

CODE OF ETHICS FOR RESEARCH

People's University, Bhopal, India, established in 2011, which follows the highest degree of ethical standards in its daily operational functioning. To ensure this People's University follows these ethical standards:

1. Orientation in ethics is given intermittently to its faculty.
2. Guest lectures by esteemed speakers are arranged on ethics.
3. Need based in-house training on ethics is provided from time to time.
4. Staff is motivated to attend external trainings on ethics outside the organization.

Ethics being inbuilt in all the operations of People's University utmost care is taken that there is no ethical violation on any count. Ethical functioning of People's University is reviewed through review of the research and other proposals and their follow up at all levels. Constructive, positive criticism is invited from coworkers in internal open house sessions, and the suggested corrections are noted down and implemented.

The People's University believes that all its coworkers have the duty to uphold the ethical standards in high esteem and follow these meticulously in its daily operations.

Importance of the Code

The People's University pursues a research ethos which encourages exceptional acquaintance and ethical responsibility in its research work. Excellent researchers are required to strive for the highest standards of excellence and morality in all research activities. The Code of Ethics for Research serves as an important guideline to inspire researchers at the People's University.

Focus of the Code

The Code identifies key values characterizing the ethos which the People's University pursues. It highlights the rights and responsibilities of researchers are applicable in research environment.

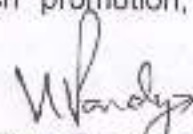
Terminology

Research freedom: It entails the complete protection of independence of investigation, data gathering, thought, expression and publication of results.

Research misconduct: Practice that constitutes a serious deviation from what is generally accepted within the scientific community in the submission, performance and reporting of research.

Animal experiments: Procedure that includes use of live animals for testing a hypothesis, information collection, research promotion, transfer of knowledge, collection and testing of product.

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Compensation: All compensation that is received for services provided. This includes salaries or form of remuneration, goods, shares and/or other items of significant economic value.

Conflict of interest: Conflict of interest arises when the individual's private or personal interest and professional obligations are contrary to such an extent that an independent observer may have doubt as to whether or not the individual's professional actions are influenced by personal considerations, financial or otherwise.

Consultant: A member of Institute who renders advice in his/her professional field to an outside person, group or organisation against payment.

Contract research: All research procedures carried out for outside organisations as part of the researcher's service dispensation in terms of the provisions of the Rules for Contract research work of the PU

Copyright: The proprietorship and control of intellectual property in inventive works captured as a-pliable form of expression from which it can be viewed, reproduced or otherwise communicated, whether directly or by means of a machine or device.

Experimental animals: All living non-human fetus of a vertebrate, non-human vertebrate, or any other species which, in the opinion of the Ethics Committee (EC) concerned, has a nervous system that can experience pain in the same way as a vertebrate.

External activities: All research activities performed by a member of staff acting as a consultant and including outside work. Contract research is excluded from this definition since it forms part of the researcher's service dispensation.

Funders of research: Institutions or individuals that provide financially support research in part / full.

Human participants in research: A living individual on whom the researcher is conducting research by:

- (a) collecting data by intervention or interaction with the individual, or
- (b) obtaining identifiable private information.

"Intervention" includes physical procedures by means of which information is gathered, along with manipulation of the participant or the participant's environment for research purposes.

Integrity: Constant maintenance of ethical values in words and behavior.

Member of staff: Any person in full-time (permanent full-time / temporary full-time) or part-time appointment at the PEOPLE'S UNIVERSITY and who is entitled to benefits and/or a salary or wage for his/her defined responsibilities. Including undergraduate and postgraduate students appointed to perform work as part of a grant or contract and who are fully or partially responsible for reporting on research.

Minimum risk: The risk of harm anticipated in the projected research does not exceed, given probability and extent, the risk that would be come across normally in daily life or during the presentation of routine physical and psychological examinations or tests.

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Open research environment: This safeguards that, as far as possible and taking into account ethical guidelines and the rights of everybody involved, students are given unlimited exposure to ideas and data, and as far as possible be given unlimited opportunities to become involved in research and to publish results.

Outside work: Work performed by researcher with or without remuneration outside People's University work, which does not form part of the course and extent of their service to the PU/ PEOPLE'S UNIVERSITY, for which they have obtained permissions.

