

RAKSHA SHAKTI UNIVERSITY



Guidelines on

THE ETHICS OF RESEARCH

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PREAMBLE

The Raksha Shakti University attaches the highest priority to the maintenance of high standards of integrity, responsibility and accountability in the research it supports and undertakes.

The Raksha Shakti University and its researchers may face ethical, sometimes legal, dilemmas from competing obligations and conflicts of interest. Therefore, a set of Ethical Guidelines have been evolved to provide a framework to guide research practice.

Enunciation of ethical principles and formulation of necessary guidelines for research are, therefore, a part of such a process, and also a necessary and desirable step. This document contains ethical principles and guidelines formulated and observed by the Raksha Shakti University.

INTRODUCTION

The Government of Gujarat has established “RAKSHA SHAKTI UNIVERSITY” vide ‘The Raksha Shakti University Act, 2009’, Gujarat bill No-16 of 2009 in the sixtieth year of the Republic of India. Among the major objects of the University, there is a clear emphasis on to facilitate research in all matters of Police Science & Internal Security.

The term ‘research’ refers to a class of activity at RSU which is designed to develop or contribute to ‘generic knowledge’. Generic knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. Research at RSU is predominantly ‘applied’ and ‘inter-disciplinary’ though concurrent interests on ‘pure’ aspects of Police Science & Internal Security is also investigated. All types of research including experimental, quasi-experimental, ex-post facto, case study, interview, survey, focus group studies, questionnaire and observation are carried out. Several ethical issues surface in the context of ‘applied’ research and human society.

As a concept, ‘research ethics’ refers to a complex set of values, standards and institutional schemes that help constitute and regulate research activity. Ethics does not exist in a vacuum. Ethics exist within a social context. All scientific activities, including those by the social scientists, are conducted with the participation of human beings or have an impact on human beings or on the wider society and environment. Therefore, it is essential that scientists/ researchers understand ethical issues and the implications of their research work and act accordingly. For making ethical judgment, the scientists/ researchers rely upon various standards of ethics, which could be universal or specific to the culture(s) or localities.

In recent years ethical considerations across the research community have come to the forefront. The ongoing discussions concerning ethical issues within research community highlight the fact that the developmental, creative and interpretative nature of research requires particular attentiveness to ethical dilemmas and tensions. In many cases, there will also be a legal requirement for consent on the part of those who actively participate in a research project, and this is also an important ethical consideration. If researchers fail to observe the legal requirements, they can be subject to penalties and other sanctions. However, it is important to underline that the sanctions ensue because researchers violate acts of legislation, not because they act at variance with the principles enshrined in this Guidelines for Research Ethics.

In the zest for pursuing knowledge, history is replete with instances of researchers wittingly or otherwise trespassing upon the rights/privileges of participating human subjects. Thereby, benefits have been deprived from those for whom the research benefits were actually intended. Unfairness has been delivered where justice was professed and proclaimed. Thus, it became imperative that certain values guide the choice of subjects or the conduct of research. There is need to develop formal checks and controls for carrying out value based research on human subjects. There is need to screen and scrutinize every research proposal, estimate the implications of their content, procedure or methodology on human rights of the target populations on whom they are being studied. There is a responsibility to recommend rejection, rectification or remediation of any or all those research proposals that appear to infringe or violate the rights of individuals being investigated. There must be clear guidelines on discrimination between honest error, negligent error and misconduct on the part of research investigators. Eventually, there is need for sentences, sanctions and prescribed punishments for defaulters or trespassers on human dignity and conduct.

The RSU, in facilitating innovative and high quality research, requires that the research it supports will be carried out to a high ethical standard. Recognizing that research and development do not happen in isolation, but in interplay with existing norms and values in our society, RSUEC (Raksha Shakti University Ethical Committee) is established. Research Ethics Committee in the university has an important role in facilitating ethical research by sharing their expertise. The principal aim of the ethics review is, as far as possible, to protect all groups involved in research: participants, institutions, funders and researchers throughout the lifetime of the research and into the dissemination process.

