the date of its issue, unless suspended or cancelled by the authority designated under sub-rule (1).
10. The function, proceedings of ethics committee and maintenance of records shall be as per the

National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

11. In case there is a change in composition of registered Ethics Committee in an institution it shall be reported to the authority designated under sub-rule (1).

SUSPENSION OR CANCELLATION OF REGISTRATION OF ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTHRESEARCH.

1. Subject to provisions of rule 17, where the Ethics Committee fails to comply with any provision ofthese rules, the authority designated under sub-rule (1), may, after giving an opportunity to show cause and after affording an opportunity of being heard, by an order in writing, take one or more of the following actions, namely:
    a. issue warning to the Ethics Committee describing the deficiency or defect observed, whichmay adversely affect the rights or well-being of the study subjects;
    b. suspend for such period as considered appropriate or cancel the registration issued underrule 17;
    c. debar its members to oversee any biomedical health research in future for such period asmay be considered appropriate.
2. Where the Ethics Committee or its member, as the case may be, is aggrieved by an order of the authority designated under sub-rule (1), it may, within a period of forty-five working days of the receipt of the order, make an appeal to the Central Government in the Ministry of Health and Family Welfare, and that Government may, after such enquiry, as deemed necessary, and after giving an opportunity of being heard, pass such order in relation thereto as may be considered appropriate in the facts and circumstances of the case.

CLINICAL TRIAL, BIOAVAILABILITY AND BIOEQUIVALENCE STUDY OF NEW DRUGS AND INVESTIGATIONAL NEW DRUGS

PART A - CLINICAL TRIAL

CONDITIONS OF PERMISSION FOR CONDUCT OF CLINICAL TRIAL

1. clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial;in case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;
2. in case of clinical trial related death or permanent disability of any subject of such trial during thetrial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

ACADEMIC CLINICAL TRIAL

1. No permission for conducting an academic clinical trial shall be required for any drug from theCentral Licencing Authority where,
    a. the clinical trial in respect of the permitted drug formulation is intended solely for academicresearch purposes for a new indication or new route of administration or new dose or new dosage form; and
    b. the clinical trial referred to in clause (i) has been initiated after prior approval by the EthicsCommittee for clinical trial; and
    c. the observations generated from such clinical trial are not required to be submitted to theCentral Licencing Authority; and
    d. the observations of such clinical trial are not used for promotional purposes.
2. In the event of a possible overlap between the academic clinical trial and clinical trial or a doubt on the nature of study, the Ethics Committee concerned shall inform the Central Licencing Authority in writing indicating its views within thirty working days from the receipt of application to that effect.
3. The Central Licencing Authority shall, after receiving the communication from the Ethics Committee referred to in sub-rule (2), examine it and issue necessary clarification, in

writing, within thirty working days from the date of receipt of such communication: Provided that where the Central Licencing Authority does not send the required communication to such Ethics Committee within thirtyworking days from the date of receipt of communication from the said Ethics Committee, it shall be presumed that no permission from the Central Licencing Authority is required.

4. The approved academic clinical trial shall be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, notified by the Indian Council of Medical Research with a viewto ensuring protection of rights, safety and wellbeing of trial subject during conduct of clinical trial oflicenced and approved drug or drug formulation for any new indication or new route of administrationor new dose or new dosage form for academic research purposes.

COMPENSATION

Compensation in case of injury or death in clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug. (1) Where any death of a trial subject occurs during a clinicaltrial or bioavailability or bioequivalence study, the legal heir of the trial subject shall be provided financial compensation by the sponsor or its representative, who has obtained permission to conductthe clinical trial or bioavailability or bioequivalence study, in accordance with the procedure specifiedin rule 42.

Procedure for compensation in case of injury or death during clinical trial, bioavailability and bioequivalence study.- (1) The investigator shall report all serious adverse events to the CentralLicencing Authority, the sponsor or its representative, who has obtained permission from the CentralLicencing Authority for conduct of clinical trial or bioavailability or bioequivalence study, as the casemay be, and the Ethics Committee that accorded approval to the study protocol, within twenty-fourhours of their occurrence; and if the investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reasons for delay to the satisfaction of the Central Licencing Authority along with the report of the serious adverse event.

