AKS University

SOP OF RESEARCH ETHICAL COMMITTEE AND RESEARCH ETHICAL POLICY

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Ethical Policy of AKS University

1. Preamble

At AKS University, ethical research practices are fundamental to our commitment to advancing knowledge and contributing positively to society. Our Research Ethical Policy outlines the principles and guidelines necessary to ensure that all research conducted within our institution adheres to the highest standards of integrity and responsibility.

AKS University is dedicated to the humane and ethical treatment of animals in research. All animal studies must comply with relevant regulations and guidelines, ensuring that animal welfare is prioritized and that research is conducted with the utmost care and respect for life.

Research involving chemicals must adhere to strict safety protocols to prevent harm to researchers, participants, and the environment. Proper handling, storage, and disposal of chemicals are required to maintain safety and regulatory compliance.

Research involving biological materials must ensure the responsible use of biological agents and adherence to biosafety standards. This includes managing risks related to pathogens and ensuring that all research complies with ethical guidelines for the use of living organisms.

The University is upholding a zero-tolerance policy towards plagiarism. All research outputs must be original and properly cited, with rigorous checks to prevent academic dishonesty.

By adhering to these guidelines, AKS University aims to foster a research environment characterized by ethical rigor, transparency, and respect for all living and non-living subjects involved.

2. Objective Of the Ethical Policy

The objective of the Ethical Policy in Research at AKS University is to uphold the highest standards of integrity and ethical conduct across all research endeavours. This policy aims to:

2.1 Ensure Integrity and Honesty: Foster a research environment where integrity and honesty are paramount, ensuring that research findings are accurate, reliable, and free from falsification or misrepresentation.

2.2 Protect Human and Animal Welfare: Safeguard the rights, dignity, and welfare of human participants and animals involved in research, ensuring that their safety and well-being are prioritized and that research is conducted in a humane and ethical manner.

2.3 Adhere to Legal and Institutional Guidelines: Comply with all relevant laws, regulations, and institutional standards related to research practices, including those governing chemical, biological, and environmental safety.

2.4 Prevent and Address Research Misconduct: Detect, prevent, and address any instances of research misconduct, including plagiarism, data fabrication, and ethical violations, to maintain the credibility and trustworthiness of research outcomes.

2.5 Promote Responsible Research Practices: Encourage responsible and transparent use of research resources and ensure that all research practices are conducted with respect for ethical standards and societal impact.

By fulfilling these objectives, AKS University aims to create a robust and ethical research culture that enhances the quality and impact of scholarly work while reinforcing public trust and academic excellence.

3. Ethical Principles

The Research Ethics Policy at AKS University embodies the principles of sound research practice and administration. It provides a detailed framework for the ethical assessment of all research activities conducted at the university. Upholding research integrity and adhering to rigorous ethical standards are central to our research endeavors, ensuring that our work contributes positively to the research community and society at large. This policy is crucial for maintaining high standards in research, particularly in our collaborations with external funders and stakeholders.

AKS University is committed to ensuring the highest ethical standards in all research conducted by its employees and students. We prioritize exceptional quality and professional integrity in our research efforts, and it is the duty of every member involved in research to uphold these principles.

Researchers, faculty, and staff at the university have a responsibility to society, their professions, and their research funders to conduct their work with integrity. They are expected to maximize the value of both internal and external investments in their research, while adhering to ethical guidelines and contributing positively to the advancement of knowledge. The Program acknowledges and encourages the application of the underlying moral guidelines as:

3.1 Prevention by harm:

During the execution of research, all faculty members and research students must prioritize the protection of subjects from psychological and physical harm. Researchers are responsible for ensuring that subjects are not exposed to unnecessary risks. Throughout the study, researchers must take appropriate measures to safeguard the physical and mental well-being of participants, maintaining their health and safety at all times.