The ethical considerations of research are neither easy to characterize, nor can they be broken down into a single pattern that is universally applicable to the variety of research methods used while remaining globally responsive to the myriad of issues under study (ranging from daily life circumstances to those marked by various sensitivities). New methods pose new ethical problems. Research methods in any discipline are dynamic, progressive and developmental, therefore unforeseen risks at the beginning of a research could arise during the course of a study. It is recommended that researchers take a more systematic approach to risk assessment. The **moral integrity** of the researcher is a critically important aspect of ensuring that the research process and a researcher's findings are trustworthy and valid. Thus, ethics is not merely providing a model of behaviour for prospective and practicing researchers. It is equally important that the moral attitudes are portrayed as explicit rules by any organization. In this sense, this document, 'Guidelines on The Ethics of Research' is a public pronouncement of a pledge by the RSU towards the subjects involved in its research.

The Guidelines for Research Ethics have been compiled to help researchers and the research community be cognizant of their ethical views and attitudes, raise their awareness of conflicting standards, promote good judgment and enhance their ability to make well-founded decisions in the face of conflicting considerations. The guidelines therefore seek to document widely held principles of research. They are framed in the recognition that, on occasions, the operation of one principle will impede the operation of another, that researchers, in common with other occupational groups, have competing obligations not all of which can be fulfilled simultaneously. Thus, implicit or explicit choices between principles will sometimes have to be made. The guidelines do not attempt to resolve these choices or to allocate greater priority to one of the principles than to another. Instead, they offer a framework within which the conscientious researcher should, for the most part, be able to work comfortably. The guidelines' first intention is thus to be informative and descriptive rather than authoritarian or

rigidly prescriptive. Secondly, they are designed to be applicable as far as possible to different areas of methodology and application. For this reason the provisions are fairly broadly drawn.

The Raksha Shakti University is aware that any effort in formulating comprehensive guidelines for such a vast field of research in such a cosmic nation like ours and beyond its territories is not going to be adequate. So, keeping in mind the immediate and long-term interests of the larger sections of people and the autonomy of researchers, the ethical guidelines given in this document may be refined through periodic reviews. Needless to add that their experience in using these guidelines would contribute immensely in updating and refinement of the existing guidelines in coming time.

OBJECTIVES

The ethical principles and guidelines for research, given in this document, are developed for the follow purpose:

- 1) To sensitize and protect researchers who are often under pressures from various quarters/forces while undertaking research.
- 2) To preserve and promote the autonomy of research through the observance of ethics, ethical values and ethical self-regulation.
- 3) To protect and promote the human rights of participants and to sensitize and encourage researchers and organizations to respect participants' rights and needs.
- 4) To improve quality, legitimacy and credibility of the research in the areas of Internal security.
- 5) To make ethics an integral part of the planning and methodology of research, and to enable organizations and individuals to develop appropriate mechanisms for ethical self-regulation.

Ethical Principles & Code of Conduct for Research

Researchers should be fully aware of the ethical issues involved in their work and adhere to the ethical principles. Responsibility for all procedures and ethical issues related to the project rests with the principal investigators. Research should be conducted in such a way that the integrity of the research enterprise is maintained, and negative after-effects which might diminish the potential for future research should be avoided.

Some of these principles are enunciated below:

- 1) Respect for Human Rights.
- 2) Researchers shall adhere to research ethics standards, regarding honesty, impartiality and willingness to accept their own fallibility.
- 3) Institutions have a responsibility to respect the autonomy of researchers and should create and maintain an environment with adequate support systems to enable researchers to follow ethical guidelines.
- 4) Principle of Beneficence implying attempts to maximize benefits while minimizing risks of potential harm for human subjects or society.
- 5) Principle of Distributive Justice meaning equitable selection of human subjects without discrimination on the basis of caste, creed, religion, age, language, status, gender, disability, region or geographical location, etc. This also implies that there is equitable distribution of both the burdens as well as benefits of population research.

6) Principle of Voluntarism suggests that the choice of either participation or otherwise in an ongoing research activity must be entirely left to the freewill, choice and self-determination of the human subjects included as sample of the study.