Medical management and compensation for injury or death relating to biomedical and health research overseen by an Ethics Committee for biomedical and health research as referred to in Chapter IV.

Not with standing anything contained in these rules, medical management and compensation for injuryor death relating to biomedical and health research, overseen by an Ethics Committee for clinical trials as referred to in Chapter IV, shall be in accordance with the National Ethical Guidelines for Biomedicaland Health Research Involving Human Participants specified by the Indian Council of Medical Researchfrom time to time.

ICMR POLICY ON RESEARCH INTEGRITYAND 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 her/his 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 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 pernorms 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. 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 toprotect 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. The RIO in consultation with RIU should make sure that their respective Institute, Centre orDivision 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 forneedful 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) toethics 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 outcomeand 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 orany other material considered relevant to the inquiry.

- If misconduct has not happened, complaint will be closed and details will be 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, 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 ona case to case basis. Every effort should be made to safeguard interests of the complainant andrespondent.

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 (1month).

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 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.

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..... Hereby, 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.
- ☐ Conflicts of Interest 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 ofthe 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 discloseresults 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 inaccuraterepresentation.
- **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.
- **Lead Investigator:** The scientist/researcher who is in charge of a research document; usuallyprepares 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.
- **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 asone'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 copiedor seven to eleven words are overlapping set of 30 letters.
- **Professional competence:** The broad professional knowledge, attitude and skills required inorder to work in a specialized area or profession.
- **Research document:** Any research manuscript, research paper, conference paper, oral presen-tation, 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 standardsessential 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

sucha way that it is easy for others to see what actions are performed.

ANNEXURE III

GUIDELINES FOR AVOIDING PLAGIARISM:

- "Acknowledgement" is the ethically right manner of crediting someone else's work. In case ofverbatim 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/hisown words in a summarised version by providing appropriate citation.
- Manipulating references is considered malpractice and is unacceptable. References used in apaper 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 someone's work without acknowledging the original author.
- **Self-Plagiarism:** A situation where the person duplicates his previous works or sentences usedin 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 forgets to cite the original source or referto 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 similarmanuscripts/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 predatory journals within a very short span of time without valid peer review and editorial board in last consecutive years. The predatory 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 Scientistsand ICMR network of Institutes to remain vigilant and may report from time to time the namesand 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 RIUfor creating a central register which can be updated based on inputs from ICMR institutes.

ANNEXURE V

List of relevant National and International guidelines

Organization	Document
International	
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
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
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
CONSORT	• CONSORT, encompasses various initiatives to alleviate the problems arising frominadequate 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
	•
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	
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

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
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

GUIDELINES AND RECOMMENDATIONS

The problem of publication ethics and predatory journals is very serious and is a global phenomenon. However, there cannot be centralized policy or solution. Each country / region, every University / institute may have to come out with its own guidelines. The committee feels that good research publication need good quality research, which can happen with enquiry, investigation, innovation and hard work. The desperation to publish poor quality work, plagiarized or fudged data in dubious journals will bring in the long run only disgrace to individuals, institutions and countries, which must be avoided.

The committee is convinced that there is an immediate need to control publications in spurious / bogus predatory journals, periodicals etc. The committee feels that the present policy of the University to strengthen research culture by providing support from its own resources is good, however more stringent methods are needed to evaluate impact and outcome of research. The committee therefore recommends the following as a policy to encourage responsible research and ethical publishing:

1. Generally, those journals which are regularly published at least for consecutive five years, do not guarantee publication in short time at cost consideration, publish true and correct information on websites, have reputed academicians on editorial boards and are members of reputed bodies like COPE can be considered as good journals and research publications in such journals can be considered for academic purposes. Papers published in private in-house journals, proceedings of workshops, seminars, refresher/orientation courses should not be considered as research publications.
2. In accordance with the UGC Regulations 2010 our University should develop comprehensive faculty-wise list of quality Journals and reputed publisher in each subject. This should be used as reference when dealing with research guides recognition, PhD / M.Phil submissions, selection, confirmation, increments, career advancement, as well as for considering scores under categories III A and B of the API.
3. To qualify individual publications in peer reviewed / reputed / refereed journals mere

ISSN number is not sufficient. The publisher / journal should be indexed in globally accepted databases, should preferably be members of reputed bodies like COPE and must follow publication ethics in a transparent manner where all true, correct and vital information is available on the journal website.

