KARNATAK UNIVERSITY DHARWAD

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Research Ethics Policy

2021-22

Message from Vice-chancellor on letterhead (optional)

DRAFT COMMITTEE

1. **Prof. M. A. Jalihal, (Chairman), Department of Philosophy, KUD**

2. **Prof. Shanmukh Kamble, Member, Department of Psychology, KUD**

3. **Prof. K.S. Devaraju, Member, Department of Biochemistry, KUD**

4. **Prof. C.B. Ganesh, Member, Department of Zoology, KUD**

5. **Prof. Sangeetha R. Mane Member, Department of Social Work, KUD**

COMMITTEE MEMBERS

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2	Dr (Smt) S. R. Mane, Dept. of Social Work, KUD	Member
3	Dr. Ashok Hulabandi, Dept. of English, KUD	Member
4	Dr. K. S. Devaraju, Dept. of Biochemistry, KUD	Member
5	Dr. C. B. Ganesh, Dept. of Zoology, KUD	Member
6	Dr. S. V. Kamble, Dept. of Psychology, KUD	Member
7	Dr. S. T. Bagalkoti, Director, IQAC, KUD	Spl Invitee
8	Dr. M. David, Director, PMEB, KUD	Convener

Research Ethics Policy

Research ethics is a set of principles governing the way any research involving interaction between the researcher and other humans or human tissue or data relating to humans is designed, managed and conducted. In preparing a research project the dignity, rights, safety and well-being of human participants must at all times be considered, respected and safeguarded. The University on one hand, is concerned to protect the rights, dignity, health, safety and privacy of research participants and on the other, to protect the health, safety, rights and academic freedom of researchers and the reputation of the University as a centre for properly conducted, high quality research.

All scientific activities, including those by the social scientists, are conducted with the participation of human beings or have an impact on human beings or on the wider society and environment. Therefore, it is essential that scientists/ researchers understand ethical issues and the implications of their research work and act accordingly. For making ethical judgment, the scientists/ researchers rely upon various standards of ethics, which could be universal or specific to the culture(s) or localities.

The University expects all researchers to consider fully the current and future ethical implications oftheir work. This procedure applies to everyone carrying out research under the auspices of theUniversity, whether their current place of work is within or outside University campus/premises. All research requires consideration of its ethical implications; however, there are some areasof research where the ethical implications will be particularly important. The following is not an exhaustive list, however some examples of such areas of research are: where it involves human participants (particularly children and vulnerable adults); where it uses human data or human material; where thereareserioushealthandsafetyimplications. In addition, the purpose of this policy is to provide ethical guidelines for researchers who are considering experiments on animals or micro-organisms stressing on the need for precautionary measures to be taken to ensure bio-safety.

The Guidelines for Research Ethics have been compiled to help researchers and the research community to be cognizant of their ethical views and attitudes, raise their awareness of conflictingstandards, promote good judgment and enhance their ability to make well-founded decisions in the face of conflicting considerations.

Objectives of Institutional Review Board (IRB)

Institutional Review Board is responsible for reviewing the applications of ethics in order to ensure that adequate consideration has been given to the ethical aspects of a research project, thus not only reducing the potential for harm and upset to the human participants/animals, but also to ensure the proper disposal of potentially harmful micro-organisms and radioactive substances.

An ethics committee will assess whether the proposed research can be considered ethical, i.e. whether:

- the research is justified, i.e whether it is likely to add to the existing knowledge base;
- it is of sufficient standard – including whether the researchers are qualified to carry out the roles proposed in the research proposal
- the risk it poses to participants is outweighed by the potential benefits of the research;
- the research appears to comply with all statutory and other guidance;
- financial arrangements appear sound – it would be unethical to start research that may not be completed because of insufficient funds.

Institutional Review Board (IRB) Membership requirements:

a. The duration of appointment is initially for a period of 3 years.
b. At the end of 3 years, as the case may be, the committee is reconstituted, and at least one-third of the members have to be replaced by new names.
c. A member can be replaced in the event of death or long-term non-availability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.

d. A member can tender resignation from the committee with proper reasons to do so.
e. All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form.
f. Conflict of interest, if any, should be declared by members of the IRB.

Quorum requirements:

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

Offices

The Chairperson will conduct all meetings of the IRB. If for reasons beyond control, the Chairperson is not available, the senior-most member from among the members present will conduct that meeting. The Member Secretary is responsible for preparing the agenda, organizing the meetings, maintaining the minutes of the meeting, 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.