7) Principle of Informed consent: Consent for participation in research is based on adequate briefing given to the participants about the details of the project. The briefing should be given both verbally and in writing in a manner and language that the participants know and understand. Researchers have a duty to ensure that the participants comprehend the information given.

Informed consent in the case of research with children (below the age of fourteen years) should be sought from the parents/guardians as well as the children themselves. The consent from parents/guardians should be waived only in special cases such as child abuse.

8) Principle of Non-Exploitation signifies that no human subject is used as means for furtherance of the interests of research investigators or at the cost of their abuse, mistreatment or disadvantage during a research process.

9) Principle of Ethical Neutrality refers to the temperament of 'equipoise' mandated for all prospective investigators. If a new intervention is being investigated against currently acceptable treatment, the researcher shall be genuinely uncertain in thought, spirit and action. In that sense, s/he should have and feel a true 'null hypothesis' regarding the outcome of the research.

10) Principle of Privacy and Confidentiality protects participating human subjects in research investigations from unauthorized observations and intrusions into their privacy. Researchers should maintain appropriate anonymity and confidentiality of information in creating, storing, accessing, transferring and disposing of records under their control, whether these are written, automated or in any other medium.

While deciding on what information should be regarded as private or confidential, the perspective of the participant(s) on the matter should also be given adequate importance.

11) Principle of Provision for Maximal Safety ensures pre-calculating risk/benefit ratios (if any) owing to the participation of human subjects in the research study.

12) Principle of Professional Competency is based on an understanding that any given research investigation is being undertaken only after a peer review and thorough study of current literature and previous studies.

13) Principle of Accountability and Transparency enunciates research investigators to take the onus on themselves for all the events or happenings to human subjects deemed to have occurred during a research process.

14) Principle of Integration & Mainstreaming as human subjects in this field may be from vulnerable sections of human society who have suffered exclusion, seclusion, victimization and separation, the responsibility of researchers gets doubled towards fostering research protocols and practices that foster social integration, inclusion or mainstreaming of such persons, their families or communities as a whole.

15) The Principle of Non-maleficence: Research must not cause harm to the participants in particular and to people in general.

16) *Public Domain*: All persons and organisations connected to research should make adequate efforts to make public in appropriate manner and form, and at appropriate time, information on the research undertaken, and the relevant results and implications of completed research.

17) The research should be carried out in full compliance with, and awareness of, local customs, standards, laws and regulations.

- 18) All research materials should be preserved in a manner that respects the agreements made with participants.
- 19) The institutions must ensure that research that complies with scholarly quality requirements is not suppressed because a topic is controversial.
- 20) Identifiable personal data collected for one particular research purpose cannot automatically be used for other research. Such data must not be used for commercial or administrative purposes.
- 21) Caution shall be exercised when deceased people are the subject of research or collecting human tissue samples.
- 22) Researchers shall respect the legitimate reasons that private businesses, special interest organisations, etc. may have for not wanting information about themselves, their members or their plans to be published.
- 23) Researchers shall show due regard for preservation needs associated with all types of cultural monuments.
- 24) Research on cultures other than the researcher's own pose special requirements for dialogue with representatives and members of the culture under investigation. Researchers must weigh consideration for the recognition of cultural differences against consideration for other fundamental values and human rights.
- 25) Plagiarism of others' text, material, ideas and research results is unacceptable and constitutes a serious breach of ethical standards. A plagiarist undermines not only his or her own reputation as a researcher, but also the credibility of the research. Researchers, shall strive to exercise good reference practice.
- 26) Supervisors are required to act in students' best interest, and not to take advantage of their dependence. This applies to professional findings as well as private lives.
- 27) Principal Investigators and researchers have a responsibility for preventing research results from being presented in a misleading manner. It is unethical to place limits on research to elicit particularly desirable results, or to produce research results in an intentionally skewed manner.
- 28) *In cases where a proxy is utilized* to answer questions on behalf of a subject, say because access to the subject is uneconomic or because the subject is too ill or too young to participate directly, care should be taken not to infringe the 'private space' of the subject or to disturb the relationship between subject and proxy.
- 29) Researchers have a right, as well as a responsibility, to refrain from undertaking or continue undertaking any research that contravenes ethical guidelines, violates the integrity of research and/or compromises their autonomy in research.
- 30) The juniors, assistants, students and trainees have a right to receive, and principal researchers have a responsibility to provide/impart, proper training and guidance regarding all aspects of research, including ethical conduct.
- 31) No researcher should impose views/beliefs on or try to seek personal, sexual or economic gain from anybody, including other researchers, juniors, assistants, trainees and students.
- 32) Students should have the right to opt out of a research project without having to face adverse consequences.
- 33) The administrative staffs associated, in some way, with the research should be briefed on ethical issues and the guidelines.
- 34) The researchers involved in a particular research and the institution where the research is conducted, have a joint right over and ownership of all raw data, including those identifying the participants.