4. A good journal that complies with ethics in publishing, which is indexed in reputed agencies like Scopus, Web of Science, Science Direct, Pubmed, SSRN etc should be considered as a reputed journals. Various types of tools and metrics developed by reputed agencies like Thomson Reuters (Science Citation Index, Impact Factor), Scopus, Scimago (*h* index, SJR) are few of the reliable indicators. Record of citations to a particular publication in other reputed journals is also a very useful parameter to judge quality of a research paper. In open access, Google Scholar offers citation records and *h*5-index, which can also be considered in primary evaluation. However, it should be kept in mind that many predatory / bogus journals have managed to enter Google Scholar. Therefore, it is always better not to rely on any single metrics agency but it is best to ensure that the Journals are indexed in at least three of the reputed indexing / metrics agencies and databases.
5. Research publications in Marathi, Hindi and other languages constitute an important aspect especially for the Faculties of Arts, Fine Arts, Humanities and Social Sciences. Due recognition to Marathi and other language journals should be given. The modalities to identify reputed research journals in Marathi and other languages shouldbe decided by a committee of senior social science professors together with external national experts duly approved by the Vice Chancellor.
6. The faculty-wise lists should be developed by independent committees to be appointed by Vice Chancellor consisting of senior professors from University and external experts including national research professors, Directors of National Institutes, Fellows of National Academies and such other distinguished academicians.Journals published by National Academies, National Institutions and National Societies should be recognized. These lists should be updated every year and shouldbe published in annual reports and displayed prominently on the University website.
7. Classification of Journals like national or international and ranking merely based on

8. impact factors is not relevant today especially because large number of predatory journals with names starting with 'international' 'global', 'world' etc are in plenty as also several counterfeit impact factor agencies are in existence. Because many counterfeits and spurious agencies have cropped up giving fake *h* index and impact factors, utmost care needs to be taken before including any journal in the official listof the University.
9. Many fake indexing agencies, societies, academies have created false identity to sound / appear similar to reputed agencies. Beall's list provide primary guidance and information on predatory publishers, predatory standalone journals, misleading metrics companies and hijacked journals http://scholarlyoa.com/2015/01/02/bealls-list-of-predatory-publishers-2015/ .
10. Very careful due diligence should be done while developing a comprehensive faculty-wise list of approved journals. For this purpose following guidelines should be followed:
    a. For Faculty of Science, Engineering, Pharmacy, Medicine: Web of Science, Scopus, Scholar, Pubmed, Scifinder, Chemical Abstract Services, Biological Abstracts and such other reputed indexing agencies as recommended by a committee of Deans, senior professors and external experts as approved by the Vice Chancellor.
    b. For Faculty of Social Sciences and Humanities: Social Science Research Network (SSRN) and such other reputed indexing agencies as recommended by a committee of Deans, senior professors and external experts as approvedby the Vice Chancellor.
    c. For Faculties of Management, Commerce, Law, Education, Physical Education, recommended by a committee of Deans, senior professors and external experts as approved by the Vice Chancellor.
    d. For Faculty of Arts and Fine Arts, Deans and senior professors should recommend to Vice Chancellor for approval suitable system for judging publications, performances or such other means.
    e. As a regional University in Maharashtra, creation and dissemination of knowledge in Marathi is an important mandate of our University. Therefore,

the University should appreciate publication of quality research in Marathi. This should also be applicable to Hindi and other languages as well as disciplines from humanities and social sciences wherever applicable.