Research / research activities: Every systematic examination aiming to contributing and or developing to, knowledge that can be generalized. Activities complying with these requirements are regarded as research, regardless of whether they are normally described as "development", "demonstration" or by any other term.

Researcher: Includes any full-time /part-time Scientist, Faculty, Research assistant (RA), Senior Research Fellow (SRF), Junior Research Fellow (JRF), undergraduate (UG) or postgraduate (PG) student of People's University or other Institute taking part in any research activity.

Tangible research goods: Items such as biological materials, computer software, databases, prototype devices and diagrams. It differs from immaterial items or intellectual property such as inventions, patents, work subject to copyright and trademarks subject to other policy guidelines.

People's University resources: These include, but are not limited to, all facilities, staff, equipment, materials, expertise, information and confidential information of the People's University and its research projects.

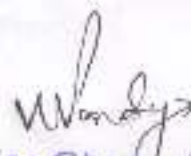
PREAMBLE

The People's University gives high priority to research as one of the primary research institute of the PU. It pursues a research ethos that promotes excellence as well as ethical responsibility in the search for and the creation, conservation and transfer of knowledge. Consequently, researchers at the People's University are required to pursue the highest standards of excellence and ethical behavior in all their research activities.

KEY VALUES

These include:

- Research freedom
- Academic environment conducive to research
- The availability of facilities, services and other resources of the PU
- Social responsibility
- Justice
- Benevolence
- Respect for the individual
- Professionalism
- Refraining from discrimination
- Refraining from the abuse of supervisory authority



- Refraining from gender harassment

THE RIGHTS OF RESEARCHERS

The right to research freedom

Researchers at People's University are free to choose the subject of their studies related to thrust area of People's University and to seek support for their research from any appropriate source. Researchers have the right to information required for their research, in so far as there is no legal or moral limitation on furnishing such information. They have the right to disseminate the results of their research, without supervision or alterations by external funders, unless this has been stipulated in advance by a signed contract.

The right to research environment conducive for research

People's University has the responsibility to create an environment that promotes research and fosters good researchers. People's University will create an environment in which research can flourish, by, among other things, visionary policy, innovative programmes, sound support services, appropriate incentives, effective financial management and the mobilization of funding.

The right to the facilities, services and other resources of the PU

The Institute has the responsibility, in so far as it is feasible, to make facilities, equipment and services available to researchers for use in research, with a view to the creation of an environment which is conducive to research. Where the People's University does not have sufficient resources to give effect to this right, it should endeavor to obtain resources from other sources and to allocate them to researchers. Researchers are allowed to negotiate facilities, funds and other resource from elsewhere for research programmes in case of limited availability of resources. With due permission from Head of Institution.

THE RESPONSIBILITIES OF RESEARCHERS

Researchers are obliged and responsible to follow key values in their research.

Social responsibility

Researchers should accept that they form part of a broader community and that their responsibilities therefore go beyond the academic environment. Consequently, they should be attuned to the needs and problems of local, national and international communities in which they are functioning. Research should contribute to the development of prosperous, free and just communities.

Justice

Fair treatment of all individuals involved in research should therefore be one of the most important objectives of researchers and research institutions.


Vice Chancellor

- **Contractual justice** refers to the fairness of specific agreements and transactions between individuals and/or representatives of institutions involved in research.
- **Distributive justice** refers to the fairness of the distribution of benefits for a specific community among its members.
- **Contributory justice** refers to the fairness of the contributions requested from individuals and organizations.
- **Retributive or affirmative justice** refers to the fairness of punishment imposed for crimes perpetrated or offences committed, or the compensation requested for rectifying offences. By the IQAC of Institutions.

Benevolence

In order to conduct research in an ethical way, all parties involved should not only be protected from harm, but efforts should also be made to ensure their well being. This falls under the principle of benevolence. The term 'benevolence' refers to generous or charitable behavior that is not compulsory for everybody. 'Benevolence' or 'goodwill' does, however, refer to an obligation that comes into effect in two general rules that are mutually complementary: Do not cause harm, and increase possible benefits and reduce possible harm.

Do not cause harm

This principle can be applied to various spheres of research to indicate that individuals, animals, the environment, etc. should not be harmed for the sake of research, regardless of the benefits that may result from such research.

