WOXSEN UNIVERSITY

POLICY DOCUMENT
RESEARCH ETHICS COMMITTEE
WOXSEN UNIVERSITY
2023

V1.0

RESEARCH ETHICS COMMITTEE

All Faculty and Scholars of Woxsen University are required to plan and conduct their research investigations in accordance with appropriate ethical standards. Faculty/Scholar should ensure that they have knowledge of any relevant disciplinary guidelines on research ethics and that any empirical research has the required approval by the Research Ethics Committees**.**

Research ethics

Research ethics is concerned with safeguarding human participants in research. Woxsen is committed to protecting the rights, privacy and welfare of participants, as well as their personal data.

Helping researchers protect participants.

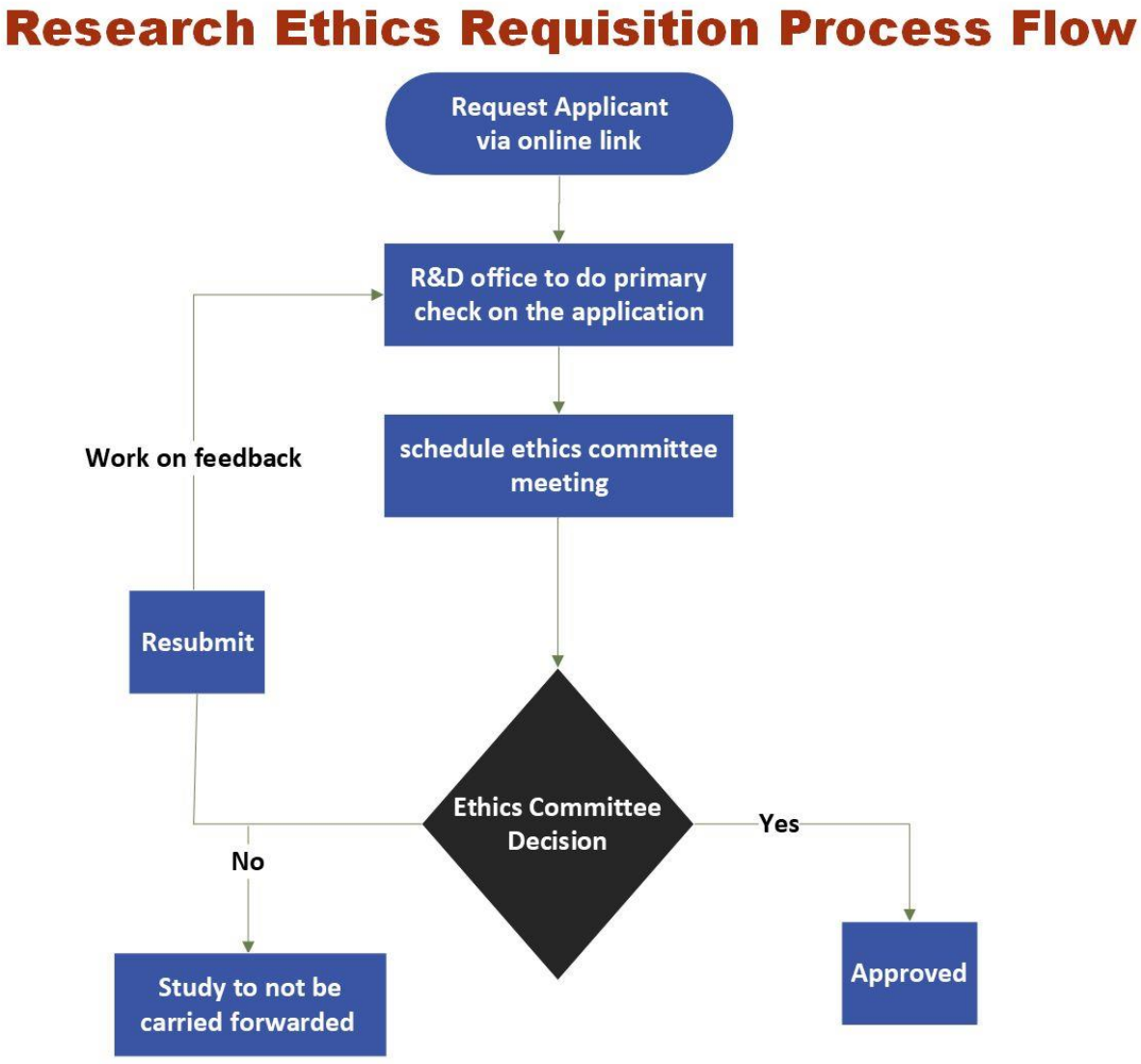
Any research that involves human participants or identifiable personal data has ethical implications. Considering those implications – and addressing any issues arising – is a key element of good research practice.