IRB Constitution:

The IRB shall consist of the following representatives:

1.Chairman (Vice Chancellor)

2. Deans (Faculties of Science, Social Sciences, Commerce, Management, Arts and Law)

3. Members (Chairpersons of the concerned Departments)

4. ProminentSocial Worker / NGO

5. Member of Ethical Boardappointed by the University (Philosophy/Theology)

6. Legal Expert

7. Special Invitees from Department- Issue based

8. Medical/Mental Health Worker

9. Member Secretary (Director, PMEB)

Meetings of IRB:

The IRB is expected to meet at reasonable intervals as and when needed(at least once in every six months). The project proposals received at least fifteen days in advance before the scheduled date of an IRB meeting will be accepted for presentation and included in the agenda for that meeting. The principal investigators of the projects or their nominated representatives are expected to make an appropriate presentation before the IRB and defend themselves against any doubts, clarifications, questions, suggestions, recommendations or corrections offered by the members thereof.

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

Decision-making

a) Members will discuss the various issues before arriving at a consensus decision.
b) A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

c) Decisions will be made only in meetings where quorum is complete.
d) Only members can make the decision. The expert consultants will only offer their opinions.
e) Decision may be to approve or revise the proposals. Specific suggestions for modifications should be given.
f) In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

Communicating the decision

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

Record keeping and Archiving

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

Standard Operating Procedures (SOP)

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

Application Procedures:

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

Application forms and Protocols

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

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

1. Project title
2. Expected duration
3. Identity of field researchers and organizational base
4. Purpose of study & Sources of funding
5. Scientific background & Design of the study
6. Potential participants and vulnerable group(s), if any
7. Potential benefits and hazards
8. Recruitment procedures & Informed consent
9. Data collection and methods of analysis
10. Data use conditions set by data providers
11. Data protection, Confidentiality and anonymity
12. Monitoring of the research & Dissemination of findings

13. Expected outcomes and impact of research

14. Researcher's assessment of ethical issues.

15. An undertaking by the researcher/s to ensure implementation of all ethical guidelines.

Review procedures:

1) The meeting of the IRB should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.

2) The proposals will be sent to members at least 10 days in advance.

3) Decisions will be taken by consensus after discussions.

4) Researchers will be invited to offer clarifications if need be.

5) Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

6) The decisions will be recorded in the minutes of the meeting and Chairperson's approval is taken in writing.

Elements of Review:

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

Follow up procedures:

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

b) Final report should be submitted at the end of study.

c) Protocol deviation, if any, should be informed with adequate justifications.

d) Any amendment to the protocol should be resubmitted for renewed approval.

e) Premature termination of study should be notified with reasons along with summary of the data obtained so far.

f) Change of investigators / sites should be informed.

Some other important aspects of Institutional Review Board Procedure:

1) The decision made for each proposal, and the grounds on which it was made, should be recorded and provided to the researchers, and a copy is kept on file with the proposal for a specified minimum period, extending at least beyond the lifetime of the project.

2) It is expected that in some cases, as research progresses, further ethical issues may arise. In such cases, Principal Investigators should go back to the IRB or the IRB itself check through the implications of the new developments and effect any changes in the project.

3) Principal Investigators and supervisors of students need to know that they must keep good records of their ethical procedures in case they are called to account for.

4) **Multi-funded research**: If there are number of funders for a project, the Karnatak University guidelines on the ethics of research must be drawn to the attention of all proposed funders during the submission for funding. Research organizations engaged in collaborative research may agree to use the services of one of their Ethical Committees to review a joint project on behalf of all participants.

5) **Multi-performer research**: Research involving participants from more than one institution should consider agreeing arrangements for accepting one another's decisions following formal ethics review. Each institution would retain formal responsibility for overseeing the ethical review of research conducted under its auspices but would accept the decisions made by the IRB of the institution where the principal investigator is based.

6) Where research is to be conducted outside INDIA, the Karnatak University expects researchers to establish whether local Institutional Review Boardis required by the host country, and if not, how the principles of the Karnatak University ethical guidelines can be followed in undertaking the research.

7) **Expedited Review**: In exceptional circumstances, it may be necessary for a proposal involving possible risk of harm to receive a full review at short notice. An expedited review will be carried out by one or more members of IRB, including itsChairperson.

8) **Legal and data requirements must be met.** Researchers must comply with legislative requirements and with those of data providers.

9) IRB generally has no authority to impose sanctions on researchers who violate ethical standards in the conduct of research involving human subjects. They may, however, withdraw ethical approval of research projects if judged necessary. Sanctions, if necessary, can be a recommendation to the University and can be in the form of fines, suspension of eligibility to receive research funding, refusal of permission to publish results, etc.