In the case of specific research projects, researchers and other members of staff of People's University are obliged to give prior consideration to maximizing the benefits and reducing the risks that may result from the research. Since the aim of research should always be the improvement and/or the promotion of the quality of life of humans as well as animals, care should be taken not to encroach upon the rights of humans and animals during the research process. Researchers should try not only to minimize future harm, but also to eliminate injustices and harm from the past.

Respect for the individual

It can be divided into two moral duties:

- The duty to recognize the autonomy of the individual, and
- The duty to protect persons with reduced autonomy.

Professionalism

Researchers should ensure that they comply with the professional standards of the occupation. They have the following professional responsibilities:

- **Integrity:** The individual integrity of every researcher should be irreproachable at all times, since the collective integrity of individual researchers constitutes the very cornerstone of science.
- **Quality:** Researchers are responsible for the academic character, accuracy and reliability of their own research and of anything done under their supervision. Researchers should always apply the highest standards of excellence with regard to the planning, implementation and reporting of research.

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- **Accountability:** Individual researchers should be held responsible for the originality of their work, for the complete disclosure and reporting – to the Research community as well as peers, journal editors, funding agencies, grant authorities and other scientific organizations concerned like CTRI.

Refraining from discrimination

Discrimination is any action resulting in the services, benefits, opportunities and/or facilities of the People's University being withheld from someone on the grounds of race, gender, pregnancy, marital status, family status, ethnic or social origin, colour, old age, disability or medical condition, religion, conscience or beliefs, culture, language and birth. Discrimination also includes any communication, whether verbal, written, electronic or non-verbal, that promotes a lack of respect or intolerance towards specific individuals or groups. The People's University strives to create a work environment that will support and reward its members of staff and students on the basis of applicable factors such as work performance and research success. Discrimination has a negative effect on this environment and should therefore be avoided at all costs by researchers.

Refraining from abusing supervisory authority

Abusing supervisory authority includes misuse of authority in any form of conditional, or apparently conditional, granting of services, benefits, opportunities or facilities on the grounds of performance or events not related to the research achievement or work performance of the person being supervised. This practice has a negative effect on the research environment and should be avoided at all costs by researchers.

Refraining from gender harassment

The People's University is a research institution striving for the creation of non-discriminatory work, living and learning environment for everybody, where it will be possible for everybody to realize his/her full potential. It recognizes that the protection of human dignity and the discouragement of offensive actions form an integral part of such environment and recognizes that gender harassment is an unacceptable encroachment on the core values of human dignity, privacy and mutual respect, and is a form of unfair discrimination. The committee involved to ensure this is Grievance Redressal Cell, People's University.

APPLYING THE KEY VALUES

The key values should be applied within the various relationships in which the researcher operates. Within these various relationships, more specific rights and responsibilities are applicable. The People's University is committed to carry out research that will contribute to the well-being and quality of life of all. They should therefore recognize the right of the community to have access to research findings and information in as far as it does not encroach upon the right to confidentiality of clients, funders or participants in research.

Researchers should be aware of the priorities concerned as identified by the government of the day (since these keep on changing according to national policies) and should try to contribute to the national well-being and prosperity. However, they must not be forced to confine their activities only to the immediate

priorities of the government of the day. The essence of the People's University as an institution lies in its capacity to combine excellence in the creation and conservation of knowledge with the establishment of life skills and values, with a view to ensuring the responsible and effective use of knowledge to the benefit of the local and worldwide communities. Researchers have the responsibility to promote knowledge as well as wisdom by pursuing truth with regard to all aspects of life.

The environment where a scientific investigation involves the physical or biological environment as subject of investigation, the researcher should go out of his/her way to prevent any irresponsible intervention in such environment. Where a scientific investigation includes the use or the production of hazardous substances, care should be taken to ensure that the risks to the environment, to community life and to human beings and animals that may come into contact with such substances after conclusion of the investigation, are kept within acceptable limits. Where an investigation involves viruses, micro-organisms or plants, the objective thereof should be ethically justifiable. Procedures should make provision for the required level of biosafety in the given circumstances and for the protection of the environment and human beings or other organisms that may be exposed to risks during the investigation.

Researchers and Funders of Research

Conflict of interest

Any conflict of interest should be avoided, and all researchers are requested to make known any potential conflict of interest. Interference by clients or funders that could compromise the integrity of the research is unacceptable. Information regarding the identity of participants in contract research will not be made available to funders, unless the individual participants agree.