Not only does it protect participants, it also protects researchers and the University. We have a robust framework in place to support researchers through this process. Any research that could have ethical implications must be approved by one of our ethics committees.

Research ethics is a vital element of research integrity, together with the scientific rigor of a project and the conduct of the researchers. It concerns the safeguarding of any participants in the research.

BEFORE APPLYING

Applicants should consider which research ethics committee that their application needs to be considered at by reviewing the **flowchart below**.



How to apply for research ethics approval

All research ethics applications must to be submitted using the Woxsen ***Research Ethics Online Form.***

You are responsible for ensuring that you obtain the appropriate and required ethical approval before you begin your research, and it is important that you consider the ethical implications of your research.

Ethical approval must be obtained before any research involving human participants, identifiable personal data and/or animals is undertaken. Failure to do so may result in disciplinary procedures being instigated and you will not be covered by Woxsen University indemnity if you do not have an approval in place. It may also result in a degree not being awarded or the data not being eligible for publication in a peer reviewed journal.

Assessing risk

Woxsen Research Ethics Committee will automatically establish the risk level of your application and route it to the correct Research Ethics Committee based on the risk. Woxsen has three levels of risk: low, medium and high. The applications are reviewed proportionately based on the level of risk of the project.

Low risk applications

Applications which are deemed low risk will be reviewed by a proportionate REC in your Department. There is some variation across the University.

For students:

Note that when you submit your application on the system, it will first be sent to your supervisor for comment/review (you may share it with your supervisor before this for comment – to find out how please see the user guide for information).

Medium risk applications

Applications deemed medium risk will be reviewed at a full research ethics committee meeting within the applicant's Department/School. For submission deadlines, turnaround times and local procedures.

High risk applications

Regardless of if the applicant is student or staff, or which School /Department the applicant is from, all applications which are deemed high risk will be submitted to Research Ethics Committee.
Research Ethics Committee meets 6 times/year.
Applications must be received 10 working days before the meeting date.
Emails outlining the outcome of the applications are sent within 10 working days of the Committee meeting.

Why is research ethics important?

Any research that involves human participants or identifiable personal data has ethical implications. At Woxsen, we affirm that human participants, animals and the environment must be protected from harm. All research must follow that principle, regardless of the discipline or subject matter of the research.

Research ethics at Woxsen

Woxsen is committed to ensuring that all research is conducted so that it:
Protects the rights, privacy and welfare of participants and their personal data minimizes risk to participants, researchers, and the institution.
Even if the research is deemed to be low risk, researchers must consider issues such as data protection, confidentiality, and anonymity. Research projects must also comply with an increasing number of professional and legal requirements.

Woxsen Research Ethics Committees oversee all aspects of the ethics of research involving human participants and personal data carried out in the institution or under the auspices of the institution, by its Schools, staff or students.
Research projects must obtain ethical approval before the research commences. Woxsen indemnity will not cover research without approval. Failure to obtain approval may also result in disciplinary procedures being instigated.
There can be no exceptions, exclusions, retrospective approval, or blanket permissions in any circumstances.