11. Jayakar Library should critically review its present list of subscribed Journals. It should maintain list of spurious publishers and predatory Journals. For this purpose Beall's List and other available reliable sources should be considered. Further, Jayakar Library may seek information on such fraud journals from the teaching community as and when they come across such journals. In this manner, the teachingcommunity can assist the library to make and maintain a database of such journals onthe library web portal. Jayakar Library should not deal with such publishers and should not subscribe any such spurious/ predatory Journals, databases and indexing agencies.
12. A committee of senior professors should develop a module of about four lectures on Publication Ethics, which should be part of library orientation course, pre-PhD course,research methodology or similar courses under every faculty. This work may be coordinated by IQAC Cell in association with Jayakar Library and Department ofLibrary and Information Sciences.
13. Research publication ethics and guidelines should be widely circulated and undertaking should be obtained from PhD guides and the research students, stating that he/she has understood the guidelines and violating them can lead to appropriate actions by the University.
14. As a good publication practice, manuscripts proposed to be published as research articles, thesis, dissertation may preferably go through screening by individual Departmental Research Committee consisting internal and external experts duly approved by the Vice-Chancellor. All such research manuscripts should be scanned through reputed anti-plagiarism software like Turnitin, which our University has subscribed.
15. Our University should create more awareness about predatory publishers and importance of publication ethics so that faculty and students are encouraged to do high quality rigorous research and not succumb to desperation to publish poor qualitywork by taking short cuts and easy ways.
16. Quality of any publication can be best judged after considering amount of work, rigor,

17. methodology, novelty etc, which can be evaluated by external experts in the field in an anonymous manner. As a long term policy, the University should strengthen its research culture and bring stringent external peer review system to critically evaluate its research output.
18. These guidelines and comprehensive faculty-wise lists of Journals in each subject should be published in the University Annual Report and prominently displayed on the University website for creating awareness and dissemination of information.

In conclusion, at present we are witnessing serious issues related to professionalism verses amateurism. The 21stcentury knowledge society demands open, transparent, objective and unbiased evaluation. It is necessary to develop right strategy, conducive environments and suitable methodologies. In the digital world, the decisions regarding quality of academic and research contributions could also be enabled by networked communities of scholars across the Universities and countries. The national Academies, Societies and international bodies like COPE can play important role in this process.

At present, increasing number of publications in most Indian Universities are coming out of compulsion. This could be for selection, increments, career advancement, assessments or for seeking higher qualifications like MPhil/ PhD. This can lead to desperation to publish and temptation to explore short cuts and easy ways. It is necessary for Universities change present system of number driven assessment and give more emphasis on quality of papers than mere quantity of papers. Institutes of national importance like IISER do not require any specified number of publications before submitting a PhD thesis. However, the rigorous training, continuous assessment, able mentorship and institutional culture empowers research students to perform with best capabilities where quality publications naturally emerge. For University like ours with large number of students, diverse disciplines and relatively limited resources, this might be a difficult task but has to be addressed on priority.

The committee wish to recognize integrity and hard work of many faculty members and students of our University who are bringing excellence despite many constrains. This is visible from high *h* index of our University. However, our University has potential to do much more. We need to gradually evolve conducive environments to nurture a culture of reading, thinking, questioning, inquisitiveness, enquiry, investigation and innovation where

high quality research becomes a pleasure. As rightly stated in an editorial of Proceedings of Indian National Science Academy, "why we publish, what we publish and where we publish should be our pleasure and not compulsion"[12].

ETHICAL CONCERN MATTERS IN RESEARCH

1. Plagiarism

Authors who present the words, data, or ideas of others with the implication that theyown the same, without attribution in a form appropriate for the medium of presentation, are committing theft of intellectual property and may be guilty of plagiarism and thus of research misconduct. This statement applies to reviews and to methodological and background/historical sections of research papers as well as to original research results or interpretations. If there is a word-for-word copying beyond a short phrase or six or seven words of someone else's text, that section should be enclosed in quotation marks or indented and referenced, at the location in the manuscript of the copied material, to the original source. The same rules apply to grant applications and proposals, to clinical research protocols, and to student papers submitted for academic credit. Not only does plagiarism violate the standardcode of conduct governing all researchers, but in many cases it could constitute an infraction of the law by infringing on a copyright held by the original author or publisher.

