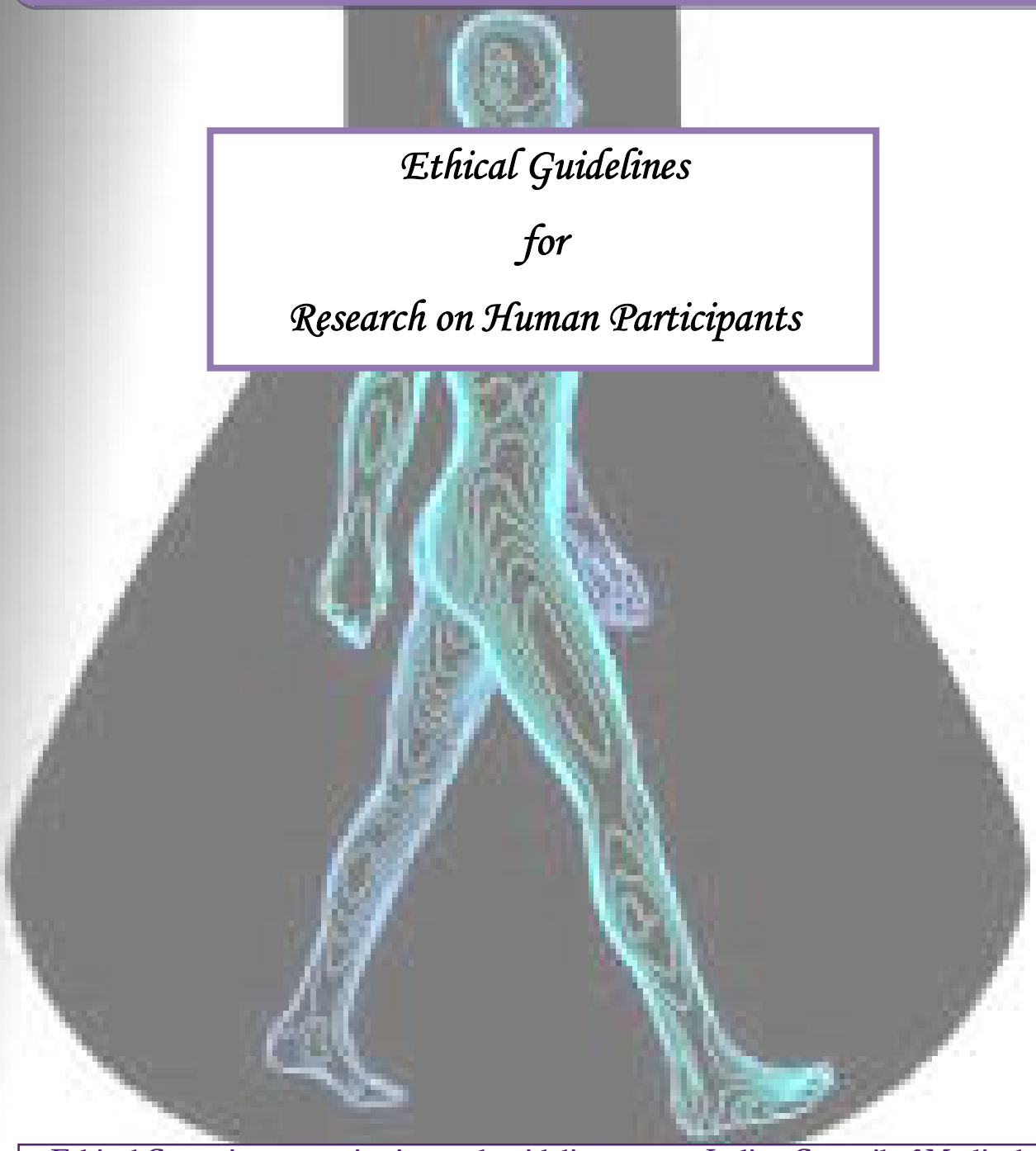
Central University of Kerala

Kasaragod



Ethical Guidelines

for

Research on Human Participants

Ethical Committee constitution and guidelines as per Indian Council of Medical Research (ICMR) Ethical Guidelines (http://icmr.nic.in/ethical_guidelines.pdf)

Ensuring:

- ✓ **Sustainable system that safeguards the rights, safety and well-being of all research participants**
- ✓ **Ethical compliance of research involving human subjects by reviewing research proposals and regular monitoring of approved research**
- ✓ **Cardinal principles of research ethics *viz.*, AUTONOMY, BENEFICENCE, NON-MALEFICENCE and JUSTICE are taken care of in planning, conduct and reporting of proposed research**
- ✓ **Universal ethical values and international scientific standards are followed in terms of local community values and customs**
- ✓ **Documentation and archiving of records with an effective retrieval mechanism**
- ✓ **Strict confidentiality during archiving and retrieval process**
- ✓ **Accessibility to inspection by authorized representatives of regulatory agencies**

Obligations:

- **Advice risk minimization strategies wherever applicable**
- **Proactive measures to ensure non-exploitation of socio-economically deprived people**
- **Ensure competency of participants to give informed consent document**
- **Examine and seek justification from researchers for proposals involving vulnerable populations and ensure that additional safeguards/protection mechanisms are in place**
- **Ensure that conflict of interest (COI) do not increase harm or lessen benefits to participants**
- **Ethical review of research proposals in Social and Behavioural Sciences involving human participants, communities etc.**
- **Review the Ethical, Legal and Social Issues (ELSI) of research involving genetic testing and/or Genome wide association study (GWAS) and ensure provision of safeguards to participants**

Duties:

- **Prepare Standard Operating Procedures (SOP) for Human Research**
- **Review research proposals involving human subjects ensuring adherence to regulatory requirements and applicable guidelines**
- **Screen and categorise proposals based on risk involved as: Exempted from review, Expedited review and Full Committee Review based on ICMR guidelines**
- **Periodic and continuing review of research as per guidelines stated in SOP**
- **Research goals not to override the health and well being of human subjects**
- **Examine predictable risks/ harms and potential benefits**
- **Review of stem cells proposals approved by Committee for Stem Cell Research and in accordance with National Guidelines for Stem Cell Research (2007, modified in 2013) (http://icmr.nic.in/guidelines/NGSCR%202013.pdf)**
- **Examine ethical compliance of research assessing Bioavailability (BA)/ Bioequivalence (BE)**
- **Examine and monitor ethical concerns of studies involving multi-centric trials**
- **Ensure ethical guidelines are followed in studies involving phytopharmaceutical drugs defined under Drugs and Cosmetics Rules, 8th Amendment 2015**
- **Ensuring benefit sharing to the Tribe/ Community prior to commercialization of products arising from folklore medicine/ethnomedicine**
- **Risk benefit assessment of clinical trials involving medical/ dental devices and biologicals/ biosimilars**
- **Reviewing the process of MoU/Material Transfer Agreement (MTA) between collaborating partners in research proposals involving outsourcing/supply of biospecimens**

Setting mechanisms that ensure:

Adequate compensation to human participants

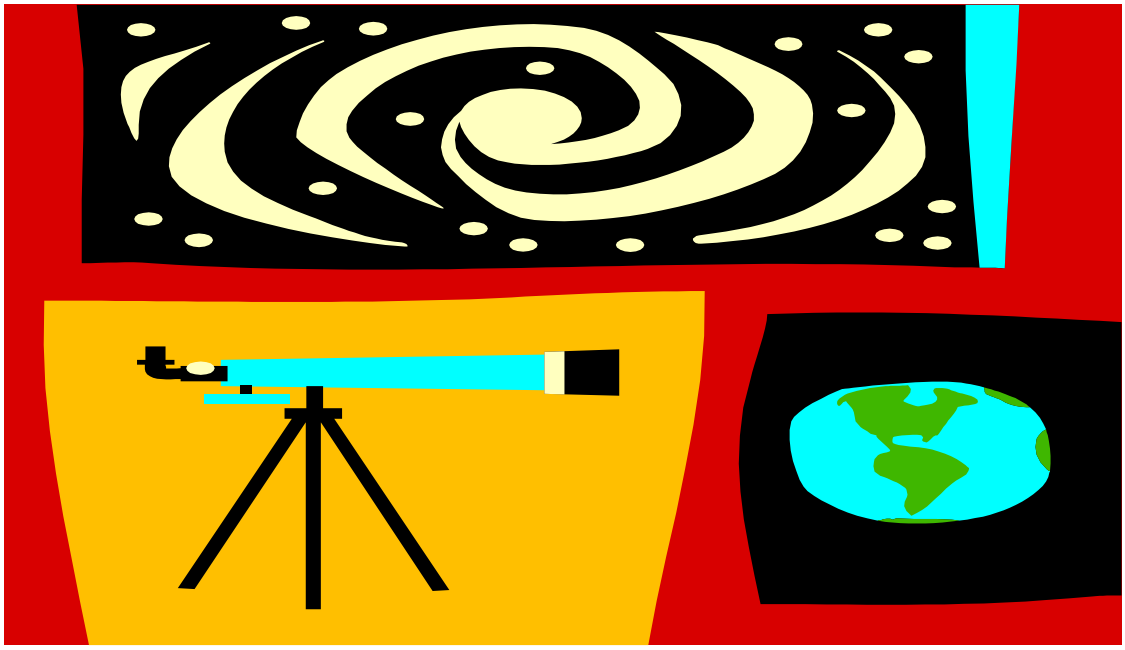
Medical (ancillary) care to participants for non-study/trial-related illnesses arising during the period of trial

Insurance coverage for trial related or unrelated illnesses (ancillary care) and compensation wherever deemed necessary

Clinical trials conducted in accordance with: The Indian Good Clinical Practices (GCP) Guidelines, Declaration of Helsinki (2013, or later versions as applicable), National Ethical (ICMR) guidelines (2016) and other applicable guidelines. The Drugs and Cosmetics Act (1940), Rules (1945) and applicable amendments (including Schedule Y), and other relevant regulations followed wherever applicable and registered with Clinical Trial Registry of India (CTRI; www.ctri.nic.in)

Central University of Kerala
Kasaragod

CODE OF ETHICS FOR RESEARCH



CENTRAL UNIVERSITY OF KERALA

2016

Preamble

CUK views research ethics as the concrete manifestation of the researcher's sense of responsibility and commitment to the society at large, fellow human beings and to the research community. The ethical dimension of research involves values, attitudes, norms, knowledge and skills to conduct, present and communicate research as a humanistic activity that synchronises with social, cultural and economic realities. Researchers need to be aware of the responsibilities placed on them in understanding and sensitive handling of the human, social, cultural and scientific issues involved in research. CUK expects every researcher to link his/her research to the highest ideals and objectives of knowledge production and communication. All research and related activities in CUK will be informed by the following:

Values: Truthfulness, trust, openness, progression, freedom from dogma,

Attitudes: Cooperation, friendliness, acceptance of critical inquiry, self reflection and criticism, acceptance of the other, commitment to common cause, commitment to the vulnerable sections of the society.

Norms: Being lead by professional norms and bench-marks, conventions and recommended practices at national and international level, incorporating subject-specific standards

Knowledge: Knowledge of social, cultural, ideological and political issues involved in research, knowledge of good practices in research, knowledge of the scientific and systematically organized ways of research, knowledge of channels of knowledge communication, knowledge of the problems and stakes of people involved in research (researchers and subjects)

Skills: Knowledge acquisition skills, knowledge generation skills, knowledge communication skills, skills to use new knowledge in practical situations, skills to identify social, economic, cultural and scientific problems and generate knowledge accordingly,

CUK expects every researcher to develop a deep understanding of its vision of the ethics of research and to ensure that their research is informed and guided by the foundational principles and objectives outlined in this document.

1.0 Foundational Principles

The philosophy and vision of CUK regarding ethical conduct of research are expressed as four foundational principles; Awareness, Commitment, Interpersonal Relations and Professional Conduct.

1.1 Awareness

1.0.1 Researchers need to be aware of the ethical, humanistic, social, cultural and ideological issues involved in research in general and in specific instances of research they undertake.

1.0.2 Researchers need to be sensitive about the stakes, problems, difficulties, expectations and apprehensions of fellow researchers, participants and users of research generated knowledge.

1.0.3 Researchers need to be aware of the economic implications of using public funds for research and be prepared to ensure that the fund is used in a productive, positive and beneficial way to the society.

1.0.4 Researchers need to be aware of the norms and standards prescribed for research by national and international bodies and also rules and regulations that relate to various aspects of research.

1.0.5 Researchers need to be aware of the potential uses and users of research generated knowledge and products of research and ensure safe practices in this regard.

1.1 Commitment

1.1.1 Researchers need to be committed to the ultimate goal of social and economic development of the country and be able to align all research activities to this end.

1.1.2 Researchers need to be committed to the ideals of honesty, transparency, generation of knowledge and upholding professional standards.

1.1.3 Researchers need to be committed to the socially, culturally and economically vulnerable groups and be prepared to use research to benefit them.

1.2 Interpersonal Relations

1.2.1 Research is to be conducted in a setting that promotes trust, mutual respect and openness between all participants including the researcher, research students and support staff.

1.2.2 Researchers are expected to ensure that participants in research are not exploited, put to psychological, economic or physical harm and are informed of their rights and possibilities of making choices.

1.3 Professional conduct

1.3.1 Researchers are expected to maintain the highest standards in the conduct of research process, documenting and communicating research and in supervising research.

1.3.2 Researchers are expected to develop a deep understanding of the skills and competencies required for research and acquire and apply them in research activities.

1.3.3 Researchers are expected to conduct research in a transparent way and open it up for critical evaluation and scrutiny.

1.3.4 Researchers are expected to systematically document research and make research data available for application and further studies.

1.3.5 Researchers are expected to ensure that their research no way prejudices the interests of others, cause harm or social embarrassment, or has detrimental economic or political effects

2.0 Professional Standards of research

a) Researchers are expected to operate on the basis of a deep and professional understanding of their discipline and methodologies and procedures of research.
b) Researchers are expected to ensure that he/she has the full competence to perform the activities, processes, experiments and techniques that are part of the research undertaken.
c) Researchers are expected to have a thorough understanding of the standards and bench-marks prescribed by professional and academic bodies in the particular field regarding research, experimentation, testing, analytic techniques and measurements, and to apply them in their work.
d) Researchers shall uphold intellectual property rights and will abide by the legal regulations of copyright.