3.2 Participants informed consent:

Participants benefit from the consent form because it reduces the risk of harm. Only if there is a convincing reason for either no or partial consent, complete participant participation is essential. Investigators should get an agreement by providing participants with useful details before they participate in the study to persuade their willingness to participate. The consenting procedure should also indicate how participants of the study will be kept up to date on the study's findings on a routine basis. Before obtaining consent, subjects should be allowed to ask queries concerning their participation in the study. It may be necessary to obtain clearance from subjects at many points during a study where more than one-off research engagement is involved. Consent can be freely provided without using force or compulsion. Subjects must be offered the chance to revoke their permission after consenting to it. Where relevant, investigators should state at what phase in the research, subjects can withdrawal their agreement or ask that their data be destroyed. Participants also will be notified about the steps that have been followed to allow them to withdraw their permission if necessary.

3.3 Reducing risk with vulnerable participants:

Certain participants, including young children, individuals with serious health conditions, and orphans, are considered inherently vulnerable due to their limited ability to provide informed consent for research studies. When

involving these vulnerable groups in research, it is essential to establish and follow additional safeguards and approval protocols to ensure their protection and ethical treatment.

3.4 Respect for participants:

Researchers should conduct their studies with careful consideration of both domestic and international norms and standards, addressing gender differences, social groupings, and the needs of marginalized or disadvantaged groups. It is crucial to respect the rights, benefits, and dignity of all participants and involved individuals. Researchers must also adhere to all relevant legal requirements and regulations throughout their research activities.

3.5 Privacy:

The confidentiality of data provided by respondents must be strictly maintained, ensuring that their identities remain protected. Careful handling is required when collecting, processing, and storing confidential, restricted, or private information. This data should be securely safeguarded against unauthorized access. Researchers must exercise the highest level of caution to ensure that personal information can only be linked back to individuals by authorized personnel. Sensitive, confidential, and personal data must be disposed of appropriately, in accordance with contractual and legal requirements.

3.6 Suitable use of rewards and incentives:

It is Institution policy neither to receive assistance nor financing that it considers to have been acquired illegally, or to chance compromising its position or affecting intellectual integrity or honesty. Involvement in research initiatives should be promoted solely on the basis to make individuals willing to participate, not on the basis of the award, which they cannot deny.

3.7 Animal Research Ethics Policy

The organizational committee crafted these recommendations in alignment with CPCSEA guidelines. Their purpose is to provide ethical standards for researchers involved in animal studies. These guidelines will be valuable for designing projects, assessing activities, and documenting and publishing results. Additionally, they aim to facilitate replication within the research community and foster open discussions about ethical practices concerning the use of animals in scientific research.

3.8 Respect for animals' self-respect

Researchers must respect animals as sentient beings, irrespective of their utility. When choosing research topics, methodologies, and disseminating results, caution must be exercised. Investigators are responsible for meeting the individual needs of each experimental animal.

3.9 Responsibility for considering choices (Replace)

Investigators are tasked with assessing potential alternatives to animal studies. They must determine whether equivalent information can be obtained through methods that do not involve laboratory animals, prioritizing these alternatives whenever possible. In cases where no suitable alternatives are available, researchers should consider postponing the study until alternative methodologies can be developed. Researchers are obliged to carefully weigh the absence of alternatives against the need to gather information when modifying animal trials.

4.0 The principle of proportionality: responsibility for considering and balancing suffering and benefit

Investigators have a responsibility to assess the potential suffering or distress that laboratory animals may experience, balancing this against the benefits the study may provide to animals, humans, or the environment. They must evaluate whether the research offers tangible and validated benefits in both the short and long term. Furthermore, it is their duty to scrutinize the scientific rigor of the studies and ascertain their potential significant scientific advancements.

4.1 Ethical Conduct:

- **Reciprocity:**
  Studies should aim to achieve mutually beneficial outcomes. They must be conducted with high standards of effectiveness and efficiency, ensuring that the benefits outweigh any potential risks or harms.

- **Accessibility:**
  Investigators should endeavor to disseminate their findings in the public interest through publications and fulfill their teaching and learning responsibilities within the institution.

- **Independence:**
  Investigators should maintain independence in their research approach and conclusions, free from undue influence by funders. Academic freedom should be upheld in conducting studies. Any conflicts of interest or biases should be fully disclosed before obtaining ethical approval.

4.2 Definite use of research funding:
Investigators should not use grant funds for purposes not specified in their grant award

4.3 Safe and Secure Data Management:

- **Study Materials:** Visual and physical information must be stored securely in a controlled environment for a minimum of five years.