The work of others should be cited or credited, whether published or unpublished and whether it had been written work, an oral presentation, or material on a website.Each journal or publisher may specify the particular form of appropriate citation. Oneneed not provide citations, however, in the case of well-established concepts that may be found in common textbooks or in the case of phrases which describe a commonly-used methodology. Special rules have been developed for citing electronic information.

2. Use and Misuse of Data

Research integrity requires not only that reported conclusions are based on accurately recorded data or observations but that all relevant observations are reported. It is considered a breach of research integrity to fail to report data that contradict or merely fail to support the reported conclusions, including the purposeful withholding of information about confounding factors. If

some data should be disregarded for a stated reason, confirmed by an approved statistical test for neglecting outliers, the reason should be stated in the published accounts. A large background of negative results must be reported. Any intentional or reckless disregard for the truth in reporting observations may be considered to be an act of research misconduct.

3. Ownership of and Access to Data

Research data obtained in studies performed at the Institution by employees of the Institution are not the property of the researcher who generated or observed them or even of the principal investigator of the research group. They belong to the Institution, which can be held accountable for the integrity of the data even if the researchers have left the Institution. Another reason for the Institution claim to ownership of research data is that the Institution, not the individual researcher, is thegrantee of sponsored research awards. Reasonable access to data, however, shouldnormally not be denied to any member of the research group in which the data were collected. If there is any possibility that a copyright or patent application might emerge from the group project, a written agreement within the group should specify the rights, if any, of each member of the group to the intellectual property. A researcher who has made a finding which may be patentable should file an InventionDisclosure with the Office of Technology Management.

A principal investigator who leaves the Institution is entitled to make a copy of data totake to another institution so as to be able to continue the research or, in some cases, to take the original data, with a written agreement to make them available to the Institution on request within a stated time period. A formal Agreement on Disposition of Research Data should be negotiated in such cases through the Office of Research. Each student, postdoctoral fellow, or other investigator in a group project should come to an understanding with the research director or principal investigator, preferably in writing, about which parts of the project he or she might continue to explore after leaving the research group. Such an understanding shouldspecify the extent to which a copy of research data may be taken. Co-investigators at another institution are entitled to access the data which they helped to obtain.

Since the scientific enterprise may be a cooperative endeavor encompassing many persons who now or in the future might pursue related research interests, and since it is in the interest of all to rely on the contributions and findings of others, every investigator has an obligation to the general scientific community to cooperate by sharing of data. Other virtues of sharing data include the

facilitation of independent confirmation or refutation of reported outcomes. It is generally accepted that the data underlying a research publication should be made available to other responsible investigators upon request after the research results have been published or accepted for publication.

4. Authorship and Other Publication Issues

Publication of research results is important as a means of communicating to the scholarly world so that readers may be informed of research results and other researchers may build on the reported findings. In fact, it is an ethical obligation for an investigator at the Institution to make research findings accessible, in a manner consistent with the relevant standards of publication. The reported data and methodsshould be sufficiently detailed so that other researchers could attempt to replicate theresults. Publication should be timely but should not be hastened unduly if premature publication involves a risk of not subjecting all results to adequate internal confirmation or of not considering adequately all possible interpretations.A commercial sponsor of a research project may not have a veto over a decision topublish, but a delay of publication for an agreed period, not to exceed six months, may be allowed in order to permit filing of a patent application.

a. Criteria for Authorship

Since academic work is informed by a multitude of sources offering concepts and information, it is essential to emphasize rightful acknowledgement in the presentationof ideas and the publication of manuscripts. Authorship should be awarded only to those persons who have made an original and significant contribution to the conceptualisation, design, execution and interpretation of the published work.