3.0 Researcher's professional integrity and honesty

a) Researchers shall not use research activities and expertise in a way that compromises professional ideals of research.
b) Researchers shall not sensationalize research findings for personal gain.
c) Researchers shall not exaggerate research findings, measurements and observations.
d) Researchers shall not involve in research for malicious or illegal purposes.
e) Researchers shall not accept grants or sponsorships that involve a conflict of interest with their professional integrity and principles.
f) Researchers shall not unfairly criticize or defame the work of other researchers.
g) Researchers shall not misrepresent or falsify the work of others for personal gain or with malicious intent
h) Researchers shall undertake only those activities for which they have competence.
i) Researchers shall not act in an arbitrary and biased way

4.0 Sense of justice and social commitment

a) Researchers shall ensure that their research is guided by the ultimate aim of social beneficence.

b) The beneficence to those who participate in the research will be a prime concern for researchers.
c) Researchers shall ensure that the research outcome provides sufficient compensation for the resources invested in the particular research by the society.

5.0 Transparency and openness

Transparency and openness are key aspects of research ethics. They relate essentially to verifiability, usability, authenticity and truthfulness of research and all processes involved in research.

a) The reporting of research should follow the criterion of transparency in all aspects.
b) The aims of research, methods used, data collection techniques, nature of data, sampling strategies, outcomes and application potential of research are to be stated in a full and clearly understandable form.
c) Data and information required for reduplication and cross checking of experiments and observations by other researchers are to be spelled out completely and clearly.
d) Limitations of research and possibilities for experimental or analytical error are to be discussed in a frank and professional manner.
e) The extent to which ideas, theoretical formulations and analytical techniques are drawn from other sources is to be made clear.
f) How the basic data is stored and can be accessed by other researchers for verification and cross-checking are to be clearly spelled out.
g) Where confidentiality criteria are applied, other possible norms for the authenticity of data are to be spelled out.
h) Details of location and dates of data collection, researchers and other staff involved in data collection, procedures adopted, information on the sample (without compromising on the confidentiality criteria) are to be recorded and maintained by the researcher and the Department concerned and to the extent relevant, stated in the report.
i) Work books, laboratory log books and registers are to be maintained systematically by all Departments and are to be made available for the purpose of verification and cross-checking by future researchers.
j) Wherever possible and applicable, video and audio recordings of experiments, research procedures, observational settings and data collection process are to be made and maintained.
k) Researchers need to be transparent in the use and distribution of all resources of research including physical facilities and money.

6.0 Interpersonal relations in research

6.0 Dealing with participants as valued equals

a) Researchers need to establish friendly and open relationships based on trust, with fellow researchers and participants.

b) When researchers are in a position to guide, direct and influence the activities of others involved in research, they will respect the individuality, rights and autonomy of the participants.
c) The dignity of the participants needs to be protected at all costs.
d) Researchers shall ensure that during participation all the participants are not exposed to situations causing embarrassment or annoyance or negative feelings. Researchers need to ensure that their actions, relations and decisions are free from bias based on culture, language, gender, nationality, caste and religion.
e) Where research involves cultural and social aspects, researchers need to take every precaution to avoid such prejudices and biases in the conduct and reporting of research.

6.1 Non-exploitation

"Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition"
The Belmont Report 1975

a) Constitutional rights of each participant will be protected Researchers shall not use their authority to impose on participants and fellow researchers decisions that are discriminatory.
b) When research is conducted on students and subordinates as participants, researchers shall ensure that their participation is guided by freedom of choice and not by perception of indirect consequences or rewards.
c) Incentives offered to participants shall be of such nature that it compensates for the time and effort the participants expend, and shall not be used as bribes.
d) Voluntary participation is the basic ethics of participation in research. It is waived only when the research is based on archival or published material.
e) Researchers shall not use positions of authority to persuade others to participate in research.
f) Researchers shall not target vulnerable groups or socio-economically deprived groups to participate in research involving potential psychological and physical stress or harm, using their deprived status to get consent.

6.2 Professional courtesy

a) Researchers shall give due respects to fellow researchers, students and all those who work in the team
b) Researchers shall not unfairly criticize or defame the work of other researchers, scholars or authors.
c) Researchers shall not involve in any action that undermines the professional dignity of other researchers.
d) Research directors and supervisors shall make every effort to protect all team members/students from possible harm or ill effects that may result from participating in the research.
e) Researchers shall extend help and assistance to fellow researchers.
f) Researchers shall take care of equipment, data, materials and infrastructural facilities.

7.0 Documentation of research

7.1 Principles of research documentation

An essential aspect of scientific research is replication and verifiability. It is assumed that when research is replicated the same result as that of the original researcher is obtained. The authenticity of research is dependent also on openness to verification of all aspects of research such as design, experimentation and measurements, data analysis and recording. Maintaining research records is hence an important part of ethical practice in research.

a) All aspects of research must be recorded in appropriate format and maintained for a relevant period by the researcher and/or the university.
b) Workbooks, laboratory logbooks and worksheets are to be carefully preserved.
c) Data collection methods, details of field work, collection of samples and physical objects and details of audio/ video recordings made in connection with the study are to be maintained.
d) Details of human participants are to be maintained remaining within the confidentiality criteria agreed upon.
e) Each department will set up a system for making available research records for verification by other researchers taking into consideration the commitment to openness and sharing and on the other hand, the intellectual property rights of the researcher who conducted the study.

7.2 Data Management

a) For each research, who will hold the data after the research is over will be decided in advance. Data can be held by the individual researcher, principal investigator, the Department /University or it can be in the public domain.
b) How long data will be held is to be decided based on the nature and relevance of the data, confidentiality criteria, potential for misuse of data and intellectual property rights.

c) University/departments will specify who can access the data and conditions for use.

d)

8.0 Authorship

Responsible authorship practices are an important part of research. Reporting and analyzing results is the key to applying research findings to the real world. Despite its vital role, authorship remains a murky and vague area for many scientists who frequently run into difficulty when deciding which colleagues should be listed as authors or co-authors, and which colleagues should instead receive acknowledgement. Despite the challenges, researchers should familiarize themselves with proper authorship practices in order to protect their work and ideas while also preventing research fraud.

A Guide to Research Ethics, University of Minnesota, Centre for Bioethics

a) Authorship credits for research and publication will be in accordance with the contribution made. Who are listed as authors and who receive acknowledgement for contribution shall is to be decided based on systematic criteria. (For example, **The International Committee of Medical Journal Editors** (ICMJE) has issued the following guideline: Authorship credit should be based only on 1) substantial contributions to conception and design, or acquisition of data, or analysis and Interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.)

b) Credits will be given to those who have contributed to the research/publication by way of materials, data, analysis, review, suggestions and specialized help such as language editing, statistical analysis, expert opinion on specific aspects or collection of specimens.

c) Intellectual property rights (copy rights and patents) will also be decided on the basis of an objective and just assessment of the actual contribution made: researchers shall not use their position of authority or position to deny the rights of fellow researchers or students who contribute to the research.

d) The consent of those who will be acknowledged should be obtained, to prevent the situation where they are perceived as endorsing research for which they are not responsible.

9.0 Confidentiality

a) Researchers are bound to keep confidential data, details of participants, opinions, and any other information collected from the participants for the purpose of research.
b) Confidentiality procedures to be followed will form part of informed consent.
c) Unless the participant has given voluntary consent to use his/her name in the data, the researcher will refer to the participant in strict anonymity in reporting and publishing the research.
d) When data is stored after the research is over, the researcher is bound to ensure that future users of the data are also bound by the original confidentiality agreement.

10.0 Research Misconduct

"Cases of misconduct in science involving fabrication, falsification, and plagiarism breach the trust that allows scientists to build on other's work, as well as eroding the trust that allows policymakers and others to make decisions based on scientific and objective evidence. The inability or refusal of research institutions to address such cases can undermine both the integrity of the research process and self governance by the research community"

Responsible Science: Ensuring the Integrity of the Research Process. Vol 1:20 NAS 1992

10.0.1 Plagiarism

The intentional copying of ideas, text, data, graphics or any such intellectual, linguistic and artistic creations/products of others comes under plagiarism. From minor plagiarism (such as using a few lines of another author without acknowledging, using creative phrases or descriptions and terminology coined by other authors without acknowledgment) to major plagiarism involving copying of extensive material, plagiarism is an act which goes against the fundamental spirit of research. Academics and researchers are bound to acknowledge the source/authorship of whatever is not original in their work. This includes;

a) **Textual material**- words, phrases and sentences that are taken from another source or drawn from conversation, interview or personal communication.
b) **Ideas**- Concepts, theories, findings, analytical approaches.
c) **Methodologies**- Procedures, experiment designs
d) **Psychological tests, questionnaires, rating scales**
e) **Graphics and pictures**- Pictures, illustrations, images, graphs, visual representations, diagrams
f) **Data**- statistical data, language data, tables, source materials.

g) **Linguistic creations**- Technical terms, neologisms and phraseologies, when these have not passed into regular use, but are special cases relating to a particular author
h) **Examples** when they are not part of common knowledge.

Piracy is often discussed as a higher and more serious form of plagiarism. This refers to the appropriation of ideas of others without acknowledgement. Unlike plagiarism, ideas appropriated from another source can be hidden to a great extent by altering, restating or translating the ideas into another language. Researchers and research supervisors need to exercise special caution to avoid this problem. The major aspects of doctoral research in progress need to be published in journals of standing and any feedback or criticism regarding piracy need to be carefully examined.

A problematic area of plagiarism and piracy relates to use of unpublished research material to which a researcher gains access in his/her capacity as reviewer or research supervisor. Each researcher needs to critically evaluate his/her thinking process and ensure that he/she is not using ideas gained thus even in an unconscious way.

10.0.2 Falsification

Falsification is defined as the wilful alteration/manipulation of data for whatever reason. It includes the following:

a) Distortion of data to support a particular hypothesis or analysis or to arrive at a particular finding/conclusion
b) Suppression/omission of parts of data to suit the analysis
c) Statistical inflation of data
d) Improper presentation of data to hide certain tendencies
e) Making references to non-existing sources
f) Using incomplete references
g) Relying on experimental observations/data not firmly established through cross checking and verification
h) Using non-random samples and representing it as random sample
i) Generalization without sufficient evidence
j) Sensationalizing and claiming unsubstantiated importance for the research

10.0.3 Fabrication

Fabrication is making up of data, observations or results not actually attested.

a) Blowing up the sample size
b) Conducting interventions for certain data sets alone and reporting for the complete set
c) Correcting data/observations to match with earlier/standard observations
d) Reporting results without conducting the specified number of trials/experimental cycles

e) Wilfully introducing factors that alter experimental outcomes
f) Reporting results not actually observed

10.0.4 Obfuscation

The intentional obliteration, mystification and darkening of research and ideas in reports and publications with a view to create a sense of importance or gravity is known as obfuscation. Researchers and authors often resort to this practice with a view to hide the actual quality of their work and provide it with a more serious, lofty and creative mien. This is a serious problem which of course cannot be regulated by law or norms, but every researcher needs to be aware of the ultimate disrepute that this practice brings to the particular piece of research and the researcher, and how it erodes the values of the research profession. Researchers need to be on guard against the following obfuscation tendencies;

a) A style of discussion, explanation and analysis that obliterates the main ideas and concepts
b) Unnecessary reference to theories or elucidation of theories and ideas not actually relevant in the context.
c) Using difficult or impenetrable language on purpose
d) Not clearly defining and explaining the concepts and scientific terms used

10.0.5 Destruction/withholding of data/ Denying access to information

a) Wilful destruction of data to prevent future verification or cross checking
b) Not providing data to sponsors of research where warranted by the terms and conditions
c) Denying access to information or sources of information to fellow researchers and students
d) Destroying or making inaccessible, databases and recorded data
e) Defacing or cutting out pages from books and journals

10.0.6 Bibliometric inflation

Listing in the bibliography, books and journals not actually consulted or referred in the text.

10.0.7 Redundant/Duplicate Publication

a) Republishing the same or substantially same part of earlier publication in another journal.

10.0.8 Personation/Ghost writing

a) Using the services of persons other than the author(s) to write parts of the research report

10.0.9 Violation of intellectual property rights

a) Researchers shall uphold intellectual property rights and shall ensure that all activities in research and publishing research are according to the rules and regulations relating to intellectual property rights. ('Intellectual Property' means any invention, discovery, improvement, copyrightable work, integrated circuit mask work, trademark, trade secret, and licensable know-how and related rights. Intellectual property includes, but is not limited to, individual or multimedia works of art or music, records of confidential information generated or maintained by the University, data, texts, instructional materials, tests, bibliographies, research findings, organisms, cells, viruses, DNA sequences, other biological materials, probes, crystallographic coordinates, plant lines, chemical compounds, and theses. Intellectual property may exist in a written or electronic form, may be raw or derived, and may be in the form of text, multimedia, computer programs, spreadsheets, formatted fields in records or forms within files, databases, graphics, digital images, video and audio recordings, live video or audio broadcasts, performances, two or three-dimensional works of art, musical compositions, executions of processes, film, film strips, slides, charts, transparencies, other visual/aural aids or CD-ROMS. University of Minnesota, Intellectual Property Policy)

10.0.10 Interfering with or impeding the work of others

a) Sabotaging the work of others, interfering with experimental procedures

11.0 Communication and sharing of research data and findings

11.0 Scholarly communication

11.1 Public communication

11.2 Publication

12.0 Accuracy and authenticity of data

Research based data, findings, analyses and interpretations are taken into general trust by the public and the research community and form the basis for further research and knowledge production. Inaccuracies and mistakes in research may not be noticed by all future researchers. This will in turn reflect on further research, and substantial resources and human capital tend to be lost and false knowledge claims become part of the discipline at least temporarily. Considered from this angle, the researcher's responsibility to maintaining a high level of accuracy in measurements, experimental observations and interpretations become a paramount ethical consideration.

a) Researchers need to own up responsibility for the accuracy and authenticity of data, observations and interpretations that are part of their research, including data, measurements or observations taken from other sources.
b) Researchers need to be aware of the possibilities of cross checking and independent verification of the data and use them wherever applicable.
c) Procedures followed to ensure accuracy and authenticity of data, interpretations and observations need to be laid down in detail.
d) Factors that may affect experimental measurements, data recording and processing are to be analyzed systematically and are to be laid down in detail along with steps adopted to minimize or negate the effect of such factors.
e) Information required to verify, re-check and compare measurements and observations, needs to be specified in research reports.
f) When errors, mistakes and inaccuracies are found or reported in the research, researchers shall take steps to bring them to the notice of the research community by issuing correction statements.
g) Researchers need to ensure that research reports and articles are free from misleading statements or statements or analyses that offer the scope of misinterpretation.
h) Where possible, measurements and observations are to be submitted for peer review and verification before publication.
i) Where generalizations are drawn based on samples, rationale for fixing the sample size, characteristics of the population and other relevant factors are to be discussed to help the potential users of the research study to know the extent to which generalization is possible in the particular piece of research.
j) Where consolidated data alone is provided in the research report, actual recorded data and worksheets are to be filed in the department/research centre for other researchers to cross check the data and findings.