10) Any disputes arising in connection with IRB shall be subjected to the jurisdiction of Dharwad city only.

Ethical concerns for research involving humans

- To protect and promote the human rights of participants and to sensitize and encourage researchers and organizations to respect participants' rights and needs.
- To improve quality, legitimacy and credibility of the research in the areas of internal security.
- To make ethics an integral part of the planning and methodology of research, and to enable organizations and individuals to develop appropriate mechanisms for ethical self-regulation.
- Voluntary participation of research participants.
- Whether or not incentives are appropriate or ethical to encourage participation, including reimbursement of participants in line with MRC guidelines.
- Full information to participants, including outlining any rights to withdraw, intended publication of the results of the research, information on data use and sharing.

- Ensuring appropriately recorded consent, allowing for cultural variations in practice whilst maintaining the central significance of consent of participants or those legally allowed consenting on their behalf.
- Adequate support for, or protection of, participants.
- Special issues relating to children and vulnerable adults.
- Risk assessment in line with Health and Safety requirements including the potential for harm, stress, anxiety, etc.
- Sensitivity of the research (e.g. drug use, cultural sensitivities, mental health, etc.)
- Feedback to participants on the research results as appropriate.
- Appropriate policy and practice concerning confidentiality, anonymity or acknowledgement of research participants.
- Data Protection compliance, particularly in relation to sensitive personal data.
- Anonymisation / pseudonymisation and secure storage of data.
- Retention, future use, sharing or disposal of data and samples in line with consent.
- Special issues relating to the Prevent Duty requirements.

Any research work pertaining to humans shall be conducted in accordance with the ICMR guidelines. The researchers are advised to refer the following website in this regard.

https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf

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Ethical concerns for research involving animals

- Persons engaged in conducting scientific experiments on animals must act in conformity with the provisions of the prevention of Cruelty to Animals Act, 1960, and the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998, asamended.
- These provisions are enforced by the independent Committee for the Purpose of Control and supervision of Experimentation on animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960, in the Ministry of

Environment andForests.

- Persons engaged in animal experimentation have a moral responsibility for the welfare of the animals after their use in experiments. Investigators are responsible for the aftercare and/or rehabilitation of animals after experimentation, and may be permitted toeuthanize.
- Animals used for biomedical purposes must be directed by a veterinarian or other scientist in a relevant discipline who is trained and experienced in the proper care, handling, and use of the species being maintained or studied. In all circumstances, veterinary care shall be provided as necessary.
- Proper use of animals in experiments and avoidance or minimization (when avoidance is not possible) of pain and suffering inflicted on experimental animals should be an issue of priority for research personnel, and unless the contrary is scientifically established, investigators should proceed on the basis that procedures that cause pain or suffering in human beings will also cause similar pain or suffering in animals. All scientific procedures adopted with animals that may cause more than momentary or slight pain and/or suffering should be performed with appropriate sedation, analgesia or anesthesia.
- The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist in a relevant discipline who is trained and experienced in the proper care, handling, and use of the species being maintained or studied. In all circumstances, veterinary care shall be provided as necessary.
- There should be an institutional policy to care animals by qualified personnel every day, including weekends and holidays, to safeguards their well - being including emergency veterinary care. In the event of an emergency, institutional security personnel and fire or police officials should be able to reach responsible persons for the animals. That can be enhanced by prominently posting emergency procedures, names, or telephone numbers in animals facilities or by placing them in the security department or telephone center. A disaster plan that takes into account both personnel and animals should be prepared as part of the

overall safety plan for the animalfacility.

Record keeping

It is essential that animal House should maintain following records:

- Animal House plans, which includes typical floor plan, all fixturesetc.
- Animal House staff record - both technical and non -technical
- Health record of staff andanimals
- All SOPs relevant to experiments, care, breeding and management ofanimals
- Breeding, stock, purchase and sales records
- Minutes of institutional Animals Ethics CommitteeMeetings
- Records of experiments conducted with the number of animals used (copy of FormD)
- Mortality, PostmortemRecord
- Clinical record of sickanimals
- Training record of staff involved in animalactivities
- Water, feed and bedding materials analysisreport
- Health monitoringRecords
- Rehabilitation Records
-

Institutional Animals Ethics Committee (IAEC)

"Institutional Animals Ethics Committee" means a body comprising of a group of persons recognized and registered by the Committee for the purpose of control and supervision of experiments on animals performed in an establishment which is constituted and operated in accordance with procedures specified for the purpose by theCommittee;

IAEC will review and approve all types of research proposals involving small animal experimentation before the start of the study. For experimentation on large animals, the case is required to be forwarded to CPCSEA in prescribed

manner with recommendation of IAEC.