- **Data Format:** Whenever possible, data should be maintained digitally and stored on a password-protected academic server for long-term preservation.

- **Informed Consent:** Respondents should be informed during the written consent process about how their collected data will be stored and for what duration**.**

4.4 Three Rs (Replacement, Reduction, Refinement):

- **Substitution:** Researchers should strive to replace animals with alternative methods whenever feasible.

- **Minimization:** Efforts should be made to minimize the number of animals used in studies.

- **Optimization:** Procedures and conditions should be optimized to minimize animal suffering and improve experimental outcomes, in accordance with CPCSEA guideline.

5.0 Ethical Bioprospecting:

- **Respect for Traditional Territories and Ideals:** Economic exploitation of natural resources must respect traditional territories, values, and relevant national and international treaties.

- **Conformity to the Universal Declaration of Bioethics and Human Rights:** Investigators should adhere to universal ethical principles that encompass all aspects of medical ethics.

5.1 Scope:

- All investigators, instructors, and trainees conducting research under the institution's supervision are bound by these guidelines. They must familiarize themselves with these guidelines before commencing research.

5.2 Bioethical Policy:

- **Framework for Ethical Implementation:** Establishes a framework for implementing ethical measures and mechanisms by research committees within the institution.
- **Responsibility of Care:** Defines key values guiding researchers' responsibilities towards study participants and the institution's obligations to practitioners and patients.
- **Integration with University Framework**: Aligns with the broader framework of scientific rights and principles upheld by the university.
- **Compliance:** Ensures compliance with relevant ethical procedures, legislative requirements, regulatory standards, professional bodies, research councils, and local council systems.
- **Intellectual Freedom:** Upholds the principles of intellectual freedom in research pursuits.
- **Comprehensive Coverage:** Encompasses all aspects of academic and administrative research, including conditions supporting the production, clarification, and dissemination of current information in formal settings such as consulting work. It also includes the collection of various types of data and materials, such as physical objects, digital images, and information obtained through digital research methods.

6.0 Ethical Policy

Academic integrity is a foundational ethical principle in education, guiding the discourse and language used in higher education. In the digital age where abundant resources are freely accessible, AKS University is preparing to introduce an Academic Integrity and Ethical Policy. This initiative aims to educate faculty and students about the importance of academic integrity in teaching, learning, and ethical research. The policy addresses three main categories of educational misconduct that require attention:

- Plagiarism
- Cheating
- Conflict of Interest

6.1 Plagiarism

The commitment to promoting academic excellence and awareness needs to be emphasized, particularly in education. The university's comprehensive policy should be established on sound principles. This document outlines the university's expectations regarding Academic Integrity in research activities. Plagiarism is defined as the unauthorized use of someone else's work, whether in part or in whole, without proper acknowledgment or consent. This encompasses the use of raw materials, ideas, statistics, code, or data without permission from the original source. Examples of plagiarism include submitting materials or sentences written by another person or previously published work. Authors are provided with guidelines to recognize and avoid plagiarism, including instances of academic misconduct. Few guidelines for authors to understand what constitutes plagiarism samples of fraud include

- Reproducing full or partial text from reports, publications, or online sources.
- Reproducing published personal content, images, statistics, third-party data, etc.

- Using content from university notes or websites and incorporating it into technical work without proper attribution, whether knowingly or unknowingly.
- Copying text from previously published works, such as journal articles or conference papers, without appropriate citations or acknowledgment.

The resources provided at the beginning of the document explain how to properly reference sources, offer additional examples of correct writing practices, and provide guidance on avoiding improper use of content.

6.2 Cheating

Cheating is a prohibited educational behavior and may be divided into various categories

i. Copying during examination, and replicating assignments, term papers or manuscripts. To approve or facilitate the copying, or writing of a report or examination of another person.

ii. Unauthorized use, copying, copying of unauthorized uses, and buying or materials from a spread of sources.

iii. Reproducing information and reporting it in thesis and literature as theirs.