Confidentiality of research results

Agreements with clients and funders of research are subject to the principle that the People's University undertakes to make research results freely available to the public within a specified and limited time framework and in a responsible manner.

Financial obligations

Remuneration agreements for participants and researchers should be set out in the contract or in the conditions of grant / funding application, as well as other approved budgetary items. Funds should be spent within the confines of the contract or grant, and in the event of any overdrawn account it is the responsibility of the project/program leader to redeem this overdrawn account by transferring the necessary funds to an appropriate account.

Funds for new fields of research

The costs of the preparation of research proposals and other activities in support of new fields of research may not be offset against funded projects or project costs intended for other purposes. Such costs should be recovered from other free sources. The costs of proposals with regard to continued research may be offset against the funds of the existing projects.

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RESEARCHERS, PEOPLE'S UNIVERSITY AND THE BROAD SCIENCE COMMUNITY

Researchers must not abuse their position and authority for any personal gain. Although they may consider their own secondary interests, these interests may never hamper or compromise their freedom of investigation. Research should always be conducted in a particularly academic and responsible manner.

Researchers should accept responsibility for:

- the design, methodology and execution of their research;
- the planning of research in such a way that the findings will be credible and valid;
- reporting their findings, and the limitations thereof, so that such findings can be subjected to peer evaluation and be made available to the public; and
- pointing out alternative interpretations where this may be applicable.

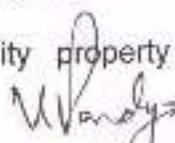
The results and findings, researchers should subscribe to the principles of honesty, completeness, intelligibility, clarity, accountability, and exposure to public testing. Where applicable, the authority of professional codes in specific disciplines should also be recognized and respected. The People's University has the right to submit to audit procedures the quality of research, the ethical acceptability of research procedures as well as the financial aspects of the research. Researchers should be prepared to submit themselves to procedures in this regard established by the People's University or by clients of the PU, as well as to peer evaluation to ensure the excellence of their work.

Research misconduct

Research misconduct should be considered within the framework of the definition of misconduct in the Statutes of the PU. Misconduct within the research environment should be avoided at all costs. If a researcher is found guilty of academic misconduct, suitable action against the person concerned will be taken as set out in the People's University conditions of service and disciplinary code.

The following actions should be avoided:

- Failure to give proper acknowledgement to the inputs of collaborators.
- Fraudulent inclusion or reporting and manipulation of factual information.
- Plagiarism as the appropriating of literary work, or portions of such work, by someone else, and the presentation thereof as if it were the guilty person's own work.
- Un-authorised use of confidential research results (research theft) where this is not in accordance with acceptable academic or collegial behaviour.
- Unacceptable acquisition, allocation and abuse of funds allocated for research purposes.
- Retribution of any nature against a person who has acted in good faith in reporting suspected or alleged academic misconduct or in giving information in this regard.
- Unlawful and un-authorised use of People's University property and equipment.
- Violation of copyrights or any other form of IPR.


Vice Chancellor
People's University

- Abuse of research by faculties, scientists, researchers, post graduate students for their own purposes.
- Failure to comply with research tasks forming part of work duties.
- Undermining other individuals' fundamental rights in the execution of research.

Conflict of interest

Academic members of staff may not allow other professional or outside activities to distract their attention from their primary responsibilities towards the People's University. They should maintain a significant and professionally acceptable presence when on active duty. Holidays and leave should be in accordance with the People's University regulations.

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

Researchers may use resources, including facilities, staff, equipment, information or confidential information as part of contract work, provided that the People's University is compensated in terms of the provisions of the Rules for Contract Work. Researchers may not use resources for any purpose other than purposes related to teaching, research or service, unless prior permission has been obtained from head of the department or higher authorities, as provided by the regulations.

Researchers should disclose in good time all potentially patentable inventions that have been discovered or created in the course and within the ambit of their service. Ownership of such inventions should be dealt with in accordance with the policy. Researchers should inform the People's University whether they have consultation agreements or work in an outside institution, before the following proposed arrangements or agreements between such institutions and the People's University will be approved: a) gifts; b) funded projects; c) technology licensing agreements; and d) allocations. In such cases formal People's University permission will be required before the proposed arrangements or agreements can proceed.