13.0 Ethical standards in human subject research

a) Researchers shall consider the human participants in research as being under their care, and shall assume responsibility for their well being and upholding their rights.
b) Researchers shall not subject the participants to experiments and procedures that are known to cause physical or psychological harm, even with informed consent when the qualitative and quantitative outcome of the intervention cannot justify the use of such procedures; in other words such procedures are to be used only when an overwhelming benefit is evident.
c) Research that exposes human subjects to potentially harmful or stressful situations and stimuli may be taken up only when there are no alternatives to study the particular question and when the research outcome has an unquestioned beneficial value.
d) Researchers shall follow all State and Central Laws and Regulations and the guidelines of competent professional bodies in the conduct of human subject research.

e) Experiments must be based on authentic theoretical study and prior testing
f) Experiments must be conducted by suitably qualified personnel.
g) Researchers shall not use procedures or interventions that are inhuman, unlawful, or dangerous.
h) When unexpected complications, harmful or painful side effects or discomfort are evident, the research intervention must be immediately terminated.
i) All measures, including specialist services should be made ready to protect the participants from any harm or pain or other negative consequences.
j) Deception in research may only be used when no other alternative is available and when the outcome of the research is of unquestioned beneficial value. (APA's "Ethical Principles and Code of Conduct" provides the following guidelines about use of deception. (1) Deception is not allowed unless it is justified by the study's scientific, educational, or applied value, and when alternative means that do not employ deception are not feasible. (2) Deception is never allowed if full disclosure of the nature of the study (potential harm, risk, discomfort, or unpleasant emotional experience) would alter the participants' willingness to take part in the study. Deception and its purpose must be fully explained to the participants following the conclusion of the experimental session or, at the latest, at the conclusion of the research project.)

14.0 Ethical standards in animal research

Regardless of where one may stand on this issue, animal research does continue, and it is governed by ethical guidelines much the same as research involving human participants is regulated. Naturally, there is no informed consent or debriefing, but the psychologist is still under obligation to treat all animals subject ethically and to weigh the cost-benefit ratio carefully while planning the research project.

a) Research involving drug testing on animals, exposing them to painful, stressful and unnatural stimuli, keeping them under prolonged deprivation and movement restriction or any similar kinds of interventions should be taken up only when it is the only source for generating knowledge on a crucial question and when the value of the outcome justifies the conduct of the study.
b) Animals should be treated with utmost care and humane consideration, and used in experiments as sparingly as possible.

c) No animal should be subjected to continuous battery of interventional tests, but subject selection should follow a rotational policy to give each animal time and rest to recover from the effects of testing.
d) All efforts should be made to minimize pain and suffering during tests.
e) When surgical procedures are involved, anaesthesia is to be administered and if needed assistance from qualified professionals may be sought.
f) Animals must be well fed and comfortably housed.
g) When animal life is to be terminated it must be done as quickly as possible, causing minimum pain and recommended procedures must be followed.

Institutional framework for implementing the code of ethics for research

2.1. Ethics committee

The overall responsibility for ensuring that all research activities in CUK are in accordance with ethical principles and rules and regulations is vested with the **Research Ethics Committee** of the University.

14.0.1 Constitution of the Research Ethics Committee

14.0.2 Responsibilities of the Research Ethics Committee

a) The Research Ethics committee is not a fault finding body but guidance and advisory body to uphold the highest ideals of research and academic practice.
b) The ethics committee shall examine all aspects of research conducted in the university, to ensure that highest ethical principles are upheld by all researchers.
c) When research involves human subject research, animal research and research with vulnerable sections, ethical committee can ask the researchers or research supervisors to make a presentation and discuss all aspects of the research, to set down ethical guidelines.
d) The ethics committee is empowered to call for records or ask for researchers to present research proposals before the committee, even in those cases where ethical review is not mandatory.
e) Ethics committee is empowered to recommend modifications/alterations in any aspect of research including research design, experimentation, data collection and procedures.
f) Where major violations are observed, the ethics committee can recommend appropriate penalties including stoppage of research, discontinuation of research grant, debarring a particular researcher and other suitable measures.

14.0.3 Major ethical issues to be examined by the ethics committee.

a) Protocols to be followed in research involving human participants
b) Animal subject based research
c) Confidentiality criteria
d) Informed consent
e) Professional integrity practices
f) Plagiarism and acknowledgement of sources
g) Professional norms and standards

2.2 Responsibilities of officers of the university in implementing the code of ethics

2.2.1 Responsibilities of Departments

a) Departments (acting through Research Committees/Doctoral Committees) are expected to conduct the preliminary ethics audit of each research proposal.
b) A prime responsibility of the Departments is to conduct an evaluation of subject specific aspects of ethical code for each proposal.
c) Departmental committees need to take into confidence the researcher and research supervisor and discuss all aspects of the research and evaluate specific ethical concerns involved in each research proposal. Where applicable, specific norms and guidelines are to be drawn up.
d) Departments are responsible for complying with research documentation guidelines. In each case the department will take a decision on whether research documents and data after the research will be held by the department or the individual researcher, how long it will be held, how it can be accessed by other researchers for verification ad further study and on maintaining confidentiality criteria.
e) While the research is in progress, the Department shall ensure proper maintenance of research records including workbooks, lab logbooks, data collection schedules, expenditure statements and consent forms.
f) In cases where research does not include animal or human participant research, drug testing (on animals or humans) or deception based data collection, the Departments can give Ethical clearance, subject to ratification by the Ethics Committee. All other cases are to be submitted to the Ethics Committee with suggestions and recommendations of the Departmental Research Committee.

2.2.2 Responsibilities of Research Supervisors

a) Research supervisors have the responsibility for sensitizing the student with all aspects of ethical code and also in evaluating the specific ethical issues in a proposal.
b) Research supervisors shall guide the student in conducting the ethical self audit and in bringing to the attention of the Departmental committees and Ethical committee, those aspects that require further scrutiny and discussion.
c) Research Supervisors shall ensure that the student follows the spirit of the ethical code of CUK and its norms, provisions and guidelines in all aspects of research.
d) Research supervisors shall strive to assess each process of ongoing research to identify any ethical issue involved and shall advise the student to adopt appropriate measures to address it, or bring it to the notice of ethical committees

2.2.3 Responsibilities of individual researchers

a) It is the responsibility of every researcher to familiarize himself/herself with the provisions and guidelines of the ethical code framed by the university and also general norms and principles of ethics laid down by international professional bodies.
b) Researchers shall make every effort to apply the guidelines of the ethical code in all aspects of their work.
c) Researchers will keep all records and documents for ethical audit and cooperate with the University and fellow researchers in ethical audit of all aspects of research.

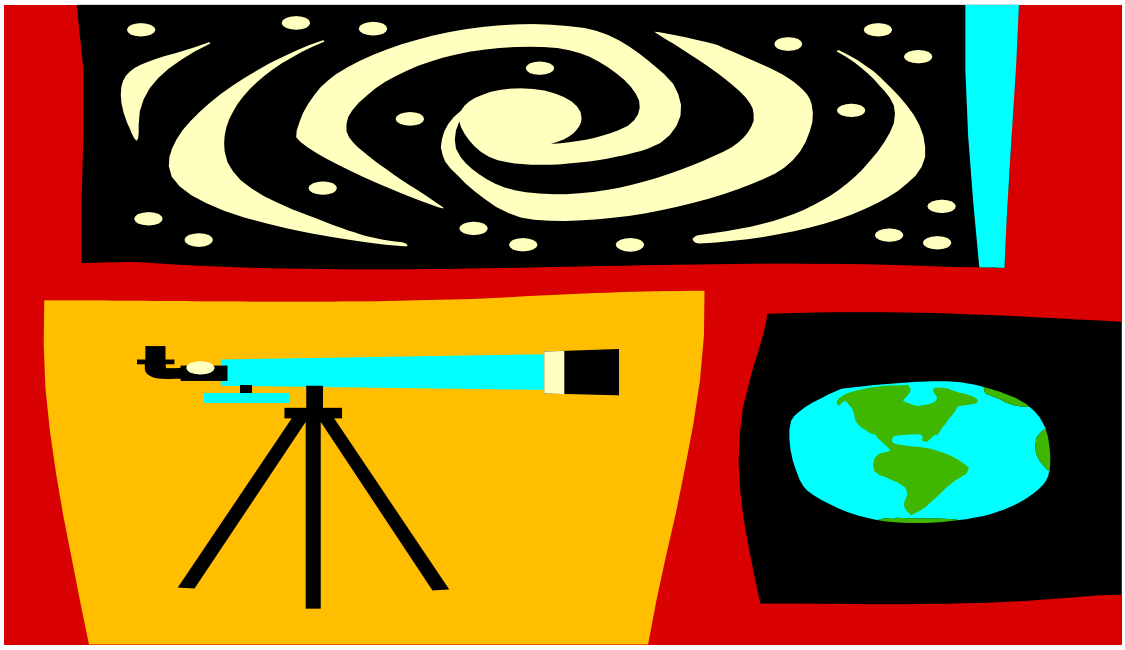
2.2.4 Documentation for ethics audit

a) **Ethical Audit Information Form:** Researchers and students taking up research projects, doctoral and MPhil research will complete and submit to the Department the **Ethical Audit Information Form** (endorsed by the Research Supervisor in the case of student researchers). This will be assessed by the Department Research Committee to decide whether ethical clearance can be given at the departmental level or to be passed on to the Ethics Committee of the University. When departmental research committee decides to grant ethical clearance, it is communicated to the Ethical Committee of the University for ratification.
b) **Informed Consent Documentation**: Where human participants are involved in research, the participants are to be briefed about the research in general, its purposes and methodology, the nature and extent of their participation, expectations from them in terms of time and performance, risks and problems involved, freedom to withdraw at any time, incentives if any, confidentiality provisions and acknowledgement of their participation. Wherever possible, their written consent is to be taken on **Research**

Participant Consent Form. In case of minors and vulnerable populations like patients, mentally or physically challenged persons, consent is to be taken from parents or responsible adults or primary caregivers.

c) **Confidentiality Statements**: Where names or other details of the participants are withheld for reasons of confidentiality in the research report, data or analyses preserved in the department will contain a statement making the confidentiality criteria mandatory on further users of the data or analysis.

CODE OF ETHICS FOR RESEARCH



CENTRAL UNIVERSITY OF KERALA

2016

Preamble

CUK views research ethics as the concrete manifestation of the researcher's sense of responsibility and commitment to the society at large, fellow human beings and to the research community. The ethical dimension of research involves values, attitudes, norms, knowledge and skills to conduct, present and communicate research as a humanistic activity that synchronises with social, cultural and economic realities. Researchers need to be aware of the responsibilities placed on them in understanding and sensitive handling of the human, social, cultural and scientific issues involved in research. CUK expects every researcher to link his/her research to the highest ideals and objectives of knowledge production and communication. All research and related activities in CUK will be informed by the following:

Values: Truthfulness, trust, openness, progression, freedom from dogma,

Attitudes: Cooperation, friendliness, acceptance of critical inquiry, self reflection and criticism, acceptance of the other, commitment to common cause, commitment to the vulnerable sections of the society.

Norms: Being lead by professional norms and bench-marks, conventions and recommended practices at national and international level, incorporating subject-specific standards

Knowledge: Knowledge of social, cultural, ideological and political issues involved in research, knowledge of good practices in research, knowledge of the scientific and systematically organized ways of research, knowledge of channels of knowledge communication, knowledge of the problems and stakes of people involved in research (researchers and subjects)

Skills: Knowledge acquisition skills, knowledge generation skills, knowledge communication skills, skills to use new knowledge in practical situations, skills to identify social, economic, cultural and scientific problems and generate knowledge accordingly,

CUK expects every researcher to develop a deep understanding of its vision of the ethics of research and to ensure that their research is informed and guided by the foundational principles and objectives outlined in this document.

1.0 Foundational Principles

The philosophy and vision of CUK regarding ethical conduct of research are expressed as four foundational principles; Awareness, Commitment, Interpersonal Relations and Professional Conduct.

1.1 Awareness

1.0.1 Researchers need to be aware of the ethical, humanistic, social, cultural and ideological issues involved in research in general and in specific instances of research they undertake.

1.0.2 Researchers need to be sensitive about the stakes, problems, difficulties, expectations and apprehensions of fellow researchers, participants and users of research generated knowledge.

1.0.3 Researchers need to be aware of the economic implications of using public funds for research and be prepared to ensure that the fund is used in a productive, positive and beneficial way to the society.

1.0.4 Researchers need to be aware of the norms and standards prescribed for research by national and international bodies and also rules and regulations that relate to various aspects of research.

1.0.5 Researchers need to be aware of the potential uses and users of research generated knowledge and products of research and ensure safe practices in this regard.

1.1 Commitment

1.1.1 Researchers need to be committed to the ultimate goal of social and economic development of the country and be able to align all research activities to this end.

1.1.2 Researchers need to be committed to the ideals of honesty, transparency, generation of knowledge and upholding professional standards.

1.1.3 Researchers need to be committed to the socially, culturally and economically vulnerable groups and be prepared to use research to benefit them.

1.2 Interpersonal Relations

1.2.1 Research is to be conducted in a setting that promotes trust, mutual respect and openness between all participants including the researcher, research students and support staff.

1.2.2 Researchers are expected to ensure that participants in research are not exploited, put to psychological, economic or physical harm and are informed of their rights and possibilities of making choices.

1.3 Professional conduct

1.3.1 Researchers are expected to maintain the highest standards in the conduct of research process, documenting and communicating research and in supervising research.

1.3.2 Researchers are expected to develop a deep understanding of the skills and competencies required for research and acquire and apply them in research activities.

1.3.3 Researchers are expected to conduct research in a transparent way and open it up for critical evaluation and scrutiny.

1.3.4 Researchers are expected to systematically document research and make research data available for application and further studies.

1.3.5 Researchers are expected to ensure that their research no way prejudices the interests of others, cause harm or social embarrassment, or has detrimental economic or political effects

2.0 Professional Standards of research

a) Researchers are expected to operate on the basis of a deep and professional understanding of their discipline and methodologies and procedures of research.
b) Researchers are expected to ensure that he/she has the full competence to perform the activities, processes, experiments and techniques that are part of the research undertaken.
c) Researchers are expected to have a thorough understanding of the standards and bench-marks prescribed by professional and academic bodies in the particular field regarding research, experimentation, testing, analytic techniques and measurements, and to apply them in their work.
d) Researchers shall uphold intellectual property rights and will abide by the legal regulations of copyright.