Below mentioned are some guidelines for educational ethics to prevent negligence and intentional dishonesty:

a. Usage an appropriate method of assessment and computational assignments. Explain accurately and blend data.

b. Carefully record and store basic and secondary data like original images, metal data readings, lab boards, and computer folders. There should be little or no photo / graphic manipulation; the primary version should be saved for later review, if needed to clearly define the changes.

c. Ensure strong re-emergence and statistical analysis and prediction. it is vital to be honest about the tiny print and not leave other data points to make a surprising statistic (often mentioned as "cherry picking").

d. Lab bookmarks should be stored neatly in bound booklets with printed page numbers to enable later viewing at the time of publication or copyright. Date must be displayed on each page.

e. The contents need to be written clearly in own words, it can have inspiration from sources, but not possibly have cut/copy and paste contents.

f. Citations to the source will solve most of the plagiarism misuses, proper citations with rewritten needed contents will make a good choice.

6.3 Conflict of Interest:

Conflicts of interest within the private interests can provoke inaccessible status, in several professions, as an example, teaching, observation, dissemination, councils, financial inquiry and consultation. It is vital to form genuine professional independence, impartiality and professionalism, and to avoid impropriety arising out of conflict of interest. Hence certain roles and responsibilities are defined below for the authors to avoid conflict of interest.

6.3.1 Student Role: Before sending a thesis / Project (UG / PG/ Ph.D.) to the varsity, the scholar is responsible for ensuring that the thesis or Paper and Project and Research is plagiarism free through the any software available which is usually provided by the university. Additionally, the scholar must confirm that they are familiar with the University's study guidelines, "a SGAD

6.3.2 Creative Role: the varsity should confirm that the proper procedures are followed within the assessment, compilation of statistics, and activities, which the data is well documented and stored for future reference. additionally, they need to analyses manuscripts and ideas carefully.

6.3.3 The Role of the University: Breach of academic integrity could also be a significant offense with lasting consequences for both the university and this may lead to punishments. for violation of the course which may be warning and / or grade of "F". depending on the severity of the reach. Repeated infringement, if considered bad enough, can cause dismissal. It's also recommended that faculty who have brought any violations to the Dean Research the Vice- Chancellor may appoint a committee to enquire on the matter and recommend appropriate action

Plagiarisms a Serious academic offence Content to be checked necessarily

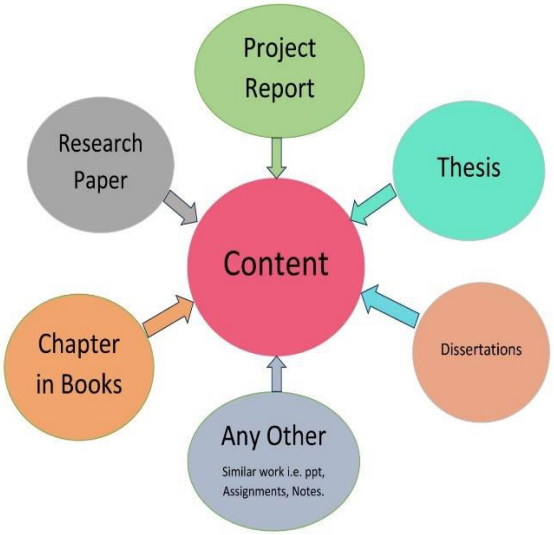

Figure1: Plagiarism report for the content

6.3.4. Levels of Plagiarism with respect to UG, PG, Ph.D.

Level 0	Similarities upto10%
Level 1	Similarities more than l0% to 40%
Level 2	Similarities more than 40% to 60%
Level 3	Similarities more than60%

6.3.5 Penalties in case of Similar Content in Academic and Research Publications

Level	Similar Content	Penalty for Faculty	Penalty for students UG, PG/PhD
Level 0	Similarities up to 10%	Slight similarities, no fine	Slight similarities no fine
Level -1	Similarities more than 10% to 25 %	Will be advised to make change to the paper	Only advised to call the manuscript and remove the similar and after resubmit
Level -2	Similarities more than 25 %to 60%	Shall be asked to withdraw manuscript	Shall be asked to withdraw manuscript
		To be attend ethic workshop 02 related how to remove the plagiarism	To be attend ethic workshops 02 related how to remove the plagiarism
		For a period of one year, he or she will not be permitted to work as a supervisor	Project / thesis will be delay fore 06 months
Level -3	Similarities more than 60 %	Will be advised to call of manuscript	Shall be asked to withdraw manuscript
		To attended at least 03 workshop on research ethics	To attend at least 05 workshop on research ethics
		For a period of 02 years, he or she will not be permitted to work as a supervisor.	Shall not allowed to be submit project/thesis for one year

References:

i. UGC guidelines on plagiarism
ii. IEEE plagiarism
iii. Elsevier
iv. Springer

UGC Reserves

However, according to the regulations,

"UGC retains the right, in collaboration with the Govt of India/ Department of Human Resource Development, to eliminate complexity in the process of applications of these Guidelines" according to the regulations.