- 35) Reporting of research and its results is the right as well as duty of every researcher and institution that conducted the study. When they agree to delegate this responsibility to funder(s)/sponsor(s) or any other individual(s)/organisation(s), they should do it only if they have received mutually agreed and expressed commitment to publish/disseminate the results/report within a stipulated period.
- 36) Authorship Credit: The following guidelines should be followed for giving authorship credit while reporting the research in any form: Authorship, and its sequence in case of more than one author, should be based on the quantum of contribution made in terms of ideas, conceptualisation, actual performance of the research, analysis and writing of the report or any publication based on the research. Authorship and its sequence should not be based on the status of the individual in the institution or elsewhere. All other individuals not satisfying the criteria for authorship but whose contribution made the conduct and completion of research or publication possible should be properly acknowledged.
- 37) *Non-disclosure of all information*: There may be genuine difficulties in accessing participants, possibility of affecting change in behaviour or responses, etc., when all the details are revealed. Thus, it is not possible to obtain the informed consent in the same way as described above. In such cases, the following should be done: **1** A detailed justification for not revealing all necessary information must be provided in the research proposal and methodology and should be subject to peer and ethical reviews. Only on approval in peer review, should such research be undertaken. **2** The participants' right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know fully the real purpose or objective for which they provide information. **3** Even if through a peer review process it is accepted that some of the information about the study need not be revealed, participants must be provided the rest of the information. Under no circumstance should the researchers withhold the information regarding physical risks, discomfort, unpleasant emotional experiences, or any such aspect that would be a major factor in taking the decision to participate. **4** As far as possible, debriefing should be done with the participants after completion of the research, giving reasons for not providing full information. As a part of the debriefing process, it might often be necessary to provide services such as counseling and referral.
- 38) Funders and sponsors have the right to get a copy of the ethical guidelines and the researchers and university report the progress of their work and submit a copy of the final report on results of research as per the schedule agreed in advance.

RSU Ethics Committee (RSUEC):

The RSUEC maybe simply viewed as a panel of chosen members bestowed with the responsibility to preserve and protect the rights, privileges, power and liberties of subjects. Ethical committees are alternatives, precursors and predecessors, to formal legal reviews. It predates and prevents later litigious complications. In that sense, ethics committees need to be treated and respected in the same manner as one would treat a jury.

RSUEC should be multidisciplinary and multisectorial in composition. Independence and competence should be the two hallmarks of the RSUEC. The Chairperson of the Committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. If required, subject experts could be invited to offer their views. They should be appointed by the Head of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country.

Membership requirements:

- a. The duration of appointment is initially for a period of 3 years.
- b. At the end of 3 years, as the case may be, the committee is reconstituted, and at least one-third of the members has to be replaced by new names.
- c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- d. A member can tender resignation from the committee with proper reasons to do so.
- e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
- f. Conflict of interest, if any should be declared by members of the RSUEC.

Quorum requirements:

The minimum of half of the total number of members are required to compose a quorum.

Offices

The Chairperson will conduct all meetings of the RSUEC. If for reasons beyond control, the Chairperson is not available, an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for preparing the agenda, organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers.