3.0 Researcher's professional integrity and honesty

a) Researchers shall not use research activities and expertise in a way that compromises professional ideals of research.
b) Researchers shall not sensationalize research findings for personal gain.
c) Researchers shall not exaggerate research findings, measurements and observations.
d) Researchers shall not involve in research for malicious or illegal purposes.
e) Researchers shall not accept grants or sponsorships that involve a conflict of interest with their professional integrity and principles.
f) Researchers shall not unfairly criticize or defame the work of other researchers.
g) Researchers shall not misrepresent or falsify the work of others for personal gain or with malicious intent
h) Researchers shall undertake only those activities for which they have competence.
i) Researchers shall not act in an arbitrary and biased way

4.0 Sense of justice and social commitment

a) Researchers shall ensure that their research is guided by the ultimate aim of social beneficence.

b) The beneficence to those who participate in the research will be a prime concern for researchers.
c) Researchers shall ensure that the research outcome provides sufficient compensation for the resources invested in the particular research by the society.

5.0 Transparency and openness

Transparency and openness are key aspects of research ethics. They relate essentially to verifiability, usability, authenticity and truthfulness of research and all processes involved in research.

a) The reporting of research should follow the criterion of transparency in all aspects.
b) The aims of research, methods used, data collection techniques, nature of data, sampling strategies, outcomes and application potential of research are to be stated in a full and clearly understandable form.
c) Data and information required for reduplication and cross checking of experiments and observations by other researchers are to be spelled out completely and clearly.
d) Limitations of research and possibilities for experimental or analytical error are to be discussed in a frank and professional manner.
e) The extent to which ideas, theoretical formulations and analytical techniques are drawn from other sources is to be made clear.
f) How the basic data is stored and can be accessed by other researchers for verification and cross-checking are to be clearly spelled out.
g) Where confidentiality criteria are applied, other possible norms for the authenticity of data are to be spelled out.
h) Details of location and dates of data collection, researchers and other staff involved in data collection, procedures adopted, information on the sample (without compromising on the confidentiality criteria) are to be recorded and maintained by the researcher and the Department concerned and to the extent relevant, stated in the report.
i) Work books, laboratory log books and registers are to be maintained systematically by all Departments and are to be made available for the purpose of verification and cross-checking by future researchers.
j) Wherever possible and applicable, video and audio recordings of experiments, research procedures, observational settings and data collection process are to be made and maintained.
k) Researchers need to be transparent in the use and distribution of all resources of research including physical facilities and money.

6.0 Interpersonal relations in research

6.0 Dealing with participants as valued equals

a) Researchers need to establish friendly and open relationships based on trust, with fellow researchers and participants.

b) When researchers are in a position to guide, direct and influence the activities of others involved in research, they will respect the individuality, rights and autonomy of the participants.
c) The dignity of the participants needs to be protected at all costs.
d) Researchers shall ensure that during participation all the participants are not exposed to situations causing embarrassment or annoyance or negative feelings. Researchers need to ensure that their actions, relations and decisions are free from bias based on culture, language, gender, nationality, caste and religion.
e) Where research involves cultural and social aspects, researchers need to take every precaution to avoid such prejudices and biases in the conduct and reporting of research.

6.1 Non-exploitation

"Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition"
The Belmont Report 1975

a) Constitutional rights of each participant will be protected Researchers shall not use their authority to impose on participants and fellow researchers decisions that are discriminatory.
b) When research is conducted on students and subordinates as participants, researchers shall ensure that their participation is guided by freedom of choice and not by perception of indirect consequences or rewards.
c) Incentives offered to participants shall be of such nature that it compensates for the time and effort the participants expend, and shall not be used as bribes.
d) Voluntary participation is the basic ethics of participation in research. It is waived only when the research is based on archival or published material.
e) Researchers shall not use positions of authority to persuade others to participate in research.
f) Researchers shall not target vulnerable groups or socio-economically deprived groups to participate in research involving potential psychological and physical stress or harm, using their deprived status to get consent.

6.2 Professional courtesy

a) Researchers shall give due respects to fellow researchers, students and all those who work in the team
b) Researchers shall not unfairly criticize or defame the work of other researchers, scholars or authors.
c) Researchers shall not involve in any action that undermines the professional dignity of other researchers.
d) Research directors and supervisors shall make every effort to protect all team members/students from possible harm or ill effects that may result from participating in the research.
e) Researchers shall extend help and assistance to fellow researchers.
f) Researchers shall take care of equipment, data, materials and infrastructural facilities.

7.0 Documentation of research

7.1 Principles of research documentation

An essential aspect of scientific research is replication and verifiability. It is assumed that when research is replicated the same result as that of the original researcher is obtained. The authenticity of research is dependent also on openness to verification of all aspects of research such as design, experimentation and measurements, data analysis and recording. Maintaining research records is hence an important part of ethical practice in research.

a) All aspects of research must be recorded in appropriate format and maintained for a relevant period by the researcher and/or the university.
b) Workbooks, laboratory logbooks and worksheets are to be carefully preserved.
c) Data collection methods, details of field work, collection of samples and physical objects and details of audio/ video recordings made in connection with the study are to be maintained.
d) Details of human participants are to be maintained remaining within the confidentiality criteria agreed upon.
e) Each department will set up a system for making available research records for verification by other researchers taking into consideration the commitment to openness and sharing and on the other hand, the intellectual property rights of the researcher who conducted the study.

7.2 Data Management

a) For each research, who will hold the data after the research is over will be decided in advance. Data can be held by the individual researcher, principal investigator, the Department /University or it can be in the public domain.
b) How long data will be held is to be decided based on the nature and relevance of the data, confidentiality criteria, potential for misuse of data and intellectual property rights.

c) University/departments will specify who can access the data and conditions for use.

d)

8.0 Authorship

Responsible authorship practices are an important part of research. Reporting and analyzing results is the key to applying research findings to the real world. Despite its vital role, authorship remains a murky and vague area for many scientists who frequently run into difficulty when deciding which colleagues should be listed as authors or co-authors, and which colleagues should instead receive acknowledgement. Despite the challenges, researchers should familiarize themselves with proper authorship practices in order to protect their work and ideas while also preventing research fraud.

A Guide to Research Ethics, University of Minnesota, Centre for Bioethics

a) Authorship credits for research and publication will be in accordance with the contribution made. Who are listed as authors and who receive acknowledgement for contribution shall is to be decided based on systematic criteria. (For example, **The International Committee of Medical Journal Editors** (ICMJE) has issued the following guideline: Authorship credit should be based only on 1) substantial contributions to conception and design, or acquisition of data, or analysis and Interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.)

b) Credits will be given to those who have contributed to the research/publication by way of materials, data, analysis, review, suggestions and specialized help such as language editing, statistical analysis, expert opinion on specific aspects or collection of specimens.

c) Intellectual property rights (copy rights and patents) will also be decided on the basis of an objective and just assessment of the actual contribution made: researchers shall not use their position of authority or position to deny the rights of fellow researchers or students who contribute to the research.

d) The consent of those who will be acknowledged should be obtained, to prevent the situation where they are perceived as endorsing research for which they are not responsible.

9.0 Confidentiality

a) Researchers are bound to keep confidential data, details of participants, opinions, and any other information collected from the participants for the purpose of research.
b) Confidentiality procedures to be followed will form part of informed consent.
c) Unless the participant has given voluntary consent to use his/her name in the data, the researcher will refer to the participant in strict anonymity in reporting and publishing the research.
d) When data is stored after the research is over, the researcher is bound to ensure that future users of the data are also bound by the original confidentiality agreement.

10.0 Research Misconduct

"Cases of misconduct in science involving fabrication, falsification, and plagiarism breach the trust that allows scientists to build on other's work, as well as eroding the trust that allows policymakers and others to make decisions based on scientific and objective evidence. The inability or refusal of research institutions to address such cases can undermine both the integrity of the research process and self governance by the research community"

Responsible Science: Ensuring the Integrity of the Research Process. Vol 1:20 NAS 1992

10.0.1 Plagiarism

The intentional copying of ideas, text, data, graphics or any such intellectual, linguistic and artistic creations/products of others comes under plagiarism. From minor plagiarism (such as using a few lines of another author without acknowledging, using creative phrases or descriptions and terminology coined by other authors without acknowledgment) to major plagiarism involving copying of extensive material, plagiarism is an act which goes against the fundamental spirit of research. Academics and researchers are bound to acknowledge the source/authorship of whatever is not original in their work. This includes;

a) **Textual material**- words, phrases and sentences that are taken from another source or drawn from conversation, interview or personal communication.
b) **Ideas**- Concepts, theories, findings, analytical approaches.
c) **Methodologies**- Procedures, experiment designs
d) **Psychological tests, questionnaires, rating scales**
e) **Graphics and pictures**- Pictures, illustrations, images, graphs, visual representations, diagrams
f) **Data**- statistical data, language data, tables, source materials.

g) **Linguistic creations**- Technical terms, neologisms and phraseologies, when these have not passed into regular use, but are special cases relating to a particular author
h) **Examples** when they are not part of common knowledge.

Piracy is often discussed as a higher and more serious form of plagiarism. This refers to the appropriation of ideas of others without acknowledgement. Unlike plagiarism, ideas appropriated from another source can be hidden to a great extent by altering, restating or translating the ideas into another language. Researchers and research supervisors need to exercise special caution to avoid this problem. The major aspects of doctoral research in progress need to be published in journals of standing and any feedback or criticism regarding piracy need to be carefully examined.

A problematic area of plagiarism and piracy relates to use of unpublished research material to which a researcher gains access in his/her capacity as reviewer or research supervisor. Each researcher needs to critically evaluate his/her thinking process and ensure that he/she is not using ideas gained thus even in an unconscious way.

10.0.2 Falsification

Falsification is defined as the wilful alteration/manipulation of data for whatever reason. It includes the following:

a) Distortion of data to support a particular hypothesis or analysis or to arrive at a particular finding/conclusion
b) Suppression/omission of parts of data to suit the analysis
c) Statistical inflation of data
d) Improper presentation of data to hide certain tendencies
e) Making references to non-existing sources
f) Using incomplete references
g) Relying on experimental observations/data not firmly established through cross checking and verification
h) Using non-random samples and representing it as random sample
i) Generalization without sufficient evidence
j) Sensationalizing and claiming unsubstantiated importance for the research

10.0.3 Fabrication

Fabrication is making up of data, observations or results not actually attested.

a) Blowing up the sample size
b) Conducting interventions for certain data sets alone and reporting for the complete set
c) Correcting data/observations to match with earlier/standard observations
d) Reporting results without conducting the specified number of trials/experimental cycles

e) Wilfully introducing factors that alter experimental outcomes
f) Reporting results not actually observed

10.0.4 Obfuscation

The intentional obliteration, mystification and darkening of research and ideas in reports and publications with a view to create a sense of importance or gravity is known as obfuscation. Researchers and authors often resort to this practice with a view to hide the actual quality of their work and provide it with a more serious, lofty and creative mien. This is a serious problem which of course cannot be regulated by law or norms, but every researcher needs to be aware of the ultimate disrepute that this practice brings to the particular piece of research and the researcher, and how it erodes the values of the research profession. Researchers need to be on guard against the following obfuscation tendencies;

a) A style of discussion, explanation and analysis that obliterates the main ideas and concepts
b) Unnecessary reference to theories or elucidation of theories and ideas not actually relevant in the context.
c) Using difficult or impenetrable language on purpose
d) Not clearly defining and explaining the concepts and scientific terms used

10.0.5 Destruction/withholding of data/ Denying access to information

a) Wilful destruction of data to prevent future verification or cross checking
b) Not providing data to sponsors of research where warranted by the terms and conditions
c) Denying access to information or sources of information to fellow researchers and students
d) Destroying or making inaccessible, databases and recorded data
e) Defacing or cutting out pages from books and journals

10.0.6 Bibliometric inflation

Listing in the bibliography, books and journals not actually consulted or referred in the text.

10.0.7 Redundant/Duplicate Publication

a) Republishing the same or substantially same part of earlier publication in another journal.

10.0.8 Personation/Ghost writing

a) Using the services of persons other than the author(s) to write parts of the research report

10.0.9 Violation of intellectual property rights

a) Researchers shall uphold intellectual property rights and shall ensure that all activities in research and publishing research are according to the rules and regulations relating to intellectual property rights. ('Intellectual Property' means any invention, discovery, improvement, copyrightable work, integrated circuit mask work, trademark, trade secret, and licensable know-how and related rights. Intellectual property includes, but is not limited to, individual or multimedia works of art or music, records of confidential information generated or maintained by the University, data, texts, instructional materials, tests, bibliographies, research findings, organisms, cells, viruses, DNA sequences, other biological materials, probes, crystallographic coordinates, plant lines, chemical compounds, and theses. Intellectual property may exist in a written or electronic form, may be raw or derived, and may be in the form of text, multimedia, computer programs, spreadsheets, formatted fields in records or forms within files, databases, graphics, digital images, video and audio recordings, live video or audio broadcasts, performances, two or three-dimensional works of art, musical compositions, executions of processes, film, film strips, slides, charts, transparencies, other visual/aural aids or CD-ROMS. University of Minnesota, Intellectual Property Policy)

10.0.10 Interfering with or impeding the work of others

a) Sabotaging the work of others, interfering with experimental procedures

11.0 Communication and sharing of research data and findings

11.0 Scholarly communication

11.1 Public communication

11.2 Publication

12.0 Accuracy and authenticity of data

Research based data, findings, analyses and interpretations are taken into general trust by the public and the research community and form the basis for further research and knowledge production. Inaccuracies and mistakes in research may not be noticed by all future researchers. This will in turn reflect on further research, and substantial resources and human capital tend to be lost and false knowledge claims become part of the discipline at least temporarily. Considered from this angle, the researcher's responsibility to maintaining a high level of accuracy in measurements, experimental observations and interpretations become a paramount ethical consideration.

a) Researchers need to own up responsibility for the accuracy and authenticity of data, observations and interpretations that are part of their research, including data, measurements or observations taken from other sources.
b) Researchers need to be aware of the possibilities of cross checking and independent verification of the data and use them wherever applicable.
c) Procedures followed to ensure accuracy and authenticity of data, interpretations and observations need to be laid down in detail.
d) Factors that may affect experimental measurements, data recording and processing are to be analyzed systematically and are to be laid down in detail along with steps adopted to minimize or negate the effect of such factors.
e) Information required to verify, re-check and compare measurements and observations, needs to be specified in research reports.
f) When errors, mistakes and inaccuracies are found or reported in the research, researchers shall take steps to bring them to the notice of the research community by issuing correction statements.
g) Researchers need to ensure that research reports and articles are free from misleading statements or statements or analyses that offer the scope of misinterpretation.
h) Where possible, measurements and observations are to be submitted for peer review and verification before publication.
i) Where generalizations are drawn based on samples, rationale for fixing the sample size, characteristics of the population and other relevant factors are to be discussed to help the potential users of the research study to know the extent to which generalization is possible in the particular piece of research.
j) Where consolidated data alone is provided in the research report, actual recorded data and worksheets are to be filed in the department/research centre for other researchers to cross check the data and findings.