COMMITTEE MEMBERS

Director R & D- Convener

VC (Ex offico's)

All deans (Ex offico's)

Dr. Rajat Gera

Dr. Ravi - SOT

Dr. Annamaneni Sreelatha (SOL)

Dr. Brundaban Mishta (SOH)

Dr. K Hemanchandran (SOB)

Prof. Sanjay Guria (SOAD)

Principles of research ethic

In addition to the scientific rigour of a project and the conduct of the researcher(s), projects should be ethical and in particular safeguard any participants and/or their data, and the researcher(s). Ethical issues are many and varied and may be quite complex. It is recognized that there are differences between disciplines, but all research should be guided by the principle that the risk of harm to the participants should be minimized, and as far as possible the benefit to the participants and/or society should be maximized.

Six key principles identified in ERC's:

- Research should aim to maximize benefit for individuals and society and minimize risk and harm.
- The rights and dignity of individuals and groups should be respected.
- Wherever possible, participation should be voluntary and appropriately informed.
- Research should be conducted with integrity and transparency.
- Lines of responsibility and accountability should be clearly defined.
- Independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.

Respect for persons - autonomy and protecting those with diminished autonomy.

All participants in research must take part voluntarily, free from any coercion or undue influence, and their rights, dignity and autonomy should be respected and appropriately protected.

An autonomous person is capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others.

By contrast, when a potential research participant may lack capacity to make autonomous decisions, respect for persons requires that they be protected against harm. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated. Some persons are in need of extensive protection, even to the point of excluding them from research that has a risk of harm.

Beneficence and non-maleficence

Research should be worthwhile and provide value that outweighs any risk or harm. Researchers should aim to maximize the benefit of the research and minimize potential risk of harm to participants and researchers. All potential risk and harm should be mitigated by robust precautions.

The need for a favorable risk/benefit assessment requires an assessment of the probabilities of both the harms and of the benefits that may arise. The term ‘risk’ is generally used for harm, but the probability of benefits also needs to be considered. Many kinds of possible harms and benefits need to be considered. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types of harms to research participants are those of psychological or physical pain or injury, there may be others costs of a social nature to consider.

Discovering what will in fact provide a benefit may require exposing people to some risk. Conducting research without any risk of causing harm would prevent many improvements in human welfare. Where the participant may benefit directly through the research, such risks are

more justifiable. However, where the research project will not benefit the participants directly, the wider benefits to others in terms of the potential to alleviate disease or other harms in the future may justify research with some risk but only after very careful evaluation.

Justice

Research should be just as between different members or groups in society. A core principle of justice in relation to research is equal treatment. This is a further expression of the principle of respect for persons. An injustice occurs when some benefit to which a person is entitled is denied to them without good reason or when some burden is imposed unduly on them. Researchers need to consider the overall societal impact of their research both in the selection of participants and the benefits and burdens arising from it.

For example, the selection of research participants needs to be scrutinized in order to determine whether some classes (e.g., particular racial minorities, one gender or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Research supported by public funds should provide advantages not just to those who can afford them, and such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Informed consent

Informed consent requires that research staff and participants should be given appropriate (a) information about the research (b) in a comprehensible manner (c) without duress or inappropriate inducement.

The information should include: the research procedure, the purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the participant the opportunity to ask questions and to withdraw at any time from the research. Where a person is not receiving treatment but is a pure volunteer, the standard of disclosure may be expected to be higher. The extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide

whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the participants should understand clearly the range of risk and the voluntary nature of participation.

Comprehension means that the manner and context in which information is conveyed is as important as the information itself. For example, presenting information too quickly or in a format that is confusing may adversely affect a participant's ability to make an informed choice. Because a participant's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the participant's capacities. Investigators are responsible for ascertaining that the participant has comprehended the information.

Special provision may need to be made when comprehension is severely limited – for example, by conditions of immaturity or mental disability (e.g., infants and young children or those with mental disabilities). Participants must have the opportunity to choose to the extent they are able, whether to participate in research. This situation also requires seeking the permission of other parties in order to protect the participants from harm and represent their best interests.