RSUEC Constitution:

The RSUEC shall consist of the following representatives

S.No.	Title of the Representative	Eligibility/qualification of the Representative
1	Chairperson	An eminent member of the State/National judiciary
2	Member Secretary	One Faculty member not below the rank of any 'Head' among Departments at RSU.
3	External Members	At least three members representing the interests of human subjects/ Science/ Social science, preferably involved in the field of research in security related areas.
4	Internal Member	One Director or One Faculty member not below the rank of any 'Head' among the Institutes/ Departments at RSU
5	Permanent Invitee Member	Director, Research & Development, RSU
6	Special Invitee Members (Optional):	Director General/ Dy. Director General/ Any other member specialized in areas under consideration co-opted for advice in situations or under circumstances requiring such counsel for the Ethical Committee.

Meetings of RSUEC:

The RSUEC is expected to meet at reasonable intervals as needed(at least once in every six months).

The project proposals received at least fifteen days in advance before the scheduled date of an RSUEC meeting will be accepted for presentation in the agenda for that meeting. The principal investigators of the projects or their nominated representatives are expected to make an appropriate presentation before the RSUEC and defend themselves against any doubts, clarifications, questions, suggestions, recommendations or corrections offered by the members thereof.

The Member Secretary shall advance inform the concerned principal investigator/s who project/s is/are scheduled for review during a given meeting of the RSUEC. Such advance

information as well as the information on final acceptance or rejection of a research proposal should be given well within one week before or after the RSUEC meeting. The Member Secretary is expected to coordinate, organize and maintain the minutes of all RSUEC meetings. All information concerning project proposals received, discussed, debated, modified, accepted or rejected shall be kept confidential. This is equally true of infringements or trespasses made by certain research investigators, penalties discussed, or sanctions recommended by the RSUEC in individual cases coming up during the meetings. The files of the RSUEC related to investigation and adjudication of cases shall also be kept confidential in the office of the Member Secretary.

Decision-making

- a) Members will discuss the various issues before arriving at a consensus decision.
- b) A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
- c) Decisions will be made only in meetings where quorum is complete.
- d) Only members can make the decision. The expert consultants will only offer their opinions.
- e) Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.
- f) In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- g) The researchers, in case of rejected projects, may appeal to the RSUEC for reconsideration supported by proper justification. In such cases RSUEC may seek recommendations of an independent three member commission formed by Hon. Director General for the specific issue. Except chairman, none of the members will be common to RSUEC.

Communicating the decision

- 1) Decision will be communicated by the Member Secretary in writing.
- 2) Suggestions for modifications, if any, should be informed to the researchers.
- 3) Reasons for rejection should be informed to the researchers.
- 4) The schedule / plan of ongoing review by the RSUEC should be communicated to the PI/ researcher.

Record keeping and Archiving

- 1) Curriculum Vitae (CV) of all members of RSUEC.
- 2) Copy of all study protocols with enclosed documents & progress reports.
- 3) Minutes of all meetings duly signed by the Chairperson.
- 4) Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.
- 5) Copy of all correspondence with members, researchers and other regulatory bodies.
- 6) Final report of the approved projects.

Standard Operating Procedures (SOP)

The objective of this SOP is to contribute to the effective functioning of the RSU Ethics Committee so that a quality and consistent ethical review mechanism for fostering research is put in place for all proposals.

Application Procedures:

- 1) All proposals should be submitted in the prescribed application format.
- 2) All relevant documents should be enclosed with application form.

- 3) Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the ethics committee.
- 4) The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
- 5) The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
- 6) Prescribed fee if any, should be remitted along with the application.

Application forms and protocols

Ethics issues must always be addressed in the proposal. All proposals must state what ethics approval the applicant(s) considers will be required for the proposed research, and why.