Precaution

- Wherever necessary, provide suitable references.
- Including for pictures, figures, illustrations, charts, and maps, include citations.
- Ensure you reorder/replace a few terms when paraphrasing.
- Before sending a file, double-check the material for authenticity.

7. Plagiarism Detecting Sources

Drill bit (Not Free)	To detect the source of a Dill bit, review audit logs for deletion events, analyze metadata for change details, and query the database for related records. Check user actions, system configurations, and automated processes that might have triggered the Dill bit. Perform integrity checks for inconsistencies.
Turnitin	To detect the source of a Turnitin match, review the originality report to identify the matched text. Check the detailed sources list for specific documents or websites. Analyze similarity percentages and highlight colors to trace the origins of the matching content and understand its context within the report.
Python	To detect the source of an issue in Python, review error messages and stack traces for details. Use debugging tools like pdb or IDE debuggers to trace code execution. Check logs and test cases for context. Analyze recent code changes and inspect relevant modules or functions for potential problems.

Access levels:

Administrator	The administrator has the ability to create tutors and access data from their Turnitin profiles.
Instructor	The teacher can use this interface to create courses and projects, apply filters, and exclude matched sources from the reserves.
Student	Here, a student can share an item from their assigned class, including the original study, and use the filter option.

Plagiarism software Available at AKS University

1. Drill bit (Not Free)
2. Turnitin
3. Python

Subscription at Central Library, AKS University

Under usage by the Institute since 2020
One-year subscription
100 user access
Originality Checking alone

Polices for Publications for Faculty Members, Ph.D. Research Scholars and PG/UG Students, AKS University, India

Research Publication will enhance your personal growth and help you in your annual appraisal and career path. Following are the **Do's and Don'ts** which we must follow while submitting Research Papers:

1. Every Faculty member must publish two research paper during the Academic Session if you are the sole author and three papers if multiple authors are involved.

2. All the papers from Faculty/Research Scholar/ PG/UG Students must be submitted as cc to Director Research office after due plagiarism check. Guides have must be essential & guide must be co – author before submission.
3. The papers which the authors intend, to submit by themselves to Journals, should be first submitted to the Director Research for record. An email mentioning that the author is willing to submit the paper has to be sent to Director Research.
4. The first author must be from AKS University if publication task is being taken care by AKS University through Director Research.
5. The first author must be the person who has contributed the most and not in the order of seniority.
6. The affiliation used should be as "<NAME>, <DESIGNATION Professor/Associate Professor/Assistant Professor/Research Scholar/PG student>, Faculty of <NAME>,AKS University, Satna , Madhya Pradesh
7. Don't use as Student in Affiliation if student is UG write only student name and affiliation
8. In case of Ph.D. Research scholars or PG students or UG as one of the authors, then their name must come as First author and supervisor name is second.
9. In UG/PG/Ph.D. student only student and Guide Name will be in the Publication other contributor name can be acknowledgment.
10. The faculty, who are from AKS University and doing Ph.D. from outside, must mention in their research paper dual affiliation AKS University' as well their name of the university from where they are doing Ph.D.
11. Maximum four authors can be there in any Publications; in case of more authors permission from the Director Research office must be sought.
12. University prefers Interdisciplinary Research so faculty member must write one Research paper with inter school.
13. The publication of COE must

Your Participation in the compliance of the above points is of paramount importance for the betterment and the future of you and AKS University.