Intellectual property

Researchers should be aware of all the provisions and should submit themselves to all the control mechanisms and guidelines of the PU. The more important principles underlying this are:

- Promotion of free and creative work to the benefit of science and society as a whole. The conservation of traditional university practices and privileges with regard to the making available and publication of academic works
- Establishment of ethical standards and procedures with regard to intellectual property
- Promotion of creative and innovative research and cooperation by the establishment of mechanisms recognizing the rights of all the parties concerned, promoting the acquisition of benefits from research, and guaranteeing the equitable distribution of benefits from research by establishing principles and procedures for distributing revenue from inventions and creative work (as per the funding agencies); Protecting and

marketing the University's assets, including its Intellectual Property, to the benefit of all interested parties.

RESEARCHERS AND THEIR COLLEAGUES OR COLLABORATORS

Authorship

Since academic work is informed by a multitude of sources offering concepts and information, it is essential to emphasize rightful acknowledgement in the presentation of ideas and the publication of manuscripts. Authorship should be awarded only to those persons who have made an original and significant contribution to the conceptualization, design, execution and interpretation of the published work. Individuals who have made smaller contributions by for instance giving advice, performing analyses or providing subject material, or who have supported the research in some other way, should be acknowledged.

The principal author should determine whether or not these individuals should be included as authors. Sometimes written permission has to be obtained for acknowledgement in the published work. In the case of co-authorship, questions arise as to the criteria for inclusion as author, the ability of each author to evaluate all aspects of the study and the sequence of the list of authors. Authors should discuss these questions openly and should make appointments before undertaking the project. The author submitting the work, or the principal author, is responsible for coordinating the completion and submission of the work and for ensuring that all the contributions and all the collaborators are given proper acknowledgement. All authors should approve the final version of the manuscript and should be prepared to accept responsibility for the work in public. Each author / co-author is responsible for the compilation, revision and verification of those parts of the manuscript, publication or presentation representing his/her contribution. All co-authors are entitled to making their own copies thereof, including figures and attached documents.

In factual or scientific reports, authors should go out of their way to quote applicable data, including those data not supporting the hypothesis proposed. It is the responsibility of the author(s) to be *au fait* with other appropriate publications and to quote from them. It is unethical, and harmful to the PU, to present as one's own the work of others, whether in part or in full, to fabricate research results or to omit or change information. Authors who wish to quote information obtained at a personal level or from unpublished written material should obtain written permission from the source. It is inappropriate and unacceptable to submit extracts from research, or reports on the same research, to more than one publisher, unless such action has been approved by the editors of each publication or multiple submission is the acceptable standard practice in the specific discipline or field. In the complete report on the work in question, reference should be made to preliminary extracts from work that has already been published.

Selecting research partners

Researchers have the right to select research partners on the grounds of the value and quality of the work of other researchers in the field, provided that both partners are able to make a significant contribution to the joint project. Researchers are encouraged to undertake joint research projects with colleagues of other local / foreign institutions and to promote inter / multidisciplinary research. In such

instances, researchers should ensure that they are familiar with the contents of the relevant policy documents of the institutions concerned, for example the intellectual property policy, and that effect is given to the applicable provisions thereof, provided that this is not in conflict with the Peoples University policy and regulations.

Assisting with the research of others

Researchers should strive to assist and support other researchers from disadvantaged communities and social groups by means of advice, information and cooperation. A researcher who takes part in the research of another researcher, whether it is a Peoples University colleague or an outside person, does so as a professional person and is therefore accountable for his/her actions.

The decision to take part must be based on the following information:

- Research protocol
- Procedures for obtaining a participant's permission
- Extent of inputs required from the researcher. A researcher who takes part as collaborator in the research as a fieldworker or data collector (and who did not take part in the planning) is obliged –
 - To work according to the research protocol;
 - To report on any additional information that was collected in the course of the field work and that may influence the research;
 - To stick to the research schedule, and
 - To give notice in good time if his/her involvement is going to be terminated.

The researcher is entitled to terminate his/her involvement in the research in due course after consultation or after giving notice and taking into consideration specific commitments. If the researcher is more than a fieldworker or collector of data and also takes part in the planning of the research and/or analysing the data, his/her contribution should be acknowledged in any resultant publication. The extent of the acknowledgement should be negotiated in advance. Research partners should be informed of the outcome of funding applications and of the research findings and outputs.