13.0 Ethical standards in human subject research

a) Researchers shall consider the human participants in research as being under their care, and shall assume responsibility for their well being and upholding their rights.
b) Researchers shall not subject the participants to experiments and procedures that are known to cause physical or psychological harm, even with informed consent when the qualitative and quantitative outcome of the intervention cannot justify the use of such procedures; in other words such procedures are to be used only when an overwhelming benefit is evident.
c) Research that exposes human subjects to potentially harmful or stressful situations and stimuli may be taken up only when there are no alternatives to study the particular question and when the research outcome has an unquestioned beneficial value.
d) Researchers shall follow all State and Central Laws and Regulations and the guidelines of competent professional bodies in the conduct of human subject research.

e) Experiments must be based on authentic theoretical study and prior testing
f) Experiments must be conducted by suitably qualified personnel.
g) Researchers shall not use procedures or interventions that are inhuman, unlawful, or dangerous.
h) When unexpected complications, harmful or painful side effects or discomfort are evident, the research intervention must be immediately terminated.
i) All measures, including specialist services should be made ready to protect the participants from any harm or pain or other negative consequences.
j) Deception in research may only be used when no other alternative is available and when the outcome of the research is of unquestioned beneficial value. (APA's "Ethical Principles and Code of Conduct" provides the following guidelines about use of deception. (1) Deception is not allowed unless it is justified by the study's scientific, educational, or applied value, and when alternative means that do not employ deception are not feasible. (2) Deception is never allowed if full disclosure of the nature of the study (potential harm, risk, discomfort, or unpleasant emotional experience) would alter the participants' willingness to take part in the study. Deception and its purpose must be fully explained to the participants following the conclusion of the experimental session or, at the latest, at the conclusion of the research project.)

14.0 Ethical standards in animal research

Regardless of where one may stand on this issue, animal research does continue, and it is governed by ethical guidelines much the same as research involving human participants is regulated. Naturally, there is no informed consent or debriefing, but the psychologist is still under obligation to treat all animals subject ethically and to weigh the cost-benefit ratio carefully while planning the research project.

a) Research involving drug testing on animals, exposing them to painful, stressful and unnatural stimuli, keeping them under prolonged deprivation and movement restriction or any similar kinds of interventions should be taken up only when it is the only source for generating knowledge on a crucial question and when the value of the outcome justifies the conduct of the study.
b) Animals should be treated with utmost care and humane consideration, and used in experiments as sparingly as possible.

c) No animal should be subjected to continuous battery of interventional tests, but subject selection should follow a rotational policy to give each animal time and rest to recover from the effects of testing.
d) All efforts should be made to minimize pain and suffering during tests.
e) When surgical procedures are involved, anaesthesia is to be administered and if needed assistance from qualified professionals may be sought.
f) Animals must be well fed and comfortably housed.
g) When animal life is to be terminated it must be done as quickly as possible, causing minimum pain and recommended procedures must be followed.

Institutional framework for implementing the code of ethics for research

2.1. Ethics committee

The overall responsibility for ensuring that all research activities in CUK are in accordance with ethical principles and rules and regulations is vested with the **Research Ethics Committee** of the University.

14.0.1 Constitution of the Research Ethics Committee

14.0.2 Responsibilities of the Research Ethics Committee

a) The Research Ethics committee is not a fault finding body but guidance and advisory body to uphold the highest ideals of research and academic practice.
b) The ethics committee shall examine all aspects of research conducted in the university, to ensure that highest ethical principles are upheld by all researchers.
c) When research involves human subject research, animal research and research with vulnerable sections, ethical committee can ask the researchers or research supervisors to make a presentation and discuss all aspects of the research, to set down ethical guidelines.
d) The ethics committee is empowered to call for records or ask for researchers to present research proposals before the committee, even in those cases where ethical review is not mandatory.
e) Ethics committee is empowered to recommend modifications/alterations in any aspect of research including research design, experimentation, data collection and procedures.
f) Where major violations are observed, the ethics committee can recommend appropriate penalties including stoppage of research, discontinuation of research grant, debarring a particular researcher and other suitable measures.

14.0.3 Major ethical issues to be examined by the ethics committee.

a) Protocols to be followed in research involving human participants
b) Animal subject based research
c) Confidentiality criteria
d) Informed consent
e) Professional integrity practices
f) Plagiarism and acknowledgement of sources
g) Professional norms and standards

2.2 Responsibilities of officers of the university in implementing the code of ethics

2.2.1 Responsibilities of Departments

a) Departments (acting through Research Committees/Doctoral Committees) are expected to conduct the preliminary ethics audit of each research proposal.
b) A prime responsibility of the Departments is to conduct an evaluation of subject specific aspects of ethical code for each proposal.
c) Departmental committees need to take into confidence the researcher and research supervisor and discuss all aspects of the research and evaluate specific ethical concerns involved in each research proposal. Where applicable, specific norms and guidelines are to be drawn up.
d) Departments are responsible for complying with research documentation guidelines. In each case the department will take a decision on whether research documents and data after the research will be held by the department or the individual researcher, how long it will be held, how it can be accessed by other researchers for verification ad further study and on maintaining confidentiality criteria.
e) While the research is in progress, the Department shall ensure proper maintenance of research records including workbooks, lab logbooks, data collection schedules, expenditure statements and consent forms.
f) In cases where research does not include animal or human participant research, drug testing (on animals or humans) or deception based data collection, the Departments can give Ethical clearance, subject to ratification by the Ethics Committee. All other cases are to be submitted to the Ethics Committee with suggestions and recommendations of the Departmental Research Committee.

2.2.2 Responsibilities of Research Supervisors

a) Research supervisors have the responsibility for sensitizing the student with all aspects of ethical code and also in evaluating the specific ethical issues in a proposal.
b) Research supervisors shall guide the student in conducting the ethical self audit and in bringing to the attention of the Departmental committees and Ethical committee, those aspects that require further scrutiny and discussion.
c) Research Supervisors shall ensure that the student follows the spirit of the ethical code of CUK and its norms, provisions and guidelines in all aspects of research.
d) Research supervisors shall strive to assess each process of ongoing research to identify any ethical issue involved and shall advise the student to adopt appropriate measures to address it, or bring it to the notice of ethical committees

2.2.3 Responsibilities of individual researchers

a) It is the responsibility of every researcher to familiarize himself/herself with the provisions and guidelines of the ethical code framed by the university and also general norms and principles of ethics laid down by international professional bodies.
b) Researchers shall make every effort to apply the guidelines of the ethical code in all aspects of their work.
c) Researchers will keep all records and documents for ethical audit and cooperate with the University and fellow researchers in ethical audit of all aspects of research.

2.2.4 Documentation for ethics audit

a) **Ethical Audit Information Form:** Researchers and students taking up research projects, doctoral and MPhil research will complete and submit to the Department the **Ethical Audit Information Form** (endorsed by the Research Supervisor in the case of student researchers). This will be assessed by the Department Research Committee to decide whether ethical clearance can be given at the departmental level or to be passed on to the Ethics Committee of the University. When departmental research committee decides to grant ethical clearance, it is communicated to the Ethical Committee of the University for ratification.
b) **Informed Consent Documentation**: Where human participants are involved in research, the participants are to be briefed about the research in general, its purposes and methodology, the nature and extent of their participation, expectations from them in terms of time and performance, risks and problems involved, freedom to withdraw at any time, incentives if any, confidentiality provisions and acknowledgement of their participation. Wherever possible, their written consent is to be taken on **Research**

Participant Consent Form. In case of minors and vulnerable populations like patients, mentally or physically challenged persons, consent is to be taken from parents or responsible adults or primary caregivers.

c) **Confidentiality Statements**: Where names or other details of the participants are withheld for reasons of confidentiality in the research report, data or analyses preserved in the department will contain a statement making the confidentiality criteria mandatory on further users of the data or analysis.

STANDARD OPERATING PROCEDURE

INSTITUTIONAL HUMAN ETHICS COMMITTEE

CENTRAL UNIVERSITY OF KERALA, KASARAGOD

TABLE OF CONTENTS

Table of Contents

1. Introduction

The Indian Council for Medical Research, Government of India has issued guidelines (under the Statement of General Principles in Biomedical research involving human participants (http://icmr.nic.in/human_ethics.htm#Guidelines) to be followed in the country to ensure ethical conduct of research studies involving human subjects.

Institutional Human Ethics Committee (IHEC) has been constituted in Central University of Kerala, Kasaragod in compliance with the "Ethical guidelines for biomedical research involving human participants" issued by the Indian Council of Medical Research. The primary aim of IHEC is to protect the welfare and rights of the participants in research studies carried out in Central University of Kerala, involving human participants. The IHEC's function is not only limited to the initial review of the proposed research protocols, but also to regularly monitor the compliance with all ethical requirements, till the completion of the study.

The Central University of Kerala (henceforth referred to as the University) will follow this Standard Operating Procedure (SOP) in all such studies to be conducted in the University. All research proposals involving human participants of the faculty and students- Masters and PhD, of all departments in CUK come under the purview for ethical clearance under IHEC.

This SOP shall be read supplemented by the ICMR guidelines in all matters not specifically dealt with herein. But in areas where the said guidelines are silent, or inadequate, it would be open to the IHEC of the University to resort to other standard national or international guidelines.

2. Objectives of CUK-IHEC

2.1. The responsibilities of IHEC are :-

a. To protect the dignity, rights and well-being of the potential research participants.
b. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
c. To assist in the development and the education of a research community responsive to local health care requirements.

2.2. The Chairman and Member Secretary are responsible for implementing these SOPs.

3. Composition of IHEC-

3.1 IHECs should be multidisciplinary and multisectoral in composition.
3.2 Independence and competence are the two hallmarks of an IHEC.
3.3 Vice chancellor will nominate the Chairperson as well as members for IHEC.
3.4 The IHEC will have a minimum of 7 and a maximum of 15 members, including the Chairperson and the Member Secretary.

The composition is as follows :-
1. Chairperson
2. 1-2 basic medical scientists
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary (From CUK nominated by Vice Chancellor)

a. Chair person: 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. Normally the chairperson presides the meeting, however in his absence or if the position is vacant, an external member will preside the meeting. Chairperson can also convene an emergency IHEC meeting with full committee or a sub-committee as per the requirement.

b. Member Secretary: The Member Secretary who generally belongs to the same Institution, should conduct the business of the Committee. The Member Secretary is in Charge of the Secretariat of the IHEC and reports to the Chairperson on all matters related to the IHEC, including monitoring of the research proposals reviewed by the IHEC.

c. Members: Members should be a mix of medical / non-medical, scientific and non-scientific persons including at least one representative of common man to reflect the differed viewpoints.

The IHEC will have a majority of members from outside the University. Care will be taken to provide adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the society. Members should be aware of local, social and cultural norms, as the IHEC review is the most important social control mechanism.

As and when required, the IHEC is authorised to invite subject experts, representatives of patient groups such as HIV or genetic disorders, or community or interest groups to offer their views on specific proposals under ethics review by the IHEC or for creating common understanding of the IHEC members on an issue. Such invited non-members do not participate in the decision-making in the IHEC, but theviews expressed by them shall be recorded.

The subcommittee will comprise of four members including member secretary , an internal member and an external member.

4. Terms of reference

4.1 Appointment, replacement and resignantion of members

a. The Vice Chancellor of the University will appoint the members who are known for their integrity.

b. The normal term of the IHEC is three years. However, no member will continue in IHEC more than two terms.

c. In case any member of the IHEC (other than ex-officio members) resign before her/his term expires, or is dead, the Vice Chancellor may appoint a new member. In case any member continuously be absent from meetings for more than four consecutive meetings, membership will cease. In such circumstances, a another person from the same category may be appointed by the Vice Chancellor within one month of the vacancy.

4.2 Responsibility to allocate time and undergo training

a. All members of the IHEC are required to allocate adequate time for fulfilling objectives of the IHEC, namely, the review of research proposals, participation in the meetings, monitoring of the ongoing research and to undergo training in bioethics.

b. In order to ensure that the IHEC has high level of competence in research bioethics, it is desirable that the members train themselves and also continuously upgrade their knowledge and skills in research bioethics.

c. It is preferable that IHEC members receive training in Good Clinical Practice Guidelines (GCPs), particularly while reviewing drug trials.

d. University shall endeavour to provide training opportunities to IHEC members as well as staff members in research bioethics and will also equip its library and documentation departments with the journals, books and other resources in research bioethics.

4.3 Meetings of IHEC

a. All research proposals will be strictly reviewed in meetings of IHEC.

b. IHEC committee may appoint sub-committees for undertaking ethics review of some proposals or for expedited review or for emergency review or for other purposes; but the decision of such review or work of the sub-committee shall be reported and ratified in the next full meeting of the IHEC.

c. The Chairperson will conduct all meetings of the IHEC.

d. The Member Secretary is responsible for 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 with the approval of the appropriate authority.

e. IHEC will convene its meetings for the review of the applications, once in three months- January, April, July and October preferably in the third week of the respective months,which will be notified through University website..

f. An annual calendar of the meetings of the IHEC will be announced in advance.
g. Frequency of the meetings will be decided by the Chairperson depending on the volume of review work and other requirements that may arise from time to time.
h. Extraordinary or emergency meetings may be convened depending on exigencies with three days notice.

4.4 Responsibility to participate in the meeting and undertake ethics review

a. At least two weeks prior to the meeting of the IHEC, the Member Secretary shall inform all members about the date and venue of the meeting, the agenda and provide soft and hard copies of the protocols for review. All members should maintain confidentiality of the documents and related matters.

b. All members are expected to allocate time for the meeting as per the agreed annual calendar of the meeting.

c. If for some unavoidable reasons, a member is not able to attend the meeting, she/he should inform the Member Secretary at the earliest in writing. However, the member shall be bound to hand over to the Secretary the review report and connected papers available with her/him in respect of the proposals allocated to her/him for review.

d. All members, irrespective of whether they are appointed as primary or secondary reviewers for specific proposals, are required to review all protocols sent to them and participate in the discussion during the meeting for their ethics review to ensure that they conform to the guidelines used by the IHEC.