Voluntariness requires that a participant make their decision without duress or other undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the participant is especially vulnerable. Unjustifiable pressures usually occur when people in positions of authority or commanding influence – especially where possible sanctions are involved – urge a course of action for a participant.

Confidentiality and data protection

Individual research participant and group preferences regarding anonymity should be respected and participant requirements concerning the confidential nature of information and personal data should be respected.

In designing the research project, researchers will consider whether personal data is to be studied, including interviews with participants. Where it is, then the process of securing informed consent will entail respect for the confidentiality of the participants. There are a range of options for the type of consent participants can give to the use of their data. These include the use of quotes with or without attribution on the one hand, to full anonymity on the other. Data generated by research must be securely stored appropriately in accordance with relevant legislation and institutional policy.

Integrity

Research should be designed, reviewed and undertaken to ensure recognized standards of integrity are met, and quality and transparency are assured.

Examples of unacceptable practices include: fabrication by the creation of false data or other aspects of research, including documentation and participant consent; falsifications by the inappropriate manipulation and/or selection of data, imagery and/or consents; plagiarism by the misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission; misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data, material interests, involvement or qualifications and improper dealing with allegations of misconduct by failing to address possible infringements including attempts to cover up misconduct or reprisals against whistle-blowers.

Conflict of interest

The independence of research should be clear, and any conflicts of interest or partiality should be explicit. A conflict of interest arises where a researcher's obligation to the institution or a funder to conduct research independently is likely to be compromised or may appear to be compromised. This can be because they may:

obtain a personal gain, or a gain to a member of their family or another person to whom they have a close personal relationship arising from the research. This gain may be financial or otherwise and/or, have commitments and obligations to another person or body that may appear to act as a potential influence over their independent conduct of the research.

There may be an appearance of conflict of interest even when no conflict actually exists. Researchers must disclose anything that may be perceived by others as a potential conflict of interest.

Research ethics approval process

The process of obtaining research ethical approval has been made as simple as possible across Woxsen and is consistent with ensuring the rights and safety of research participants and researchers.

Research ethics approval outcomes and appeals

Once your application form has been reviewed by one of Woxsen research ethics committees, you will be notified of the outcome of the review.

Application outcome decisions

Possible application outcome decisions are as follows:

Approved as submitted.

The research ethics committee is content that the study does not raise any ethical issues and no amendments to the application, or the recruitment documents are required.

Approved with conditions.

The research ethics committee is content that the study does not raise any ethical issues and the application is approved subject to some minor specified conditions/changes to the application (e.g. the wording of a section of the PIS).

No resubmission is required, and the Committee does not need to see evidence of the changes. Supervisors are responsible for ensuring that students have made the requested changes before data collection begins.

Request amendments

Minor amendments/clarifications (to be approved by Chair's action):

Some minor amendments/clarifications are required before approval can be granted.

Major amendments (to be reviewed again by a sub-committee or a research ethics committee):

The applicant is required to address the amendments/clarifications requested by the research ethics committee and submit them for review either by a sub-committee or a full research ethics committee meeting.

Returned for resubmission.

The application does not provide the research ethics committee with enough information to make a decision, or the application and/or the accompanying documents are not of an acceptable standard. The applicant will be required to resubmit an updated application for review to the research ethics committee.

(Note that applications may be returned without review if the application includes technical language without common explanation, if the application is poorly constructed grammatically, or if the application is unclear.)

Rejected

The proposal is ethically unacceptable and will not be approved by Woxsen research ethics committees.

Ethics guidance and resources

Woxsen expects high standards of ethical conduct from our researchers. This is paramount for the reputation of both the university and individual researchers.

Supporting and protecting our researchers

These resources will help you to:

- Understand and fulfil your responsibilities as a researcher.
- Develop research projects that are rigorous and protects all parties from unnecessary risk.
- Write an effective application to submit to the relevant research ethics committee.
- Produce research that meets the expectations of funders, your peers and the public.

