



YENEPOYA

(DEEMED TO BE UNIVERSITY)

Recognized under Sec 3(A) of the UGC Act 1956

Accredited by NAAC with 'A' Grade

Code of Research Ethics



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University Road, Deralakatte, Mangaluru – 575 018

No. Y/REG/PA/BOM-53/Notification/005/2021

Date: 31.03.2021

NOTIFICATION

Sub: Code of Research Ethics - reg.

Ref: 53rd meeting of the BoM held on 23.03.2021 – Agenda 6.

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As discussed under Agenda 6 of the 53rd Board of Management Online meeting held on 23rd March 2021, it was resolved to approve the Code of Research Ethics and the same is being notified with effect from 31st March 2021.

Dr. Gangadhara Somayaji K.S.
Registrar Registrar
YENEPOYA
(Deemed to be University)

Encl:
Code of Research Ethics

To:
Centre for Ethics.

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Code of Research Ethics
Yenepoya (Deemed to be University)

Preamble: With the growth of the University and rapid recognition on the global scene, Yenepoya deemed to be University perceives the need to revise and strengthen its Institutional Code of Research Integrity and Publication Ethics to match global standards and yet weave the local cultural flavour into the fabric of professional conduct.

Yenepoya deemed to be University stands by the principles enshrined in this code and encourages and supports all its faculty members, employees and students to conduct research as prescribed.

Scope and definitions: This code shall apply to all the following stakeholders and activities in Yenepoya deemed to be University:

1. Research:

Any scientific activity undertaken to answer a specific research question, that is conducted systematically and within the existing regulations, utilizing human participants, patients, biological samples, data, animals with the objective of generating new knowledge, or adding to the body of existing knowledge, or disseminating such information as gathered in the course of healthcare or research.

2. Researcher:

- a. Any appropriately qualified, trained and experienced person conducting research on human participants, patients, biological samples, data, animals in Yenepoya deemed to be University, its constituent colleges, centres and the community it serves.
- b. Teacher: Any employee of Yenepoya deemed to be University who is engaged in research (includes all types of teachers such as full-time, part-

time, adjunct, additional, temporary, permanent, contractual and honorary/emeritus.

- c. Student: Any learner, with bonafide credentials (admitted provisionally or otherwise), to any course approved by the Academic Council, and offered by any of the constituent units/centres of Yenepoya deemed to be University, including and up to the point of receiving the degree/diploma, in the convocation.
- d. Research Scholar/ Assistant/ Fellow: Any person appointed in the Yenepoya deemed to be University or its constituent units for conducting research

3. Patient and Research participant:

- a. Any person irrespective of caste, religion, gender or social status, visiting the outpatient department of the hospitals in the University, or being seen by any healthcare provider for health reasons (including in the villages, primary health centres, community, etc) or admitted to the wards of any of the teaching hospitals coming under the ambit of the University for reasons of health care (including their attendant caregivers) and or research.
- b. Any animal bred, used or sacrificed for the purpose of research

4. Biological sample:

- a. Human Biological Sample: Any tissue, fluid, cells, body part, specimen taken from a patient, a research participant, a cadaver or any animal for the purpose of conducting research, or in the course of healthcare, taken for diagnosis or therapy or follow-up
- b. Other biological samples: Any tissue, fluid, cells, body part, specimen taken from a non-human source for the purpose of research.

5. Ethics committee:

A committee constituted by the Yenepoya deemed to be University as per the bye laws and existing regulations, whose main objective is to discuss and

deliberate on the ethical issues arising out of biomedical and healthcare research protocols on human participants or biological samples and give ethical approval for the same and ensure the safety of research participants throughout the course of the research study.

6. Animal ethics committee:

A committee constituted by the Yenepoya deemed to be University as per existing regulations, whose main objective is to discuss and deliberate on the ethical issues arising out of research protocols on animals give ethical clearance for the same.