IAEC is required to monitor the research throughout the study and after completion of study through periodic reports and visit to animal house and laboratory where the experiments are conducted. The committee has to ensure compliance with all regulatory requirements, applicable rules, guidelines and laws.

Composition ofIAEC

Institutional Animals Ethics committee shall include members as follows.

1. A biologicalscientist,
2. Two scientists from different biologicaldisciplines,
3. A veterinarian involved in the care ofanimal,
4. Scientist in charge of animals facility of the establishmentconcerned,
5. A scientist from, outside theinstitute,
6. A non scientific socially aware memberand
7. A nominee ofCPCSEA

Specialist may be co-opted while reviewing special project using hazardous agents such as radio-active substance and deadly microorganisms.

The Chairperson of the Committee and Member Secretary would be nominated by the Institution from amongst the eight members. Members against Serial number 5, 6 and 7 will be nominated by CPCSEA, with a provision of a Link nominee for CPCSEAnominee.

For further information, standard operating procedures and guidelines on the regulation of scientific experiments on animals, the researchers are advised to refer the following CPCSEA website.

http://cpcsea.nic.in/WriteReadData/userfiles/file/SOP_CPCSEA_inner_page.pdf

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Ethical concerns for Research involving Genetic Engineering organisms (GE) / hazardous microorganisms or radioactive substances

In compliance with Rules 1989, an Institutional Bio-safety Committee (IBSC) is to be constituted by every organization engaged in research, use & application activities related to genetic engineering (GE) organisms (GE organisms include microorganisms, animals, plants, arthropods, aquatic animals, etc.) and hazardous microorganisms ("microorganisms" shall include all the bacteria, viruses, fungi, mycoplasma, cells lines, algae, protozoan's and nematodes). IBSC is the nodal agency within an organization for implementation of the bio-safety regulatory framework.

Institutional Bio-safety Committee (IBSC) is to be constituted in all centers engaged in genetic engineeringresearch and production activities. The Committee will constitute thefollowing.

(i) Head of the institution or hisnominee

(ii) 3 or more scientists engaged in DNA work or molecular biology with an outside expert in the relevantdiscipline.

(iii) A member with medical qualification-Bio-safety officer (in case of work with pathogenic agents/large scale used.)

(iv) One member nominated byDBT

The Institutional Bio-safety Committee shall be the point for interaction within institution for implementation of the guidelines. Any research project which is likely to have biohazard potential (as envisaged by the guidelines) during the execution stage or which involve the production of either micro-organisms or biologically active molecules that might cause biohazard should be notified to IBSC. The IBSC will allow genetic engineering activity on classified organisms only at places where such work should be performed as per guidelines. Provision of suitable safe storage facility of donor, vectors, recipients and other materials involved in experimental work should be made and may be subjected to inspection onaccountability.

The Bio-safety functions and activity include the following:

(a). Registration of Bio-safety Committee membership composition with Review Committee on Genetic Manipulation (RCGM) and submission ofreport.

ISBC will provide half yearly reports on the ongoing projects to RCGM regarding the observance of the safety guidelines on accidents, risks and on deviations if any. A computerized Central Registry for collation of periodic reports on approved projects will be setup with RCGM to monitor compliance on safeguards as stipulated in the guidelines.

(b). Review and clearance of project proposals falling under restricted category that meets the requirements under theguidelines.

IBSC would make efforts to issue clearance certificates quickly on receiving the research proposals from investigators.

(c). Tailoring bio-safety program to the level of risk assessment (d). Training of personnel on biosafety

(e). Instituting health monitoring program for laboratory personnel Complete medical checkup of personnel working in projects involving work with potentially dangerous microorganism should be done prior to starting such projects. Follow up medical checkups including pathological test should be done periodically, at annually for scientific workers involved in such projects. Their medical record should be accessible to the RCGM. It will provide half yearly reports on the ongoing projects to RCGM regarding the observance of the safety guidelines on accidents, risks and on deviations ifany.

The researchers engaged in the relevant field are advised to conduct research work in accordance with the IBSC guidelines. For more information, the following website can be visited.

https://ibkp.dbtindia.gov.in/Content/FlashPDF/IBSC%20Handbook.pdf

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Ethical concerns for research involving Plants Herbarium

Researchers who are interested in using plant material including collection of Plants from other places must comply with research and ethical committee Guidelines of KUD.