4.5 Quorum Requirement:

a. Generally there shall be a quorum of 50 percent of institutional and non-institutional members.

b. For the review of clinical trial proposals, the quorum of IHEC should be atleast 5 members with the following representations:

(i) basic medical scientists.
(ii) clinician
(iii) legal expert
(iv) social scientist / representative of non-governmental voluntary agency /philosopher / ethicist / theologian or a similar person
(v) lay person from the community.

c. In case the meeting is unable to conduct for want of quorum, the meeting shall be held on the seventh working day of the University from the scheduled day of meeting. The member secretary shall communicate the proposed date to the members.

4.6. Decision Making

a. In order to evolve or attain consensus of views of the members, the IHEC would promote extensive discussion among members. As far as possible, the decisions in the IHEC will be taken by arriving at consensus.
b. In the event of the members not being able to reach a consensus, the decision will be taken on the basis of the majority of those present and voting.
c. Only those IHEC members who are independent of the clinical trial and the sponsor of the trial should vote / provide opinion in matters related to the study.

4.7. Compensation and Reimbursement

a. A sitting fee as per University norms shall be paid to all non-institutional members of the IHEC for each meeting**.**

b. All members of the IHEC, including the Chairperson, will be reimbursed for travel costs and other secretarial expenses at GOI rates and the claim for the amount should be submitted with appropriate bills/copies of tickets to the IHEC Secretariat.
c. Accomodation will be provided for members outside Kasaragod District.

4.8. Confidentiality and Conflict of Interest

a. Subject to statutory exceptions, the IHEC members will maintain confidentiality with regard to the identifiable research information to which they have access to as a part of their work on the IHEC, and will sign a statement or agreement to that effect.

b. Any member having a pecuniary or other conflict of interest will declare it in writing to the Chairperson at the time of appointment to the IHEC.

c. If an IHEC member submits a project proposals as an Investigator (PI) or is associated as a consultant or in any other way significantly involved in a research proposal submitted to IHEC, the member should declare her/his conflict of interest to the Chair. He/she will not participate in the review and withdraw from the meeting when this proposal is discussed and decided upon in the IHEC meeting.

5. Submission of application materials for IHEC review

a. All research proposals must be submitted in English language only. Application in hardcopies (10 copies) shall be submitted to Member Secretary, IHEC, Central University of Kerala and a soft copy can be sent to membersecretaryihec@cukerala.ac.in .

The following are the essentials of an IHEC application.

1. **A covering letter** addressed to the Chairperson, IHEC, CUK with details of the documents enclosed for review.

2. ***Technical Advisory Clearance (TAC) certificate***- The IHEC will consider only proposals that have been certified by the Technical Advisory Committees (TACs) within the academic schools of the University. TAC is a sub- committee under the IHEC in every school that undertake human research and shall review the study proposals for its scientific soundness and technical feasibility. The Dean of the School may constitute a Technical Advisory Committee (TAC) within each school and may communicate the details of the same to the IHEC.

3. ***IHEC Application form***: The Principal Investigator/researcher must fill up the ethics review application form in simple non- jargonized language taking care that each point is adequately explained; and submit it with enclosures to the Member Secretary of the IHEC at least **FOUR WEEKS** prior to the scheduled date of the IHEC meeting. The deadline for submission will be communicated in the University website.

4. **Original proposal in detail submitted to Technical Advisory Committee.**

5. ***Supporting documents of research*** such as details on insurance coverage in case of clinical trials, permission certificates if conducted in another institutions should be submitted.

6.. It is mandatory that all clinical trials should be registered online at Clinical Trial registry - India (CTRI) (www.ctri.in) and the registration number should be submitted to the IHEC before initiation of the study. The CTRI is an online register of clinical trials being conducted in India. Any researcher who plans to conduct a trial involving human participants, of any intervention (drug, surgical procedure, preventive measures, lifestyle modifications, devices, educational or behavioural treatment, rehabilitation strategies and complementary therapies) are expected to register the trial in CTRI before enrolment of the first participant.

7. ***Participant information sheet*** should be in English as well as in the language that the participant can read and comprehend (local/regional language). Participant Information sheet explains the nature and the objectives of the study, it benefits and risks for the study participant, voluntariness to participate in the study and permission to withdraw at any stage of the study.

8. Informed consent *in English as well as in the language the participant can read, understand , comprehend and agree by signing the document.*

9. A certificate by a gazetted officer *stating that the translated version is the true translation of the English version needs to be attached.*

b. The Member Secretary will scrutinize the application and enclosures to satisfy themselves that all sections in the application form are adequately filled up / answered, and the enclosures are in order**.**

6. Processing fee

a. A processing fee may be charged as per the University rules.

b. No processing fee shall be charged from the Students of CUK.

7. Review Process

a. Ethics review of the new proposals, revised proposals, amendment in the proposals already approved, reports of the adverse events in the research already going on and so on will be reviewed in an ethical review process.

b. The Member Secretary should not recieve or assign a proposal for ethics review unless the application form is completely and adequately filled up with the enclosures.

c. All the proposals that are to be discussed in the meeting shall be circulated to the members of the IHEC **two weeks** prior to the meeting.

d. The Member Secretary in consultation with the Chairperson may give each member responsibility to undertake rigorous review of a few proposals as primary or secondary reviewer.

e. Appointment of Reviewers: In consultation with the Chairperson, the Member Secretary will appoint one Primary Reviewer and one Secondary Reviewer for each proposal received.

f. Responsibilities of Reviewers: The Primary and Secondary reviewers appointed for specific proposals will summarize the proposals, scrutinize them for each ethical issue, identify inadequacies and problems (if any), formulate proposals for changes needed (if any) to make proposed research ethical.
Both primary and secondary reviewers may discuss their observations. The principal investigators may be invited to make a brief presentation on the proposals to the IHEC members. Primary and secondary reviewers may clarify their doubts and seek explanation if required. At the time of the deliberation on the proposal and the final decision on it, the applicant should not be present in the meeting. Care should be taken to maintain confidentiality of the member raising such issues, and such queries should be communicated as collective queries of the IHEC.

g. Communicating decision: The Member Secretary shall communicate decision of the IHEC in writing to the applicant within two weeks time.

Any decision suggesting changes in the proposal would contain the information on specific changes suggested and clear reasons for the same. Negative decision should always be supported by clearly defined reasons.

h. Reversing positive decision: The IHEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk ratio.

i. Withdrawing proposal/application from review process: After making an application for the ethics review, in case the PI wishes to withdraw a proposal from the review process she/he should submit a written request to the Member secretary, IHEC at least three weeks prior to the date of IHEC meeting.

j. Discontinuation of Trial: As per the application form, all research proposals must specify conditions that would lead to discontinuation of research (particularly trials) approved by the IHEC. When the IHEC finds that such conditions for discontinuation have reached in the research process and when it is found that researchers themselves have not stopped the research, it may order discontinuation of such research. One of the grounds for discontinuation is the achievement of the goals of the trial midway or the results proving or disproving the hypothesis unequivocally. All research pre-maturely terminated should be notified to the IHEC along with (a) reasons for termination and (b) a summary of the results of research conducted till date.

k. Matters to be brought to the attention of the IHEC by the researchers:
Researchers have the responsibility to bring to the notice of the IHEC the following matters related to their research:

(i). Any proposed amendment to the protocol in the originally approved protocol with proper justification. Such amendment must be reviewed by the IHEC before it is incorporated in the protocol.
(ii) Serious and unexpected adverse events and remedial steps taken to tackle them as well as any new information that may influence the conduct of the study, including the need to amend the protocol and the informed consent form.

l. Outcome of review
Approval categories used by the IHEC for the proposals reviewed: Broadly there are three categories of approval,
(i) study can begin
(ii) study cannot begin until changes suggested by the IHEC are incorporated in the protocol and/or approved by the IHEC
(iii) denial of approval.

There are sub-categories and/or requirements for each:

(i). Study can begin: There are two sub-categories of approval:
(*a*) Straight approval or approval with comment:

Granted when the Committee has no questions about the application. But the members may, however, make comments about this approval or recommendations for future submissions. Such comments will be included in the approval letter itself.

(*b*) Conditional approval:

Granted when the Committee approves an application with conditions that the committee recommends; but require a response to those conditions. Conditional approval can also be given if a PI is asked to submit a finalized version of a questionnaire or letters of support from others including Institute's departments cooperating in the research and that is complied with. Conditional approval may not be given if government/legal requirements are not met. Conditions will be explained in the approval letter. Once the PI responds to the conditions, an approval letter is sent out by the Member Secretary by the authority vested in her/him by the committee.

(ii). Study cannot begin until changes suggested by the IHEC are incorporated in the protocol and/or approved by the IHEC:
There are two sub-categories of approval:
(*a*) Contingent Approval: The Committee approves the study in principle. However, the members require a written response from the PI regarding particular items of concern. The members may ask the PI to clarify a point, provide further information, make revisions in, for example, the protocol, recruitment, and/or consent form. Normally, only the Chairperson reviews the response from the PI. The Chair has the option of sending the response to the IHEC Committee or a Subcommittee.
At this stage, as far as possible, no new or additional issues should be raised by the IHEC unless (i) it is found that some aspects of government/legal requirements were overlooked during the Committee review and/or (ii) in the opinion of the Chair, the new or additional issue is of high importance and was inadvertently overlooked during the Committee review. No approval number is given until the questions and/or concerns of the Committee have been satisfactorily addressed by the PI and approved by the Chair.

(*b*) Returned for additional information: Committee is not prepared to approve the study without additional information and review. This is resorted to when serious concerns are raised about the risk/benefit ratio or other issues of participants' protection, and the members agree that additional information, justification, or changes are needed before approval can be reconsidered. The PI must respond to this request in writing and then the IHEC Committee or the Subcommittee reviews this response depending on the decision of the members or the Chair.
If the revised proposal meets the requirements, it is granted contingent, conditional, or straight approval at the time of the second review. However, the proposal may be returned again if the committee decides so.

(iii)Denial of approval: The denial can be based on several considerations. It may be because the IHEC disapproves the study in principle. It may deny approval because members' concerns for the protection of the participants have not been satisfactorily addressed even after the revision. Whatever may be the reason for the denial, before the proposal/project is denied approval, the IHEC must invite the PI to present her/his views/justification and the same are discussed by the members of the IHEC with the PI, and also among themselves.
The denial letter should provide adequate information on the grounds for the denial.

m. Certification of the protocol:

After the approval is granted by the IHEC, in addition to sending the approval letter to the PI, the Member Secretary certifies the protocol and a copy of the same is kept in the Secretariat.

n. **Minutes of the meeting:**The minutes of all meetings of the IHEC are prepared by the Member Secretary and sent to all members of the IHEC after approval of the Chairperson. These minutes are read out in the next meeting of the IHEC, discussed and confirmed with or without amendments.

8. Exemption from Ethics review

The IHEC may exempt certain human research activities from the ethics review. The IHEC will consider the following categories of human research activities for exemption from ethics review:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special educational instruction strategies, or (ii) research on the effectiveness of or the comparison among instruction techniques, curricula, or classroom management methods.
b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation or do him psychological harm.
(iii) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

c. While normally the research in the above three categories will be considered for exemption, it may not be considered for exemption if it is involving children or other vulnerable groups as participants.

8.1 Procedure for obtaining exemption from ethics review:

a. If a PI believes that her/his research activities may be exempted from review, she/he should submit to the TAC a request for exemption from review along with a summary of the proposed research.

b. The TAC may recommend the proposal for exemption review before the Member Secretary, IHEC.

c. On receipt of such application, the Member Secretary in consultation with the Chairperson may allow the application to be reviewed by the subcommittee for an exemption. Such proposals shall be placed before the next IHEC meeting for ratification.

d. If the research is not clearly exempt, PI may be advised to submit the proposal to the IHEC committee. The PI will be notified of the final decision in writing.

e. When the decision to exempt a particular research is taken by the subcommittee, it should clearly mention the applicable provision given in section above for providing such exemption.

9. Ethics Sub-Committee for Expedited reviews.

a. Sub committee will comprise of four members including Member Secretary.

b. At least one of the members in the subcommittee shall be an IHEC member from outside the institution.

10. Waiver of informed consent requirements

a. Obtaining informed consent is a requirement of all studies being undertaken.

b. However, under special circumstances, such as when the research involves no more than minimal risk or when the participant and researcher do not come into contact or when it is necessitated for research in emergency situations, the IHEC may consider waivers based on the following criteria:
(i) When the research cannot be conducted with the written consent of the participant due to reasons related to the research process and this may be required due to reasons related to social or cultural sensitivity and stigma
(ii) When the research is on already published documents, references, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programmes for the benefit of the public having a bearing on public health programmes and consumer acceptance studies.
(iii) Research on anonymised biological samples from deceeased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral associates, DNA or RNA

from recognized institutions or qualified investigators, samples or data from repositories or registries etc.

11. Continuing review/amendment

a. IHEC has the right to reconsider or cancel or modify the approvals granted.

b. All ongoing approved studies may be reviewed on the discretion of the committee as and when necessary.

c. In case the PI intends to make any change/ changes to the approved proposals, an application for amendment shall be submitted to the IHEC. Such applications shall be reviewed by the subcommittee/ IHEC committee as deemed necessary, as the case may be.

12. Completion report

PI shall submit a completion report with major findings/outcome of the study.

13. Monitoring of research for its ethical conduct.

a. The IHEC is empowered to make visits to the research sites, review actual conduct and to appoint a Data and Safety Monitoring Board (DSMB) for continuing review of the research and take any other appropriate measures to ensure that the research is conducted according to the approved proposal/protocol.

b. The DSMB shall provide recommendations to IHEC as and when called upon to do so.

14. Appeal for re-consideration

a. Any person aggrieved by the decision of the IHEC may file an application for reconsideration to the Chairperson within two months from the date of receipt of the IHEC feedback from the Member Secretary.

b. On receipt of such application, the Chairperson may place the proposal before the IHEC for reconsideration. In such cases, decision of the IHEC is final.

15. Maintaining records

a. All documents and communications relating to the functions of the IHEC are to be dated, filed and maintained according to written procedures.
b. Strict confidentiality needs to be maintained during access and retrieval procedures.
c. All confidential records will be carefully and systematically stored in the form of electronic or hard copies in a separate room or cupboards in the secretariat by the Member-Secretary, who will be the custodian. Such confidential documents include, among others:
(i) Copies of protocols submitted for review;
(ii) All correspondence with IHEC members and investigators regarding application, decision and follow up;
(iii) Agenda of all IHEC meetings;
(iv) Minutes of all IHEC meetings with signature of the Chairperson;

(v) Copies of decisions communicated to the applicants;
(vi) Record of all notifications issued for premature termination of a study with a summary of the reasons;
(vii) Final report of the study including microfilms, CDs and Video recordings.

d. All records will be maintained for at least 3 years in the form of electronic or hard copies, if it is not possible to maintain the same permanently.
e. The Member-Secretary must hand over full custody of such records to her/his successor, and the handing over must be documented.