RESEARCHERS AND STUDENTS UNDER THEIR SUPERVISION

Supervising students' academic work

The People's University is responsible for teaching Undergraduate (UG) and postgraduate (PG) students and preparing them to enter society and to practice their disciplines according to high ethical standards. The People's University and its staff have an obligation towards the broad academic community, the students and the public to ensure that all students involved in academic and research activities do so with responsibility and with respect for the highest professional standards.

Study leaders, research leaders and administrative heads share the responsibility for providing an open and equal research environment to persons undergoing training. They must ensure that students are given fair acknowledgement for original work, that students are not taken advantage of for the study leader's own research purposes, that demands made on students are reasonable and that they are treated as peers with the same professional courtesy. Opportunities should be created for students who feel that their supervision or training is inadequate. Study

and research leaders should regularly meet with students, colleagues and other collaborators to evaluate the work and progress being made. They should encourage students to critical and independent thought and to share ideas and information with other members of the academic community. They should ensure that the experience gained by the students will contribute to preparing them for their future as independent researchers.

Training of PG students in research ethics and integrity

Ethical issues in the carrying out of research should form an integral part of the training of all senior UG and PG students. A study leader should require students to have at least a basic understanding of research ethics and should encourage them to be able to identify and deal with the ethical issues relating to their research, results and publications. Every study leader is responsible for the establishment and execution of the principles of research ethics among students and research staff under his/her supervision. Study and project leaders should also serve as role models for students in the manner in which they conduct their research.

RESEARCHERS AND HUMAN PARTICIPANTS IN RESEARCH

The ICMR guidelines for Biomedical Research are being followed

(Annexure-1)

Basic principles

In their relationship with human participants in the research process, researchers should consider the principles of respect for personal autonomy, benevolence and justice. It is important to understand that these ethical principles do not exist in isolation from each other. Furthermore, good judgement and sensitivity are required in the application of potentially conflicting principles, as are often found in this type of research. An awareness of potential conflict should lead to the development of useful strategies for combating conflict.

Applying the principles: Evaluating risks and benefits

The researcher must always consider the ethical applicability and foreseeable consequences of the research. Determining the risks and benefits of the research requires a careful collection of relevant data and, in some cases, alternative methods for achieving the benefits aimed at in the research. The researcher should care about the interests of vulnerable participants such as children, disabled persons and the aged.

The nature and extent of risks and benefits

The requirement that research can be justified only on the basis of a favorable risk/benefit evaluation is closely related to the principle of benevolence. Risks and benefits of research may have an effect on individual participants, the families of

Individual participants and the community as a whole (or specific groups of participants in the community). Various types of possible harm and benefits should be considered. The researcher should protect participants in research against foreseeable physical, psychological or social harm or suffering that may be experienced in the course, or as a result, of research. When research has unforeseen or undesirable consequences, the researcher is responsible for identifying and, where possible, rectifying these consequences.

The systematic evaluation of the risks and benefits

The ideal of a systematic, non-arbitrary analysis of the risks and benefits should be pursued as far as possible. This ideal requires that those persons taking decisions regarding the justification of the research are thorough in the collection and evaluation of information concerning all aspects of the research, and that alternative possibilities should be considered systematically.

In the evaluation of the justification of the research, at least the following considerations should be taken into account:

- Brutal, inhuman treatment of human participants is never morally justified.
- Risks should be reduced to those risks that are essential for achieving the objective of the research. It should be ascertained whether it is indeed essential to use human participants. It will probably never be possible to completely eliminate risk, but risk can be reduced by careful consideration of alternative procedures.
- When research implies a considerable risk with regard to serious harm, ECs should put exceptional emphasis on the justification of the risk.
- When vulnerable communities are involved in research, the applicability of their involvement in the research should be indicated. In this judgement, a number of variables are important, including the nature and degree of the risk, the condition of the community or individuals concerned, and the level of expected benefits.
- Risks and benefits to be expected should be clearly indicated in documents, and procedures should be applied to obtain informed permission.
- Research and the pursuit of knowledge should never be seen as the highest objective at the cost of other personal, social and cultural values.

Informed consent

Satisfactory standards of informed, understood, witnessed, signed consent should be complied with. Before participation in research takes place, a clear and equitable agreement with participants should therefore be arrived. The process of consent should include the elements of information, understanding and voluntary participation.