Email – research@woxsen.edu.in

*********THANK YOU*********

APPLICATION FOR REC APPROVAL

Date: / /

Title of Research:

Title of Study (for lay public):

Acronym (if any):

Protocol ID (if any):

Is this research related Business Studies/Humanities/interdisciplinary) – (Yes/No)

Does this involve observational protocol - (Yes/No)

Name of the Principal Investigator (PI):

(Department/Designation):

Employee Number:

Funding agency (if applicable):

E-mail of PI: Mobile:

Name of the Co-Co-Principal Investigator/s:

(Department/Designation):

Employee Number:

Funding agency (if applicable):

E-mail of Co-PI: Mobile:

Department/location where research will be carried out:

Name of the institution/s where research will be carried:

Duration:

Source/s of monetary or material support:

Internal Grant:

Research Grant:

External Grant:

Department Fund: (Yes/No)

Approval letter from HOU/HOD (if applicable): Yes/No

Does the outcome of this project involve patenting: Yes/No (if yes furnish details)

In case of patenting what are the benefits for Woxsen University as an institution in terms of patenting and royalties received? (Yes/No)

Aims and Objectives of the study (include research hypothesis/hypotheses):

Summary of the proposed research scheme (250-500 words):

Current knowledge and relevant bibliography (whether justification is based on a gap found in the extant literature or otherwise, please justify)

Preliminary work done/pilot study conducted: (please furnish details)

List of publications of the PI or co-PI in the field (domain/methodology)

Structured abstract:

Detailed research plan:

Participant recruitment:

Context/setting:

Sampling method:

Methods of data collection:

Participant anonymity required:

Analysis (tentative):

Translations (if required):

Informed consent documents: (please submit all translated & original consent forms)

Outcome to the participant as an outcome of participation:

If any vulnerable groups to be enrolled (if applicable):

Any incentives offered to participants: (yes/no)

Potential risks to participants (if any):

Publications plans: (list all potential authors and their likely contribution)

Categories of contribution:

Category I: Significant contribution to the conception or design of the work. Acquisition of analysis and/or interpretation of data.

Category II: Drafting the work/revising it critically for methodological appropriateness.

Inter-departmental cooperation: (Please describe internal arrangements with other departments)

Attachment:	Yes	No
1. Questionnaire	☐	☐
2. Consent forms template for the participants	☐	☐

Signature of PI:

Signature of HOD/HOU:

Co-investigators' consent:

I/We give my/our consent to be a part and co-investigator and provide my/our expertise to the project. I have/We have approved this version of the protocol and contributed substantially to its development.

Name Department Signature Date

Format for Informed Consent Form for Subjects

Informed Consent form to participate in a research study

Study Title:

Study Number: _____

Subject's Initials: _____ Subject's Name:
_____

Date of Birth / Age: _____

(Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that *the Sponsor of the project, others working on the Sponsor's behalf (delete as appropriate)*, the Ethics Committee and the regulatory authorities will not need my permission to the data that I furnished. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

ONLINE APPLICATION FORMAT

(Apply to click here)

WOXSEN UNIVERSITY

APPLICATION FOR REC APPROVAL

Hi, Office of Research and Development WoU. When you submit this form, the owner will see your name and email address.

* Required

Download the Application for REC Approval Link Below

https://shorturl.at/yFQS9

1. Name of faculty/scholar *

Enter your answer

2. School Name

- ◯ School of Arts and Design
- ◯ School of Architecture and Planning
- ◯ School of Business
- ◯ School of Law

- ◯ School of Liberal Arts and Humanities
- ◯ School of Sciences
- ◯ School of Technology

3. Mobile Number *

Enter your answer

4. Title of Research *

Enter your answer

5. Is this research related Business Studies/Humanities/interdisciplinary) *

- ◯ Yes
- ◯ No