-Sd-
Director Research
AKS University

Copy of the above is forwarded to the following for the data and important action:

1 CEO- (for kind information please)
2. Vice Chancellor (for kind information please)
3. All Dean /Director/ HoD / Research Coordinators
4. Director – IQAC

STANDARD OPERATING PROCEDURE FOR AKS UNIVERSITY RESEARCH ETHICAL COMMITTEE

1. Preamble:

The Research Ethical Committee at AKS University was established to ensure that all research activities adhere to high ethical standards, prioritizing the protection of human rights across all societal groups. This committee plays a crucial role in upholding the fundamental principles of biomedical research, especially in studies involving human or animal participants. It is mandatory for all biomedical research proposals, which involve either human or animal subjects, to be reviewed and approved by the University Research Ethics Committee before proceeding. This process ensures that all research conducted at the university aligns with ethical guidelines and respects the welfare of the participants. By implementing these measures, the committee aims to promote ethical integrity and safeguard the well-being of both human and animal subjects in research activities.

2. Scope of the University Ethics Committee

2.1 Review of Research Proposals:

- Evaluate and approve research proposals involving human or animal subjects to ensure compliance with ethical standards and university guidelines.

2.2 Ethical Standards Enforcement:

- Ensure that all research conducted adheres to both international scientific standards and local ethical practices, respecting the privacy, dignity, and rights of participants.

2.3 Guidance and Education:

- Provide guidance on ethical issues and best practices in research. Educate researchers about ethical considerations and local healthcare needs to enhance the quality and relevance of research.

2.4 Monitoring and Compliance:

- Oversee ongoing research to ensure continued adherence to ethical standards. Address any ethical concerns or violations that arise during the research process.

2.5 Community and Cultural Sensitivity:

- Promote research practices that are sensitive to the values and norms of local communities, ensuring that studies are conducted in a culturally respectful manner.

2.6 Policy Development:

- Develop and update university policies related to research ethics, ensuring they reflect current best practices and regulatory requirements.

2.7 Conflict Resolution:

- Address and resolve ethical dilemmas and conflicts that may arise in the course of research activities.

3. Standard Operating Procedure (SOP)

The Chair Person and Member Secretary are responsible for implementing these standard operating procedure (SOP).

3.1 Composition Of University Research Ethics Committee

The Research Ethics Committee should consist of a diverse team of researchers from various scientific disciplines. The composition is as follows:

1. **Chairperson**: Vice Chancellor or Dean, appointed by the Vice Chancellor.
2. **Member**: Three senior faculty members at the rank of Professor or Associate Professor.
3. **Member**: One external expert from outside the University.
4. **Member Secretary**: A faculty member from the University, holding the rank of Professor or Associate Professor.

3.2 Meetings of University Research Ethics Committee Meetings:

The Chairperson of the Research Ethics Committee will preside over all meetings. The Member Secretary will be responsible for organizing these meetings, maintaining accurate records, preparing the Minutes of the Meeting (MoM) for the Chairperson's approval, and handling communication with all relevant members and participants.

3.3 Submission of Proposal University Research Ethics Committee:

All investigators and researchers must adhere to the implementing guidelines before commencing any research involving human subjects, animals, or bio-materials.

- The Principal Investigator (PI) or Co-Principal Investigator (Co-PI) must submit their research proposal in both soft and hard copies using the Research Ethics Committee's designated forms, and include all required documents in English.
- Proposals should be submitted exclusively to the office of the Member Secretary of the Research Ethics Committee. For Ph.D., PG, or UG research projects, only registered research scholars or students may submit proposals through their supervisors.
- For sponsored projects, the committee will only review those that have been approved. However, the University Research Ethics Committee may issue a No Objection Certificate (NOC) if required by the funding agency.
- All proposals must include the consent form signed by the participants.

3.4 Examination of Proposals

- All members of Research Ethics Committee are responsible for examining the Proposals before conducting any research in which human /animal(s)/Bio medical is used.
- The Member-secretary will examine the completeness of proposals prior to submission for evaluation of the Research ethical committee
- The Research Ethics Committee members will evaluate the possible ethical issues, risks involved with the participants, completeness of the documentation for participants privacy, confidentiality and judicial issue.
- All the reviews will be done in the formal meetings of University Research Ethics
- Committee and the investigators make their presentation before the committee.
- In case any expert opinion is required the committee can invite additional member(s).
- Within 15 days of the meeting the decision of the University Research Ethics Committee will be communicated to the applicant in writing.
- If approved, certificate of approval will be issued and all approval will valid for 3 years or for the period of project (if less than 3 years). If project is more than 3 years than investigators have to take the fresh approval.