16. Amendment to the Standard Operating Procedure (SOP)

The Institutional Human Ethics Committee has the right to modify/ amend the SOP as and when deemed necessary.

[This standard operating procedure is developed based on "Ethical Guidelines for Biomedical Research on Human Participants" by the Indian Council of Medical Research, New Delhi and adapted from Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum]

****

केरल केन्द्रीय विश्वविद्यालय

CENTRAL UNIVERSITY OF KERALA

TEJASWINI HILLS, PERIYE P.O, KASARAGOD-671316

No.CUK/RPC/54/12

NOTIFICATION

Dated, 22nd November, 2012.

In compliance to the guidelines put forth by Indian Council for Medical Research (ICMR), the Vice-chancellor is pleased to reconstitute the Institutional Human Ethics Committee (IHEC) of Central University of Kerala based on the recommendation of Executive Council with the following members.

Sl.No.	Name and Adress	Designation
1	Prof.(Dr.) Jayaprasad Kodoth, Head, Department of Periodontics, CDER, Kasaragod:- Kodoth House, Krishnan Mandir, Corcss Road, Kanhangad	Chairperson
2	Dr.Rajendra Pilankatta, Associate Professor, Department of Biochemistry & Molecular Biology, Central University of Kerala	Member
3	Adv. Sreekanth K, Opp.LFGHS School, Hosdurg PO, Kanhangad	Member
4	Dr.Amruth G Kumar, Associate Professor, Department of Education, Central University of Kerala	Member
5	Dr. Jayakrishnan Thavody, Associate Professor, Department of Community Medicine, Government Medical Collge, Kozhikode, Kerala	Member
6	Shri P Krishnan, District Coordinator, Kerala State Biodiversity Board, Azhithala, Thaikadapuram PO, Kasaragod	Member
7	Shri Vineesh Kumar K.V, Thulichery House, Athikkadav, Bela PO, Kasaragod	Member
8	Ms. Sreedevi E, Payyanganam House Kuttikol (P.O), via Chengala, Kasaragod	Member
9	Dr.Ranjith N Kumavath, Assistant Professor, Department of Genomic Science, Central University of Kerala	Member
10	Dr.Satheesh Kumar, Associate Professor, Department of Economics, St.Pious College Rajapuram-671 532	Member
11	Dr.Elezebeth Mathews, Assistant Professor, Department of Public Health and Community Medicine, Central University of Kerala	Member Secretary

The Institutional Human Ethics Committee (IHEC) of Central University of Kerala is constituted for reviewing and approving all type of research proposals involving human participant with a view to safeguard the dignity, rights, safety and well-being of all actual and potential research participant.

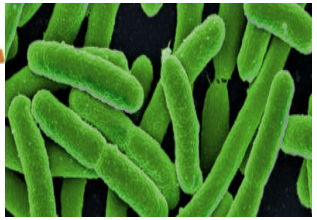
The Member Secretary shall submit all the details for registration to Central Drugs Standard Control Organization, Government of India through the University at the earliest.

The Institutional Human Ethics Committee (IHEC) shall function as per the guidelines issued by Indian Council for Medical Research (ICMR) and Central University of Kerala in this regard and submit activities report to the University periodically.

This issued to in supersession of this Office Notification of even no dated 22nd August, 2012.

Central University of Kerala
Kasaragod

Guidelines for Biosafety Committee



Statutory Committee constituted as per Rules 1989 and guidelines issued by Department of Biotechnology (DBT), GoI

Responsibilities:

- **Preparation of Standard Operating Procedures (SOPs) for use of biological materials including access to Genetically Modified Organisms (GMOs)/ Living Modified Organisms (LMOs), Recombinant DNA (rDNA) materials and environment risk assessment**
- **Evaluation of research proposals and direction for submission to appropriate agencies for statutory approvals**
- **Examine conflict of interest (CoI) if any, in the proposal and if required, request for full disclosure of CoI**
- **Maintain confidentiality of research proposals and other related information**
- **Verify information in terms of physical containment conditions and categorization in terms of risk assessment as prescribed in DBT guidelines**
- **Inspection of containment facilities, unit process areas, greenhouses etc. involved in GMOs/LMOs and rDNA research**
- **Guidance to Principal Investigator (PI) on issues related to biosafety while using GMOs/LMOs and rDNA research**
- **Review emergency plan proposed by PI for responding to an accidental release of GMO**

- **Assess field experiments to ensure that the proposed risk assessment, risk management and emergency plans are sufficient**
- **Information of all relevant activities involving the use of GMOs/LMOs and rDNA research to Review Committee on Genetic Manipulation (RCGM)**
- **Detailed documentation of activities**
- **Review of disposal methods and clearance of "regulated waste" as per stipulated rDNA safety guidelines**
- **Evaluating permissions from researchers seeking transfer/shipment of indigenous etiological agents, diagnostic specimens, GMOs/LMOs and biological products thereof in the required format as prescribed by DBT**

Updating information to:

- **Biosafety Regulatory website (http://dbtbiosafety.nic.in) about composition, agenda and minutes of IBSC meetings**
- **Furnishing annual report to RCGM in prescribed proforma regarding observance of safety guidelines**
- **Providing information on projects/activities being undertaken to Indian GMO Research Information System (IGMORIS) (http://www.igmoris.nic.in)**
- **Reporting information to RCGM on non-compliance of the biosafety guidelines or any significant research-related accidents/illnesses and spills**

Facilities subject to inspection for accountability on biosafety

Recommend emergency plan in case of large-scale operations involving large volumes of cultures and organisms for production, transport, storage or disposal etc.

Review of research activities related to transgenic plants as per "Revised Guidelines for Research in Transgenic Plants 1998" by DBT, GoI (http://dbtbiosafety.nic.in)

Central University of Kerala

Kasaragod

Institutional Human Ethics Committee
Central University of Kerala

Background

The Institutional human Ethics Committee was constituted in 2016 and reconstituted to review research proposals involving human participants from the faculty and students (Masters and PhD) to conduct research in an ethical manner following the principles of bioethics, namely, beneficence, non-maleficence and justice. It further aims to safeguard the dignity, rights and wellbeing of the research participants

The responsibilities of IHEC are :- 1. To protect the dignity, rights and well-being of the potential research participants. 2. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs. 4 3. To assist in the development and the education of a research community responsive to local health care requirements.

Year	Number of ethics approval given	Number of meetings
2017-18	16	2
2018-19	32	2
2019-20	30	2
2020-21	31	2
2021-22	3	1
Total	112	

STANDARD OPERATING PROCEDURE

INSTITUTIONAL HUMAN ETHICS COMMITTEE

CENTRAL UNIVERSITY OF KERALA, KASARAGOD

TABLE OF CONTENTS

Table of Contents

1. Introduction

The Declaration of Helsinki and other international guidelines for biomedical research on human subjects, emphasize the need for the clearance of the research proposals by the Institutional Ethics Committee (IECs), also known as Institutional review boards, to protect the welfare and rights of the participants. The responsibility of Ethics Committees are not only limited to the initial review of the proposed research protocols, but also to regularly monitor the compliance with all ethical requirements, till the completion of the study.

The Indian Council for Medical Research has issued guidelines (under the Statement of General Principles in Biomedical research involving human participants (http://icmr.nic.in/human_ethics.htm#Guidelines) to be followed in the country to ensure ethical conduct of research studies involving human subjects. The Central University of Kerala (henceforth referred to as the University) will follow these ICMR guidelines in all such studies to be conducted in the University. This standard operating procedure (SOP) shall be read supplemented by the ICMR guidelines in all matters not specifically dealt with herein. But in areas where the said guidelines are silent, or inadequate, it would be open to the Ethics committee of the University to resort to other standard national or international guidelines.

The Central University of Kerala, in accordance with the ICMR guidelines, has established such an Institutional Human Ethics Committee.

2. Objectives of CUK-IHEC

The responsibilities of IHEC are :-
1. To protect the dignity, rights and well being of the potential research participants.
2. To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

3. To assist in the development and the education of a research community responsive to local health care requirements.

The Chairman and Member Secretary are responsible for implementing these SOPs.

3. Composition of IHEC-

IHECs should be multidisciplinary and multisectorial in composition. Independence and competence are the two hallmarks of an IHEC. Vice chancellor will nominate the Chairperson as well as members for IHEC from the panel submitted by Dean, School of Medicine and Public Health. The IHEC will have a minimum of 7 and a maximum of 15 members, including the Chairperson and the Member Secretary

The composition is as follows :-
1. Chairperson
2. 1-2 basic medical scientists
3. 1-2 clinicians from various Institutes
4. One legal expert or retired judge
5. One social scientist / representative of non-governmental voluntary agency
6. One philosopher / ethicist / theologian
7. One lay person from the community
8. Member-Secretary (From CUK nominated by Vice Chancellor)

3.1 Chair person: 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. Normally the chairperson presides the meeting, however in his absence or if the position is vacant, an external member will preside the meeting. Chairperson can also convene an emergency IHEC meeting with full committee or a sub-committee as per the requirement.

3.2 Member Secretary: The Member Secretary who generally belongs to the same Institution, should conduct the business of the Committee. The Member Secretary is in Charge of the Secretariat of the IHEC and reports to the Chairperson on all matters related to the IHEC, including monitoring of the research proposals reviewed by the IHEC.

3.3 Members: Members should be a mix of medical / non-medical, scientific and non-scientific persons including at least one representative of common man to reflect the differed viewpoints.

The IHEC will have a majority of members from outside the University. Care will be taken to provide adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the society. Members should be aware of local, social and cultural norms, as the IHEC review is the most important social control mechanism.

As and when required, the IEC is authorised to invite subject experts, representatives of patient groups such as HIV or genetic disorders, or community or interest groups to offer their views on specific proposals under ethics review by the IHEC or for creating common understanding of the IHEC members on an issue. Such invited non-members do not participate in the decision-making in the IHEC, but theviews expressed by them shall be recorded.

The subcommittee will comprise of the member secretary , an internal member and an ethicist.

4. Terms of reference

4.1 Appointment, replacement and resignantion of members

The Vice Chancellor of the University will appoint the members.

The normal term of the IHEC is three years. However, no member will continue in IHEC more than two terms.

Should any member of the IEC (other than ex-officio members) resign before her/his term expires, or is dead, the Vice Chancellor may appoint a new member. In case any member continuously misses meetings due to illness or unforeseen circumstances for more than four meetings, membership will cease. In such circumstances, a substitute member may be appointed by the Vice Chancellor.

4.2 Responsibility to allocate time and undergo training

All members of the IHEC are required to allocate adequate time for fulfilling objectives of the IHEC, namely, the review of research proposals, participation in the meetings, monitoring of the ongoing research and to undergo training in bioethics.

In order to ensure that the IHEC has high level of competence in research bioethics, it is desirable that the members train themselves and also continuously upgrade their knowledge and skills in research bioethics. It is preferable that IHEC members receive training in Good Clinical Practice Guidelines (GCPs), particularly while reviewing drug trials.

University shall endeavour to provide training opportunities to IHEC members as well as staff members in research bioethics and will also equip its library and documentation departments with the journals, books and other resources in research bioethics. Efforts should also be made to bring recent changes in regulatory requirements to the notice of the IHEC members.

4.3 Formal meetings

All research proposals will be strictly reviewed in formal meetings organised by the IHEC. However the Chairperson may appoint sub-committees for undertaking ethics review of some proposals or for expedited review or for emergency review or for other purposes; but the decision of such review or work of the sub-committee shall be reported in the next full meeting of the IHEC.
The Chairperson will conduct all meetings of the IHEC. The Member Secretary is responsible for 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 with the approval of the appropriate authority. IHEC will convene its meetings for the review of the applications, once in three months- January, April, July and October in the third week of the resepctive months.

4.4 Responsibility to participate in the meeting and undertake ethics review

An annual calendar of the meetings of the IHEC will be announced in advance so that unnecessary delays in the process of technical and ethics clearance of the proposals are avoided. The IHEC will normally meet once in three months on a fixed date, which will be notified through University website. Frequency of the meetings will be decided by the Chairperson depending on the volume of review work and other requirements that may arise from time to time. Extraordinary or special meetings may be convened depending on exigencies.

At least three weeks prior to the meeting of the IEC, Member Secretary, shall inform all members about the date and venue of the meeting, the agenda and provide copies of the protocols for review.

All members are expected to allocate time for the meeting as per the agreed annual calendar of the meeting.

If for some unavoidable reasons a member is not able to attend the meeting, she/he should inform the Member Secretary at the earliest.

However, the member shall be bound to hand over to the Secretary the review report and connected papers available with her/him in respect of the proposals allocated to her/him for review.

All members, irrespective of whether they are appointed as primary or secondary reviewers for specific proposals, are required to read all protocols sent to them and participate in the discussion during the meeting for their ethics review to ensure that they conform to the guidelines used by the IEC.

4.5 Quorum Requirement: There should be a quorum of 50 percent of institutional and non-institutional members. For review of each protocol the 6 quorum of IHEC should be atleast 5 members with the following representations:

(a) basic medical scientists (preferably one pharmacologist).
(b) clinician
(c) legal expert
(d) social scientist / representative of non-governmental voluntary agency /philosopher / ethicist / theologian or a similar person
(e) lay person from the community.

In any case, the ethics committee must include at least one member whose primary area of interest / specialization is nonscientific and at least one member who is independent of the University Besides, there should be appropriate gender representation on the Ethics Committee.

4.6. Decision Making: In order to evolve or attain consensus of views of the members, the IHEC would promote extensive discussion among members. As far as possible, the decisions in the IHEC will be taken by arriving at consensus. But in the event of the members not being able to reach a consensus, the decision will be taken on the basis of the majority of those present and voting. Only those IHEC members who are independent of the clinical trial and the Sponsor of the trial should vote / provide opinion in matters related to the study.

4.7. Compensation and Reimbursement

A sitting fee as per University norms shall be paid to all non-institutional members of the IHEC for each meeting**.**

All members of the IHEC, including the Chairperson, will be reimbursed for travel costs (outside Kasaragod) and other secretarial expenses at GOI rates and the claim for the amount should be submitted with appropriate bills/copies of tickets to the IHEC Secretariat.

4.8. Confidentiality and Conflict of Interest

Subject to statutory exceptions, the IHEC members will maintain confidentiality with regard to the identifiable research information to which they have access to as a part of their work on the IHEC, and will sign a statement or agreement to that effect.

Any member having a pecuniary or other conflict of interest will declare it in writing to the Chairperson at the time of appointment to the IHEC.