Individuals who have made smaller contributions by for instance giving advice performing analyses or providing subject material, or who have supported the research in some other way, should also be acknowledged. The principal author should determine whether or not these individuals should be included as authors.Sometimes written permission has to be obtained for acknowledgement in the published work and even the format thereof is prescribed by the party concerned.

In the case of co-authorship, questions arise as to the criteria for inclusion as author,the

ability of each author to evaluate all aspects of the study and the sequence of the list of authors. Authors should discuss these questions openly and should make appointments before undertaking a co-author project. The author submitting the work, or the principal author, is responsible for coordinating the completion and submission of the work and for ensuring that all the contributions and all the collaborators are given proper acknowledgement. All authors should approve thefinal version of the manuscript and should be prepared to accept responsibility forthe work in public.

Each author or co-author is responsible for the compilation, revision and verification on those parts of the manuscript, publication or presentation representing his/her contribution. All co-authors are entitled to making their own copies thereof, includingfigures and attached documents.

In factual or scientific reports, authors should go out of their way to quote applicabledata, including those data not supporting the hypothesis proposed. It is the responsibility of the author(s) to be *au fait* with other appropriate publications and toquote from them.

It is unethical, and harmful to the academy, to present as one's own the work of others, whether in part or in full, to fabricate research results or to omit or changeinformation.

Authors who wish to quote information obtained at a personal level or from unpublished written material should obtain written permission from the source.

It is inappropriate and unacceptable to submit extracts from research, or reports on the same research, to more than one publisher, unless such action has been approved by the editors of each publication or multiple submissions is the acceptablestandard practice in the specific discipline or field. In the complete report on the workin question, reference should be made to preliminary extracts from work that has already been published.

b. Order of Authors

Customs regarding the order in which co-authors' name(s) appear vary with the discipline Whatever the discipline, it is important that all co-authors understand thebasis for assigning an order of names and agree in advance to the assignments.

A corresponding, or senior author (usually the first or last of the listed names in a multi-

authored manuscript) should be designated for every paper, who will be responsible for communicating with the publisher or editor, for informing all co- authors of the status of review and publication, and for ensuring that all listed authorshave approved the submitted version of the manuscript. This person has a greater responsibility than other co-authors to vouch for the integrity of the research report and should make every effort to understand and defend every element of the reported research.

c. Self-citations

In citing one's own unpublished work, an author must be careful not to imply an unwarranted status of a manuscript. A paper should not be listed as submitted, in anticipation of expected submission. A paper should not be listed as accepted for publication or in press unless the author has received galley proof or page proof orhas received a letter from an editor or publisher stating that publication has been approved, subject perhaps only to copy-editing.

d. Duplicate Publication

Researchers should not publish the same article in two different places without verygood reason to do so, unless appropriate citation is made in the later publication to the earlier one, and unless the editor is explicitly informed. The same rule applies toabstracts. If there is unexplained duplication of publication without citation, sometimes referred to as self-plagiarism, a reader may be deceived as to the amount of original research data.

It is improper in most fields to allow the same manuscript to be under review by morethan one journal at the same time. Very often journals specify that a submitted work should not have been published or submitted for publication elsewhere, and some journals require that a submitted manuscript be accompanied by a statement to that effect.

An author should not divide a research paper that is a self-contained integral wholeinto a number of smaller papers merely for the sake of expanding the number of items in the author's bibliography.

5. Conflict of Interest

Academic members of staff may not allow other professional or outside activities to distract

their attention from their primary responsibilities towards the Institution. They should maintain a significant and professionally acceptable presence on campus during each semester in which they are on active duty. Holidays and leave should bein accordance with the Institution regulations.

They should create an atmosphere of academic freedom by promoting the open andtimely disclosure of the results of their academic activities, by ensuring that their advice to students and postdoctoral associates is not influenced by personal interests, and by disclosing external activities that could affect the free flow of academic information between themselves, students and colleagues.

Researchers may use Institution resources, including facilities, staff, equipment,information or confidential information as part of contract work, provided that the Institution is compensated in terms of the provisions of the Rules for Contract Work of the Institution. Researchers may not use Institution resources for any purpose other than purposes related to tuition, research or service by the Institution ,unless prior permission has been obtained by the head of the department and/or thedean, as provided by the Institution regulations.