3.5 Decision Making

- The committee members will review and discuss proposals during meetings.
- If a committee member has a conflict of interest regarding a proposal, they must withdraw from the discussion of that proposal. This withdrawal must be approved by the Chairperson and recorded in the Minutes of the Meeting (MoM).
- A quorum must be present for the Research Ethics Committee to make any final decisions.
- Invited members are permitted to offer their opinions only.
- The committee has the authority to approve, reject, or request revisions to a proposal.

3.6 Communicating the "Decision"

- The decision will be communicated by the Member Secretary in writing.
- Suggestions for modifications, if any, should be sent by University Research Ethics Committee.
- Reasons for rejection should be informed to the Researchers.

3.7 University Research Ethics Policy:

For any clarifications, please refer the university's research ethics policy.

4.Proposal Forms

FORM 1: PART 1 - CONTENT FOR CONSENT FORM INFORMATION FOR PARTICIPANTS OF THE STUDY

FORM2

FORM 3

FORM 5

FORM 5 (Consent Form)

For more details contact Member Secretary, University Research Ethics Committee of AKS University

Annx-I

PART 1 – CONTENT FOR CONSENT FORM INFORMATION FOR PARTICIPANTS OF THE STUDY

This is the Participants Information Sheet. All Principal Investigators must submit this information to the Ethics Committee.

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide
- The patient information sheet must be duly signed by the investigation

Annx-II

PART 2 - CONTENT FOR PARTICIPANT CONSENT FORM

Participant's name:

Address:

Title of the project:

I have received written details about the study and have had them explained to me in my own language. I confirm that I understand the study and have had the opportunity to ask questions. I acknowledge that my participation is voluntary, and I can withdraw at any time without providing a reason, without affecting the standard medical care I would normally receive from the research team. I consent to the use of any data or results from this study for scientific purposes only. I have been provided with an information sheet detailing the study. I give my full consent to participate in the study.

Signature of the Participant: _____ Date: _____

Signature of the Witness: Date: _____ Date: _____

Signature of the Investigator: Date: _____ Date:----------

Note: Consent form part 2, should be appropriately worded for adults and children (less than 18 years) e.g. If the participant is less than 18 years of age, instead of 'my participation', 'my child's/ward's participation' needs to be replaced.

Annx-III

FORM – 1 APPLICATION FOR PERMISSION FOR STUDIES ON HUMAN SUBJECTS

1. Faculty Name:

2. Name of Investigator: Designation:

3. Email Address and Phone No. of Investigator:

4. Place where study will be conducted:

5. Date of commencement & duration of study:

6. Funding agency / sponsor:

Investigator's Declaration

Certified that

1.The research proposal is not duplicative of previously reported research

2. All investigators working on this proposal are aware of the ICMR ethical guidelines

3. I / we have reviewed the pertinent scientific literature

4. I / we will obtain approval from RESEARCH ETHICS COMMITTEE before initiating any deviation / changes in the study

5.The study shall be initiated only upon review & approval of RESEARCH ETHICS COMMITTEE

6. 1 /we shall maintain all the records as per format [form 2 or 4]

7. Informed consent will be obtained & confidentiality of the subjects will be maintained

Place: **Chief Investigator**

Date

For Office use only

Proposal number

Date of receipt **Date received after revision**

Approval date **Expiry date**

Annx-IV

FORM -2 (For Practical Labs only)

Proforma for routine UG/PG class work (Practical's) involving Human/Animal Subjects.

1. Name of the faculty

2. List of Practical's and their Nature in brief.

(Including Objectives and Methods : to be employed)

3. Specify the method of Subject selection for Practical class work

(a) UG/PG Students

(b) Patients

(c) Students (from other Institutions.)

(d) Any other, specify

4. Specify the source of obtaining blood samples

UNDERTAKING

It is certified that,

Work is conducted purely as part of routine curriculum by UG/PG students.

Signature of the Faculty -in-charge.