If an IHEC member submits a project proposals as an Investigator (PI) or is associated as a consultant or in any other way significantly involved in a research proposal submitted to IHEC, the member should declare her/his conflict of interest to the Chair. He/she will not participate in the review and withdraw from the meeting when this proposal is discussed and decided upon in the IHEC meeting.

5. Submission of application materials for IHEC review

All research proposals must be submitted in English language only. Application in hardcopies (8 copies) can be submitted to Member Secretary, IHEC, Central University of Kerala and a soft copy can be sent to membersecretaryihec@cukerala.ac.in .

The following are the essentials of an IHEC application.

1. ***Technical advisory Clearance (TAC) certificate***- The IHEC will consider only proposals that have been certified by the Technical Advisory Committees (TACs) within the academic departments of the University. TAC is a sub- committee under the IHEC in every department that undertake human research and shall review the study proposals for its scientific soundness and technical feasibility. The Head of the Deaprtment may constitute a Technical Advisory Committee (TAC) within each department and may communicate the details of the same to the IHEC.

2. ***IHEC Application form***: The Principal Investigator must fill up the ethics review application form in simple non- jargonized language taking care that each point is adequately explained; and submit it with enclosures

to the Member Secretary of the IHEC at least **THREE WEEKS** prior to the scheduled date of the IHEC meeting. The deadline for submission will be communicated in the University website.

3. **Original proposal in detail submitted to Technical Advisory Committee.**

4. ***Supporting documents of research*** such as details on insurance coverage in case of clinical trials, permission certificates if conducted in another institutions should be submitted.

5. It is mandatory that all clinical trials should be registered online at Clinical Trial egistry - India (CTRI) (www.ctri.in) and the registration number should be submitted to the IHEC before initiation of the study. The CTRI is an online register of clinical trials being conducted in India. Any researcher who plans to conduct a trial involving human participants, of any intervention (drug, surgical 8procedure, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies and complementary therapies) are expected to register the trial in CTRI before enrollment of the first participant.

6. ***Participant information sheet*** should be in English as well as in the language that the participant can read and comprehend. Participant Information sheet explains the nature and the objectives of the study, it benefits and risks for the study participant, voluntariness to participate in the study and permission to withdraw at any stage of the study.

7. Informed consent in English as well as in the language the participant can read, understand , comprehend and agree by signing the document.

8. Processing fee

Externally funded projects of the University - Only approved projects are eligible for clearance by the committee. All projects funded by the national and international organisations will have to pay a processing fee of Rs 5000/- and 10,000/- respectively in favour of Institutional Human Ethics Committe, Central University of Kerala. They may submit the paid chalan along with the application.

Funded projects by individuals/ institutions outside the University that seeks ethical clearance from the IHEC, University may submit their application in prescribed format with a processing fee of Rs 15,000/- in

favour of Institutional Human Ethics Committe, Central University of Kerala.
Student Projects: MPH, Mphil and PhD research projects can be submitted for the approval after getting a TAC certificate from the Technical Advisory Committee of their Department.

A **no objection letter** will be provided by the Sub-committee for the purpose of seeking funds from various funding sources, on submission of the proposal, with an exemption for the processing fee. However, once funded, the same will be deducted from the project funds.

There will not be any additional fee for amendments and adverse event report submissions to the IHEC. Once the project is approved, 5% of the total budget will be deducted as a part of the over-head and credited to the IHEC corpus fund.

The Member Secretary will scrutinize the application and enclosures to satisfy themselves that all sections in the application form are adequately filled up / answered, and the enclosures are in order

6. Review Process

Ethics review of the new proposals, revised proposals, amendment in the proposals already approved, reports of the adverse events in the research already going on and so on will be reviewed in an ethical review process.

The Member Secretary should not recieve or assign a proposal for ethics review unless the application form is completely and adequately filled up with the enclosures.

All the proposals that are to be discussed in the meeting shall be circulated to the members of the IHEC. The Member Secretary in consultation with the Chairperson may give each member responsibility to undertake rigorous review of a few proposals as primary or secondary reviewer.

Appointment of Reviewers: In consultation with the Chairperson, the Member Secretary will appoint one Primary Reviewer and one Secondary Reviewer for each proposal received.

Responsibilities of Reviewers: The Primary and Secondary reviewers appointed for specific proposals will summarize the proposals, scrutinize

them for each ethical issue, identify inadequacies and problems (if any), formulate proposals for changes needed (if any) to make proposed research ethical. Both primary and secondary reviewers may discuss their observations. The principal investigators will be invited to make a ten minute presentation on the proposals to the IHEC members. Primary and secondary reviewers may clarify their doubts and seek explanation if required. At the time of the deliberation on the proposal and the final decision on it, the applicant should not be present in the meeting. Care should be taken to maintain confidentiality of the member raising such issues, and such queries should be communicated as collective queries of the IEC.

Communicating decision: The Member Secretary will communicate decision of the IEC in writing to the applicant. Any decision suggesting changes in the proposal would contain the information on specific changes suggested and clear reasons for the same. Negative decision should always be supported by clearly defined reasons.

Reversing positive decision: The IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk rat**io.**

Withdrawing proposal/application from review process: After making an application for the ethics review, in case the PI wishes to withdraw a proposal from the review process she/he should submit a written request to the Member secretary, IHEC at least one week prior to the date of IHEC meeting.

Discontinuation of Trial: As per the application form, all research proposals must specify conditions that would lead to discontinuation of research (particularly trials) approved by the IHEC. When the IHEC finds that such conditions for discontinuation have reached in the research process and when it is found that researchers themselves have not stopped the research, it may order discontinuation of such research. One of the grounds for discontinuation is the achievement of the goals of the trial midway or the results proving or disproving the hypothesis unequivocally. All research pre-maturely terminated should be notified to the IHEC along with (a) reasons for termination and (b) a summary of the results of research conducted till date.

Matters to be brought to the attention of the IEC by the researchers:
Researchers have the responsibility to bring to the notice of the IHEC the following matters related to their research:

1. Any proposed amendment to the protocol in the originally approved protocol with proper justification. Such amendment must be reviewed by the IEC before it is incorporated in the protocol.
2. Serious and unexpected adverse events and remedial steps taken to tackle them as well as any new information that may influence the conduct of the study, including the need to amend the protocol and the informed consent form.
3. Approval categories used by the IHEC for the proposals reviewed: Broadly there are three categories of approval,
a. study can begin
b. study cannot begin until changes suggested by the IHEC are incorporated in the protocol and/or approved by the IHEC
c. denial of approval.

There are sub-categories and/or requirements for each:

a. Study can begin: There are two sub-categories of approval:
(i) Straight approval or approval with comment: Granted when the Committee has no questions about the application. But the members may, however, make comments about this approval or recommendations for future submissions. Such comments will be included in the approval letter itself.

(ii) Conditional approval: Granted when the Committee approves an application with conditions that the committee recommends; but require a response to those conditions. Conditional approval can also be given if a PI is asked to submit a finalized version of a questionnaire or letters of support from others including Institute's departments cooperating in the research and that is complied with. Conditional approval may not be given if government/legal requirements are not met. Conditions will be explained in the approval letter. Once the PI responds to the conditions, an approval letter is sent out by the
Member Secretary by the authority vested in her/him by the committee.

b. Study cannot begin until changes suggested by the IHEC are incorporated in the protocol and/or approved by the IHEC: There are two sub-categories of approval:
(i) Contingent Approval: The Committee approves the study in principle. However, the members require a written response from the PI regarding particular items of concern. The members may ask the PI to clarify a point, provide further information, make revisions in, for example, the protocol, recruitment, and/or consent form. Normally, only the Chairperson reviews the response from the PI. The Chair has the option of sending the response to the Full Committee or a Subcommittee.
At this stage, as far as possible, no new or additional issues should be raised by the IHEC unless (i) it is found that some aspects of government/legal

requirements were overlooked during the Committee review and/or (ii) in the opinion of the Chair, the new or additional issue is of high importance and was inadvertently overlooked during the Committee review. No approval number is given until the questions and/or concerns of the Committee have been satisfactorily addressed by the PI and approved by the Chair.

(ii) Returned for additional information: Committee is not prepared to approve the study without additional information and review. This is resorted to when serious concerns are raised about the risk/benefit ratio or other issues of participants' protection, and the members agree that additional information, justification, or changes are needed before approval can be reconsidered. The PI must respond to this request in writing and then the Full Committee or the Subcommittee reviews this response depending on the decision of the members or the Chair.
If the revised proposal meets the requirements, it is granted contingent, conditional, or straight approval at the time of the second review. However, the proposal may be returned again if the committee decides so.

(c)Denial of approval: The denial can be based on several considerations. It may be because the IHEC disapproves the study in principle. It may deny approval because members' concerns for the protection of the participants have not been satisfactorily addressed even after the revision. Whatever may be the reason for the denial, before the proposal/project is denied approval, the IHEC must invite the PI to present her/his views/justification and the same are discussed by the members of the IHEC with the PI, and also among themselves.
The denial letter should provide adequate information on the grounds for the denial.

Certification of the protocol: After the approval is granted by the IHEC, in addition to sending the approval letter to the PI, the Member Secretary certifies the protocol and a copy of the same is preserved in the Secretariat.

Minutes of the meeting: The minutes of all meetings of the IHEC are prepared by the Member Secretary and sent to all members of the IEC after approval of the Chairperson. These minutes are read out in the next meeting of the IEC, discussed and confirmed with or without amendments.

7. Exemption from Ethics review

The IHEC may exempt certain human research activities from the ethics review. The IHEC will consider the following categories of human research activities for exemption from ethics review:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special educational instruction strategies, or (ii) research on the effectiveness of or the comparison among instruction techniques, curricula, or classroom management methods.

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation or do him psychological harm.

(iii) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

c. While normally the research in the above three categories will be considered for exemption, it may not be considered for exemption if it is involving children or other vulnerable groups as participants.

Procedure for obtaining exemption from ethics review:

If a PI believes that her/his research activities may be exempted from review, she/he should submit to the TAC a request for exemption from review along with a summary of the proposed research. The TAC may recommend the proposal for exemption or expedited review; the Chair or her/his nominee will review the request. If the research can be exempted, the Member Secretary will notify the PI in writing and report the decision at the next convened meeting of the IHEC. If the research is not clearly exempt, PI may be advised to submit the proposal to the full committee. The PI will be notified of the final decision in writing. When the decision to exempt a particular research is taken by the Chair or nominee of the Chair or by the IEC, it should clearly mention the applicable provision given in section above for providing such exemption.

8. Ethics Sub-Committee for Expedited reviews.

Certain research proposals may not require review by a full Committee. Such proposals may be considered for the expedited review. The expedited review process may be appropriate for research involving no more than minimal risk. The IHEC will designate a proposal as having minimal risk when the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. All expedited approvals will be given in a meeting of the Sub-Committee of three members (nominated by the Chairman). All the three members, including the Member Secretary should be present for the meeting.

If the PI believes that her/his proposal qualifies for the expedited review, she/he should make a request for the same while submitting application for review to the TAC and IHEC. The Chair will judge whether the proposal clearly qualifies for the expedited review on receipt of the recommendation from TAC.

9. Waiver of informed consent requirements

Obtaining informed consent is a requirement of all studies being undertaken. However, under special circumstances, such as when the research involves no more than minimal risk or when the participant and researcher do not come into contact or when it is necessitated for research in emergency situations, the IHEC may consider waivers based on the following criteria:

(i) When the research cannot be conducted with the written consent of the participant due to reasons related to the research process and this may be required due to reasons related to social or cultural sensitivity and stigma

(ii) When the research is on already published documents, references, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programmes for the benefit of the public having a bearing on public health programmes and consumer acceptance studies.

(iii) Research on anonymised biological samples from diseased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral associates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc.

10. Continuing review/amemdment

Every approved protocol shall be submitted for continuing review before the end of each year of the study. This applies to all protocols that have not been formally closed or ended and includes those where data has been collected and the remaining activities only involve data analysis. The PIs are required to make a submission to the TAC mentioning the study title, the progress and amendment made to the proposal, if any, before the anniversary of the previous review. The IHEC will recommend continuation of the study on recommendation of the TAC and the Member Secretary may issue approval letters. If there are no changes, the continuing review will be through an expedited process.

In case of changes made to the protocol, the request for revisions will go to a full committee, unless the changes are eligible for expedited review under regular circumstances.

If an application for continuing review is not made within three months of the expiry of the IHEC clearance, it will be deemed terminated. Any changes in subject population, recruitment plans, advertising materials, consent requirements, research procedures, study instruments, study sites, investigators instrumental to the design or execution of the study, or in any other materials used or to be used in conjunction with the study, must be approved by the Committee before the change is implemented. The Principal Investigator is responsible for filing a Request for Approval of Amendment with all supporting documentation. Minor changes may be approved through expedited review. Other changes must be reviewed and approved at a convened meeting before the changes can be implemented. An exception is made in the rare circumstance in which a change without approval is necessary to eliminate apparent immediate hazards to the research subjects. In this case, the IHEC should be promptly informed of the change following its implementation and should review the change to determine whether it is consistent with protection of human subjects.

New information that may affect the risk/benefit assessment must be promptly reported to, and reviewed by, the Committee to ensure adequate protection of human subjects. Significant protocol amendments should be incorporated into the written protocol/proposal.

11. Monitoring of research for its ethical conduct.

The IHEC is empowered to make visits to the research sites, review actual conduct /or appoint a Data and Safety Monitoring Board (DSMB) for

continuing review of the research and take any other appropriate measures to ensure that the research is conducted according to the approved proposal/protocol. The DSMB shall provide recommendations to IHEC as and when called upon to do so.

12. Record Keeping

All other documents and communications relating to the functions of the IHEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval procedures. All such confidential records will be carefully and systematically stored in the form of electronic or hard copies in a separate room or cupboards in the secretariat by the Member-Secretary, who will be the custodian. Such confidential documents include, among others:
a) Copies of protocols submitted for review;
(b) All correspondence with IHEC members and investigators regarding application, decision and follow up;
(c) Agenda of all IHEC meetings;
(d) Minutes of all IHEC meetings with signature of the Chairperson;
(e) Copies of decisions communicated to the applicants;
(f) Record of all notifications issued for premature termination of a study with a summary of the reasons;
(g) Final report of the study including microfilms, CDs and Video recordings.

All records will be maintained for at least 3 years in the form of electronic or hard copies, if it is not possible to maintain the same permanently.
The Member-Secretary must hand over full custody of such records to her/his successor, and the handing over must be documented.

[This standard operating procedure is developed based on “Ethical Guidelines for Biomedical Research on Human Participants” by the Indian Council of Medical Research, New Delhi and adapted from Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum]

****