Researchers should disclose in good time all potentially patentable inventions that have been discovered or created in the course and within the ambit of their service to the Institution. Ownership of such inventions should be dealt with in accordance with the policy of Institution. The inventors will, together with the Institution, share in the benefits or royalties earned in accordance with the provisions ofthe Institution Intellectual Property Policy.

Researchers should inform the Institution whether they (or members of their families)have consultation agreements or work in an outside institution, before the following proposed arrangements or agreements between such institutions and the Institution will be approved: a) gifts; b) funded projects; c) technology licensingagreements; and d) allocations.In such cases formal Institution permission will be required before the proposedarrangements or agreements can proceed.Institution researchers should not allow their names to be used as "ghost" authors ofmanuscripts written or provided by commercial sponsors.

Faculty may be allowed to engage in outside professional activities such as consulting or service on a scientific advisory board, but approval of each such activity from the

academic supervisor must be obtained in advance. In no case are Institution facilities to be used in the conduct of an outside activity, and the Institution name and logo may be used by outside entities only with permission of designated Institution officers. Research performed for an external entity should be conducted by means of a sponsored research contract and not by way of consulting.In some schools a contract for consulting must be approved in advance, to ensure, among other things, that remuneration is related to specific services and that legitimate intellectual property rights of the Institution are not compromised.

6. Obligation to Report

a. Reporting Suspected Misconduct

Reporting suspected research misconduct is a shared and serious responsibility of all members of the academic community. Any person who suspects research misconduct has an obligation to report the allegation to the HoD of the department inwhich the suspected misconduct occurred or to the Dean of Academic Research.

Allegations are handled under procedures described in the Institution's Policy. All reports are treated confidentially to the extent possible, and no adverse action will betaken, either directly or indirectly, against a person who makes such an allegation in good faith.

b. Correction of Errors

If a finding of error, either intentional or inadvertent, or of plagiarism should be made subsequent to publication, the investigator has an obligation to submit a correction orretraction in a form specified by the editor or publisher.

7. Responsibilities of a Research Investigator

An investigator who leads a research group has leadership and supervisory responsibilities with respect to the research performed by members of the group. A principal investigator must not only put together the research group but also arrange for the assembly of an adequate financial and administrative structure to support theresearch. A supervisor not only provides guidance and advice to individual membersof the group in the responsible conduct of the research but also has ultimate responsibility for the scientific integrity of the whole

research project. He or she should thus take all reasonable steps to check the details of experimental procedures and the validity of the data or observations reported by members of the group, including periodic reviews of primary data in addition to summary tables, graphs, and oral reports prepared by members of the group.

An investigator serves not only as a research manager with respect to members of the research group but also as a mentor responsible for the intellectual and professional development of graduate students, postdoctoral fellows, and junior faculty in the group, including awareness and sensitivity to issues in research ethics.A researcher should be open to collaborative work with investigators having differentbut complementary skills at the Institution.

8. Responsibilities to Funding Agencies

An investigator should be aware that the same standards of accuracy and integrity pertain to grant applications and proposals as to manuscripts submitted for publication. Reporting of results of experiments not yet performed as evidence in support of the proposed research funding, for example, is considered to be fabrication and is subject to a finding of research misconduct, even if the proposal is subsequently rejected for funding or is withdrawn before full consideration for fundingis completed. The same definition of plagiarism applies to an application or proposal, including background and methodological sections, as to a publication.

An investigator must submit progress and final research reports to a sponsor at times specified in the award. He or she must authorize expenditures in a manner consistent with the approved budget and should review financial reports carefully.

Investigators, who enter into agreements with commercial sponsors of research, as negotiated by the Office of Research, should familiarize themselves with the specialterms of such agreements, such as those, for example, concerning reporting of results, disclosure of inventions, and confidentiality. Failure to comply with the provisions might sometimes constitute a breach of contract or might compromise the Institution's claims to intellectual property.

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Additional Readings:

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