7. Scientific review board:

A board constituted by the Yenepoya deemed to be University or its constituent units whose main objective is to discuss and deliberate on the scientific issues arising out of research protocols approve the same.

8. Institutional Stem Cell Research Committee:

A committee constituted by the Yenepoya deemed to be University or its constituent unit as per the existing regulations, whose main objective is to discuss and deliberate on the scientific issues arising out of research protocols involving stem cells and approve the same.

The code of ethics for research:

A. Human biomedical and healthcare research:

1. Research involving human participants, directly or indirectly, must be conducted in accordance with the Indian Council of Medical Research's ethical guidelines, and Indian Good Clinical Practice guidelines, as applicable from time to time
2. Research involving human participants - directly or indirectly - must comply with the regulations in force from time to time
3. Research involving human participants - directly or indirectly - must be pre-approved by the Ethics Committee and must be conducted as per the approved protocol

4. During the conception, design and implementation of the research protocol, and during the dissemination of the results of research, participants' safety should be of prime importance and researcher should not compromise the participants' safety in the interest of science.
5. Researchers must comply with the post-approval requirements of the Ethics Committees within the broad framework of the regulations, guidelines and the Standard Operating Procedure (SOP) Manual of the Ethics Committees.
6. Research on stem cells must be conducted only after due permissions of the concerned stem cell research review committees (national, wherever applicable and institutional) and the Ethics Committee.
7. Research protocols must be submitted for approval from the respective Scientific Review Board(s) and other scientific review boards as applicable (eg. stem cells research)
8. Researchers must be qualified, trained and have experience in the subject in which they are conducting the research.
9. Researcher must undergo the requisite training in the field of research methodology, biostatistics and research ethics
10. Research should be conducted with integrity, keeping in mind accountability and transparency and with total responsibility
11. Research on human participants conducted outside the University must have requisite permissions from the concerned authorities
12. Human tissue samples/data shared with researchers or laboratories outside the University for the purpose of research must be done only after requisite permissions are obtained as per the current regulations and guidelines
13. Human tissues/samples/data/records obtained in the course of healthcare should not be subjected to research without approval of the Ethics Committee and wherever required, with the informed consent of the patients.

14. Manuscripts sent for publication must be checked for plagiarism and must not have more than permissible amount of similarities, within the framework of the University policy
15. Publications arising out of the research conducted in the Yenepoya deemed to be University must duly acknowledge the affiliation to the University
16. Authors listed in the manuscripts for publication must satisfy the criteria for authorship by the International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE) and author placements should be decided at the time of protocol writing.
17. Research related documents must be kept confidential and stored for a period of time as per applicable regulations and guidelines from time to time.
18. Researchers and authors must declare conflicts of interest (financial and non-financial) as and when it arises and within the scope of the regulations and guidelines.
19. Yenepoya deemed to be University is committed to protecting the environment and strongly encourages all researchers to reduce the burden on the ecosystems through responsible use of biological tissues/samples and proper disposal.

B. Research involving animals:

1. Research involving animals must be conducted in accordance with the Central Government's Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)
2. Research involving animals - directly or indirectly - must be pre-approved by the Institutional Animal Ethics Committee of the University and must be conducted as per the approved protocol
3. Yenepoya deemed to be University is committed to the protection and welfare of animals and requires its researchers to only conduct necessary research (with no other alternative model) keeping in mind the principles of reduce, reuse, recycle and rehabilitate.

Code of ethics for Ethics Committees:

1. The code of ethics is applicable to both human and animal ethics committees
2. The Ethics Committees must review, approve the research protocols keeping in mind the protection of the participants
3. The Ethics committees must maintain the highest standard for review and post-approval activities
4. The Ethics Committee must monitor the study until its completion
5. The Ethics Committees must follow the applicable guidelines and regulations applicable from time to time
6. The Ethics Committees must review and approve protocols in an independent manner adhering to the Standard operating procedures