Information

It should ensure that sufficient information is given to participants. The research procedure, the objective thereof, the risks and expected benefits, alternative procedures (in the case of therapy) and a statement making it clear that the participant has the opportunity to put questions and withdraw from the research at any time without giving any reason. Information on how participants are selected and particulars of persons responsible for the research may be added. The extent and nature of the information should be such that persons, even if they know that

the procedure is not essential for them to be cared for, and even if they do not understand everything, are able to take a reasoned decision concerning their participation in the promotion of knowledge. Even if the procedure implies direct benefit to them, participants should understand the degree of the risk and the voluntary nature of participation.

Understanding

The way and the context in which the information is conveyed are as important as the information itself. Since the participant's ability to understand is a function of intelligence, rationality, maturity and language usage, it is essential to adapt the presentation of information according to the participant's abilities. Special precautions should be taken when understanding is considerably limited, for example in cases of illiteracy, immaturity, minority or mental deficiency.

Each class of participants having a lack of understanding (for example, babies or young children, mentally deranged patients, terminally ill persons and patients in a coma) should be treated in their own terms. Even for these persons, respect requires that they are given the opportunity, to the extent to which they are capable, to choose whether or not to take part in the research. Respect for persons also requires that the permission of other parties be obtained in order to protect the participants from any harm. The third parties selected should be a person who is well acquainted with the participant's situation and who can and will act in his/her best interests. The person with the authority to act on behalf of the participant should be given the opportunity to observe the research as it occurs, in order to be able to withdraw the participant from the research if this is in the best interests of the participant.

Voluntary action

An agreement to take part in research is considered to be valid consent only if it is given voluntarily. It requires circumstances free of coercion and of undue influencing. Unjustifiable pressure usually takes place when people in positions of authority or great influence – especially where possible sanctions are involved – demand certain action from a participant. The researcher should respect the right of the individual to take part in the research and to withdraw at any stage.

Selection of participants

The principle of benevolence in risk/benefit evaluation, the principle of justice brings to the fore the moral requirement that there should be fair procedures and outcomes regarding the selection of the participants in there search.

Justice applies at two levels regarding the selection of participants: the social and the individual level. At the *individual* level, it is required that researchers should exercise fairness in the selection of participants; they should therefore not offer potentially beneficial research only to certain patients enjoying their favour, or they should not select "undesirable" persons for potentially dangerous research. At the social level, justice requires that a distinction be made between groups of people that should not take part in the research concerned because the load would be too heavy for them or because they are already overloaded, and groups where this is not the case and who should therefore take part in the research.

Certain groups, such as racially based minority groups, the economically less privileged, seriously ill persons and institutionalized mentally deranged persons, students, should be protected against the danger of being involved in research merely for the administrative convenience thereof, or because they can be easily manipulated because of their illness or socioeconomic position.

Privacy and confidentiality

Privacy enjoys high priority, not only because certain information can be regarded as humiliating or in other ways injurious to the participant, but also because privacy is essential for intimate, personal and spiritual relationships (i.e. those relationships that are sometimes regarded as "holy"). When a participant in research confides in a researcher, the researcher is obliged not to share this information with others without the participant's permission, except if there are laws to protect the public interest (for instance, the compulsory notification of child abuse). Breach of confidence can cause irreparable harm in the relationship of trust between the researcher and the participant, as well as in the relationship with other individuals and parties. In order to understand what information can be regarded as private and confidential by prospective participants, it is essential to have a participant-oriented perspective.

Researchers should always be aware of applicable legislation within their jurisdiction and should make themselves acquainted with the expectations that participants may have with regard to privacy and confidentiality. In view of the rapid development of information technology, researchers must take suitable steps to ensure that confidential information is safeguarded. There is considerable public interest in the extent to which researchers are allowed to have access to certain private information, not only to expand knowledge, but also to achieve a number of social objectives, such as the establishment of adequate public healthcare programmes and maintenance of the democratic process.

ANIMALS USED IN RESEARCH

The CPCSEA guideline are being followed

(Annexure-II)

In dealing with experiments with animals, strategies to refine the methodology and operative procedures should be applied as a fundamental obligation with a view to reducing the number of animals used and, where possible, replacing the use of animals with an alternative approach or experimental system. People involved in research with animals furthermore have the obligation to respect the interests of laboratory animals and to recognize that they are sensitive to pain, that they may become anxious and that they may experience fear if they remember such experiences.