Research proposals, submitted for approval to RSUEC might be expected to include the following information in a way that is understandable to all members:

- Project title
- Expected duration
- Identity of field researchers and organizational base
- Purpose of study & Sources of funding
- Scientific background & Design of the study
- Potential participants and vulnerable group, if any
- Potential benefits and hazards
- Recruitment procedures & Informed consent
- Data collection and analysis methods
- Data use conditions set by data providers
- Data protection, Confidentiality and anonymity
- Monitoring of the research & Dissemination of findings
- Expected outcomes and impact of research
- Researcher's assessment of ethical issues.
- An undertaking by the researcher/s to ensure implementation of all ethical guidelines.

Review procedures:

- 1) The meeting of the IEC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.
- 2) The proposals will be sent to members at least 10 days in advance.
- 3) Decisions will be taken by consensus after discussions, and whenever needed voting will be done.
- 4) Researchers will be invited to offer clarifications if need be.
- 5) Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.
- 6) The decisions will be minuted and Chairperson's approval taken in writing.

Elements of Review:

RSUEC should review research proposals in terms of their ethics probity. The RSUEC must review all important facets of research as mentioned in Application form. In addition to those, RSUEC may also review Compensation provisions and adherence to all regulatory requirements & applicable guidelines.

Follow up procedures:

- a. Reports should be submitted at prescribed intervals for review.

- b. Final report should be submitted at the end of study.
- c. Protocol deviation, if any, should be informed with adequate justifications.
- e. Any amendment to the protocol should be resubmitted for renewed approval.
- f. Premature termination of study should be notified with reasons along with summary of the data obtained so far.
- h. Change of investigators / sites should be informed.

Some other Important aspects of Research Ethics Review Procedure:

- 1) The decision made for each proposal, and the grounds on which it was made, should be recorded and provided to the researchers, and a copy kept on file with the proposal for a specified minimum period, extending at least beyond the lifetime of the project.
- 2) It is expected that in some cases as research progresses, further ethics issues may arise. In such cases, Principal Investigators should go back to the RSUEC or the RSUEC itself check through the implications of the new developments and effect any changes in the project.
- 3) RSUEC may undertake occasional ad hoc audits of research projects. Principal Investigators and supervisors of students need to know that they must keep good records of their ethics procedures in case they are called to account.
- 4) **Multi-funded research:** If there are number of funders of a project, the RSU guidelines on the ethics of research must be drawn to the attention of all proposed funders during the submission for funding. Research organizations engaged in collaborative research may agree to use the services of one of their Ethical Committees to review a joint project on behalf of all participants.
- 5) **Multi-performer research:** Research involving participants from more than one institution should consider agreeing arrangements for accepting one another's decisions following formal ethics review. Each institution would retain formal responsibility for overseeing the ethics review of research conducted under its auspices but would accept the decisions made by the Ethical Committee of the institution where the principal investigator is based.
- 6) Where research is to be conducted outside the INDIA, the RSU expects researchers to establish whether local ethics review is required by the host country, and if not, how the principles of the RSU ethical guidelines can be followed in undertaking the research.
- 7) **Expedited Review.** In exceptional circumstances, it may be necessary for a proposal involving possible risk of harm to receive a full review at short notice. An expedited review will be carried out by one or more members of RSUEC, commonly its Chair.
- 8) **Legal and data requirements must be met.** Researchers must comply with legislative requirements and with those of data providers.
- 9) RSUEC generally has no authority to impose sanctions on researchers who violate ethical standards in the conduct of research involving human subjects. They may, however, withdraw ethical approval of research projects if judged necessary. Sanctions, if necessary, can be a recommendation to the university and can be in the form of fines, suspension of eligibility to receive research funding, refusal of permission to publish results, etc.

ANNEXURES

Annexure 1

APPLICATION FORM FOR SEEKING APPROVAL FROM RSU ETHICS COMMITTEE

(For Office Use) Reference No. _____

S.No.	FIELD	DETAILS
1	Title of Project	
2	Principal Investigator	
3	Co-Investigators (If any)	
4	Proposed Duration of Project	
5	Estimated Budget Requirements	
6	Source of Funding	
7	Statement of the Problems & Objectives	
8	Purpose of study	
9	Scientific background	
10	Design of the study	
11	Potential participants and vulnerable group, if any	
12	Recruitment procedures	
13	Potential benefits and hazards of the study	
14	Informed consent format	
15	Data collection and analysis methods	
16	Data use conditions set by secondary data providers	
17	Data protection provision	
18	Mechanism for Monitoring of the research	
19	Expected outcomes and impact of research	
20	Mode & timing of Dissemination of findings	
21	Researcher's assessment of ethical issues.	
22	Identity of field researchers and organizational base	

- Use additional sheets wherever required.