Researcher carrying out collection of plants should submit the voucher specimens.

The same specimen should be deposited in a public herbarium with details of the specimen.

If the plant material involves from other countries should also take the National Biodiversity Authority Permission and this procedure should be taken care by the Research and Ethical Committee of KUD. In case of Organisms the same condition apply, with due concern with the Quarantine station of India

They will communicate clearly and honestly to all with whom they work the objectives and possible consequences of their research. If the research has a commercial objective, researchers will make that explicit, and will disclose within reason the expectations for results;

B.

They will comply with all rules and limitations that local people, their communities, or their institutions place on the research, provided that such rules and limitations do not violate other guidelines. They will not attempt to gain information through deception, nor will they "trick" people into revealing "secret" information. They will offer to supply any reports or materials resulting from their research

C.

They will respect any request for confidence made by those providing data or materials, provided that maintaining such confidence does not compromise other ethical considerations;

They will respect individuals' rights to anonymity and the rights of privacy of those with whom they work;

They will refrain from any activity which appears to represent a conflict of interest;

They will ensure humane treatment of Humans/Animals used for plant experimentation;

http://www.nbaindia.org/

https://kbb.karnataka.gov.in/

https://kbb.karnataka.gov.in/storage/pdf-files/Biological-Diversity-Act-Rules-Book-complete-version-2016-17.pdf

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Annexure 1

APPLICATION FORM FOR SEEKING APPROVAL FROM IRB

(For Office Use) Reference No. _____

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

*Use additional sheets wherever required.

DECLARATION

I, Dr / Mr./ Ms. _____have read the 'Guidelines on The Ethics of Research' being followed by the Karnatak University Dharwad. I promise to abide by all the guidelines enunciated therein during the execution of the project titled_____.

I shall proceed to commence work on my project only after securing a written approval from IRB. I agree to be held accountable for any unforeseen mishaps, insults, injuries or harms occurring to my human research subjects during their participation in the research process.

Date: (Principal Investigator)

Annexure 2

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

Information to the Participants:

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

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

The translated version must be necessarily true and representative of the original version.

Informed Consent

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

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

Signature of Parent/ Guardian — Signature of Witness

(Name and Address) — (Name of Witness)

Date:

Signature of Investigator

Name and Designation

Annexure 3

SPECIMEN FORMAT FOR ACCEPTANCE/ REJECTION OF 'ETHICS APPROVAL' FOR RESEARCH PROJECTS AT KARNATAK UNIVERSITY, DHARWAD

INSTITUTIONAL REVIEW BOARD

Title of Project: _____

Principal Investigator: _____

Co-Investigators (If any): _____

Proposed Duration of Project: _____

Estimated Budget Requirements: _____

Source of Funding: _____

Reference Number of the Proposal:_____

Date on which IRB Meeting was held: _____

Decision of the IRB _____

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

_____

_____

ADVICE & SUGGESTIONS (IF ANY):

_____

_____

Date: Name & Signature of Member Secretary

REFERENCES:

1) Margit Sutrop and Prof. Carmen Florea Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research, 2010.
2) Ron Iphofen, *Ethical Decision-Making in Social Research. A Practical Guide*, London: Palgrave Macmillan, 2009, p. 19.
3) National Committee for Ethics in Social Science Research in Health (NCESSRH). *Ethical guidelines for social science research in health* by Centre for Enquiry into Health and Allied Themes, 2004.
4) ForskningsetiskeKomiteer. *Guidelines for research ethics in the social sciences, law and the humanities*. National Committees for research ethics in Norway, 2006.
5) ESRC Framework for Research Ethics (FRE) 2010 & 2012.
6) Social Research Association. *Ethical Guidelines*, 2003.
7) Indian Council of Medical Research. *Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research.*
8) Paul de Guchteneire. UNESCO. *Code of conduct in social science research.*
9) All India Institute of Speech & Hearing, Mysore. Ethical guidelines for bio-behavioural research.
10) https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
11) http://cpcsea.nic.in/WriteReadData/userfiles/file/SOP_CPCSEA_inner_page.pdf
https://ibkp.dbtindia.gov.in/Content/FlashPDF/IBSC%20Handbook.pdf
12) http://www.nbaindia.org/
13) https://kbb.karnataka.gov.in/
14) https://kbb.karnataka.gov.in/storage/pdf-files/Biological-Diversity-Act-Rules-Book-complete-version-2016-17.pdf