Applying the principles

Planning and preparation

An experiment with animals should be planned carefully and scientifically in accordance with the available knowledge regarding the problem being studied and the questions being put. It should be designed in such a way that the results, whether positive or negative, will not result in the justification for the experiment being questioned. Initially, a written protocol should be prepared as a document for approval by the relevant EC of People's University and also by a relevant research

committee where this is required by the faculty. No experiment or tuition involving animals may commence before such approval has been obtained.

Selection of experimental animals

The selection of the most suitable animal species for a given research objective is fundamental to the successful design of the experiment. It is recommended that persons with expertise in the biology of laboratory animals and their health and disease conditions be consulted before a final selection is made. The use of *in vitro* biological systems and theoretic modelling systems should for ethical, practical and financial reasons be considered as an alternative to the use of laboratory animals if it can produce data of equally good or even better quality.

Avoiding / minimizing discomfort, anxiety and pain

A humane approach in animal experiments relates to the elimination or minimizing of the pain, anxiety and discomfort that may be caused by the experimental method applied. Caring for experimental animals should therefore be the responsibility of persons who are well qualified by training and experience (veterinarians or qualified laboratory animal technologists) and who are sensitive to the manifestation of pain, fear, discomfort and anxiety in commonly used laboratory species. Laboratory animals may not be subjected to pain, discomfort or anxiety in animal experiments, except where the information obtained from such experiments is of exceptional importance. In such a case, a thorough ethical evaluation will be the decisive factor.

Limited use of laboratory animals

Animals that have already been used in an experiment may not be subjected to any further procedures, except if the first procedure was of a minor and non radical nature and the use of such animals in further projects has been sanctioned by the relevant EC of the PU.

Euthanasia

Euthanasia may be essential at the conclusion of an experiment either to get rid of animals or ending their pain and anxiety, that cannot be relieved by medicines or other treatment, or where it may be expected that the pathological changes caused by the experiment could be accompanied by serious disease or radical physical changes and disability (for example the growth of tumors and the collection of body fluids). Terminal points for such experiments should be determined in advance and criteria should be established for the determination of such terminal points. Research protocols should offer guidelines for the application of euthanasia to animals during / at the conclusion of experiments. Methods of euthanasia should be described in detail in the research protocol.

Euthanasia should be compulsory in the case of an experimental procedure that fails or if anything happens that may compromise the validity of the collection of research data from experimental animals. In the last-mentioned case, the collection of data from the animal should be terminated for scientific as well as ethical reasons.

The selection of specific agents and methods for euthanasia will depend on the species involved and the objectives of the protocol. Euthanasia should be

performed by members of staff who are competent in the method appropriate to the species concerned. It should be performed in a professional and merciful manner. Animals killed by euthanasia may not be removed before a careful clinical examination has determined that the animal is dead.

Minimizing pain, anxiety and discomfort

When an experiment causes unavoidable pain, anxiety and discomfort, analgesic or other suitable medicines should be used to prevent or reduce such conditions. In the event of radical operation procedures, the use of anaesthetics as prescribed in veterinary practice is compulsory.

Animal care and accommodation

The clinical care of animals used in experiments should be under the direct control of a qualified veterinarian as per the law of the land.

Farming with animals should be on a high standard and the animals' need for water, food, sanitation, sleep and waste removal and the control of diseases should be taken into account. Animals should be cared for daily by a qualified person, including during weekends and holidays, to ensure their well-being and to comply with research requirements. Emergency veterinary services should be available after office hours and during weekends and holidays. In an emergency, security personnel should be able to contact persons responsible for caring for the animals.

Care should be taken to eliminate disease, injury, overpopulation and stress factors and to protect animals from infection with ecto- and endoparasites. Consideration should also be given to the animals' social needs in terms of physical contact and communication by means of visual, auditive and olfactory signals. Where applicable, animals should be kept in social groups.

Training

It is the responsibility of the head of the academic section where the research on animals is conducted, to ensure that the persons performing animal experiments are well qualified. This requires that such persons should receive formal training in the laboratory care of animals and also, where necessary, use the programme offered by the Institute to teaching and research staff.

Public policy statements regarding the use of laboratory animals

Principles for the care and use of animals in tests, research and training have been established by CPCSEA, New Delhi, India. These statements contain detailed information on the standards of keeping, caring for and using animals. It is mandatory to follow the enshrined standards.


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