DECLARATION

I, Dr / Mr./ Ms. _____ have read the 'Guidelines on The Ethics of Research' being followed by the Raksha Shakti University. I promise to abide by all the guidelines enunciated therein during the execution of the project titled _____. I shall proceed to commence work on my project only after securing a written approval from RSUEC. I agree to be held accountable for any unforeseen mishaps, insults, injuries or harms occurring to my human research subjects during their participation in research process.

Date:

(Principal Investigator)

Annexure 2

SPECIMEN FORMAT FOR SEEKING INFORMED CONSENT FROM HUMAN SUBJECTS INVOLVED IN RESEARCH PROJECTS AT RSU

Information to the Participants:

In this section, include information on the title and objectives of the study being undertaken along with the type or number of human subjects being included or excluded as part of this research investigation. Also include under this section, details on 'why' or 'what' of the said research study being undertaken on human subjects. Highlight the risk/benefit elements involved for the human research subjects willing to participate in the said study. Emphasize that the privacy-confidentiality-anonymity of participating human subjects will be ensured from beginning to end of the study. Place on record the view that the investigators respect the autonomy and ability for free-choice of the human subjects and that they are entirely on their own either to participate or reject as per their will or wish without any resulting damage to the later services made available for such persons at the university. It is to be clarified that there is no element of coercion, influence or pressure of any kind by the researchers or the investigating institutions to participate as human subjects in the given study. There should be information on expected duration of the subject's involvement in the research study, the total time needed and the possible number of visits to be made when included as part of the investigation. If any monies are to be paid towards participation or travel, the subjects should be explained on such terms and conditions in clear and explicit terms.

*Please note that the above format is only a guideline, which may need to be modified according to the situation or need for special research projects. It may also require changes depending on whether the participating human subject is a child, adult, person with disability, guardian or caregiver. Further, if the participant is not proficient in English, it must be ensured that the consent form is given in a language read or understood easily by the subject. The informed consent format could in minimum of three languages including English, Hindi and the local language. The translated version must be necessarily true and representative of the original version.

Informed Consent

I have been informed about the aims, objectives and the procedure of the study. The possible risks-benefits of my participation as human subject in the study are clearly understood by me. I understand that I have a right to refuse participation as subject or withdraw my consent at any time without adversely affecting my/my ward's treatment by RSU. I am also aware that by subjecting to this investigation, I will have to give more time for assessments by the investigating team and that these assessments may not result in any benefits to me. I have the freedom to write to Chairman, RSUEC, in case of any violation of these provisions without the danger of my being denied any rights to secure any services at RSU.

I, _____, the undersigned, give my consent to be participant of this investigation/study/program.

Signature of Parent/ Guardian
Witness
(Name and Address)

Signature of
(Name of Witness)

Date:

Signature of Investigator
Name and Designation

Annexure 3

SPECIMEN FORMAT FOR ACCEPTANCE/ REJECTION OF 'ETHICS APPROVAL' FOR RESEARCH PROJECTS AT RSU

RSU ETHICS COMMITTEE

Title of Project: _____

Principal Investigator: _____

Co-Investigators (If any): _____

Proposed Duration of Project: _____

Estimated Budget Requirements: _____

Source of Funding: _____

Reference Number of the Proposal: _____

Date on which RSUEC Meeting was held: _____

Decision of the RSUEC _____

Clear Statement of Decision Reached at RSUEC Meeting in the event of a proposal being not approved, a statement of reasons for the same must be indicated:

ADVICE & SUGGESTIONS (IF ANY):

Date:

Name & Signature of Member Secretary

REFERENCES:

- 1) Margit Sutrop and Prof. Carmen Florea Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research, 2010.
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