Annx-V

FORM -3 : APPLICATION FOR PERMISSION FOR STUDIES ON HUMAN/ANIMAL SUBJECTS

Particulars	Name designation and Qualification	Address / Email/ M Phone	Signature
Name of the PI /PhD Candidate			
Research Guide			
Co-PI if any			
Place where the study will be conducted			
Date of the commencement and duration of the study			
Funding agency			

Investigator's Declaration

Certified that

i. The research proposal is not duplicative of previously reported research
ii. All investigators working on this proposal are aware of the ICMR ethical guidelines
iii. I/ we have reviewed the pertinent scientific literature
iv. I/we will obtain approval from RESEARCH ETHICS COMMITTEE before initiating any
v. deviation/changes in the study
vi. The study shall be initiated only upon review & approval of RESEARCH ETHICS COMMITTEE
vii. I /we shall maintain all the records as per format [form 2 or 4]
viii. Informed consent will be obtained & confidentiality of the subjects will be maintained

Place: **Chief Investigator**

Date

For Office use only

Proposal number Date received after revision Approval Date
Date of receipt Date received
Date of Expiry

Member Secretary **Chairman**

Annx-VI

University Research Ethics Committee
FORM - 4
Proforma for submission to University Research Ethics Committee,
for undertaking studies involving human/animal subjects

Title: Thick one: PhD/ Sponsored project /PG/UG dissertation			
2. Details of Investigating Team			
	Name & Designation/Qualification	Dept. Address Tel & Email	Signature
Investigator			
Research Guide			
Any Others			
Name of sponsor			
Expertise of the investigation team			
3. Type of study: a. Epidemiological Basic Science Survey Clinical: Single center Multicentric Behavioral (b) Data Collection: From Records Using Questionnaire (c) Any other, specify			
4. Duration of the study : Probable date of Commencement : Date of Completion			
5. Pre-clinical studies done, if any : (in brief) Publications, if any			

Note: It is compulsory to provide all the required information, incomplete applications will be rejected.

6. Study design
[Brief description of the proposal — Introduction, aim (s) & objectives, justification for study, methodology describing number of subjects, Inclusion / exclusion criteria, dosages of drug, duration of treatment, potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale. Attach sheet with maximum 500 words.

7. Will any advertising be done for recruitment of Subjects?
(posters, flyers, brochure, websites — if so kindly attach a copy)

8. Does the study involve
(a) Anthropometric Measurements: Yes / No
(b) Blood samples: Yes / No
(c) Urine analysis: Yes/No
(d) Lifestyle modification: Yes/No
(e) Other (specify).
If answer is Yes to (b) & (c) mention the test

9. Intervention Studies- Oral
(a) Product evaluation: Yes / No
(b) Dietary: Yes / No
(c) Synthetic : Yes / No
(d) If Yes, is toxicological evaluation carried out :
(e) Known medication: Yes/No
If yes, give a brief summary of dosage, administration, Contra indications (if any)

10. Use of biological/hazardous material : Yes No (If the answer is Yes, give details)

11. Consent : Written Oral i. Subject consent form - enclose
ii. Who will obtain consent PI/Co-PI Nurse/Counsellor
Research staff Any other

12. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits Yes No to subjects / community / country
ii. Is there physical / social / psychological risk / discomfort Yes No
iii.Is there a benefit a) to the subject Direct Indirect
b) Benefit to society Direct Indirect if yes
Explain

13 i. Are the subject remunerated for their involvement in the research
Yes NO
ii. If yes , is this remuneration provided irrespective their social and economical conditions
iii. Compensation for travel, Specify amount and type

14 **Data Monitoring**
i. Is there a data and safety monitoring committee Yes /No

ii. Is there a plan for reporting adverse events if yes report is done to Sponsor and the ethic committee	Yes/No
15 Is there any conflict of interest (Financial /non-financial) if yes Specify	

Signature and Designation of the Applicant

Pace

Date

Checklist for attached documents

i. Form -1 : 1 Copy
ii. Project proposal : 2 copies (form 2 or 4 as applicable)
iii. Informed Consent form: 1 copy
iv. Investigators' brochure for recruiting subject, if any
v. Advertisement /Information Brochure
vi. Copy of the clinical protocol
vii. PhD Registration conformation letter
viii. Project sanction copy

Note: One copy each of the items 4,5, 6 to be attached only if applicable to the study