



Investing in Africa's future

**Annex to Africa University Research Policy
Section 5.6 and Section 8**

Research Ethics Committee Functions And Terms Of Reference

**Adopted by Senate, 25 February 2014
Approved by the Board of Directors, 21 March 2014**

Africa University Research Ethics Committee

Authority

The Research Ethics Committee derives its authority from the University Senate

Contact

Questions about the Research Ethics Committee can be answered by:

Professor B. Ikubolajeh Logan

Deputy Vice Chancellor and Head of Research

Telephone: +263 (0) 20 64912; +263 (0) 20 61611/61618/66968 – Ext. 1004

E-mail: dvc@africau.edu; dvcsec@africau.edu

Dr. Anderson B. Shankanga

Senior Adviser

Office of Research and Outreach Programmes

Telephone: +263 (0) 20 60588; +263 (0) 20 61611/61618/66968 - Ext. 1064

E-mail: adviser@africau.edu; researchsec@africau.edu

Mr. George Miti

Research Ethics Programme Officer

Secretary to the Research Ethics Committee

Telephone: +263 (0) 20 61611/61618/66968 - Ext. 1156

E-Mail: aurec@africau.edu

Table of Contents

1. Introduction and Policy Context	1
1.1 The principle of research ethics.....	1
1.2 Responsible conduct of research	2
1.3 Research integrity.....	2
1.4 Academic conflict of interest.....	3
1.5 Conflict of commitment.....	3
2. Africa University Research Ethics Committee	3
2.1 Authority and Status of the Research Ethics Committee	3
2.2 Relationship with the Medical Research Council of Zimbabwe.....	4
2.3 Composition and membership of AUREC	5
2.4 AUREC Functions and Terms of Reference.....	5
2.5 Appointment and Terms of Service of Members of AUREC	6
2.6 Responsibilities and commitments of AUREC Members	6
2.7 AUREC members conflict of interest	7
2.8 Termination of appointment to AUREC	7
2.9 Meetings of AUREC	7
2.10 AUREC Standard Operating Procedures	8
2.11 Administrative Arrangements	8
2.12 Local and International Standards and Guidelines	9

Research Ethics Committee Functions And Terms Of Reference

1. Introduction and Policy Context

Section 5.6 and Section 8 of the research policy adopted by Senate on 15 November 2013 and approved by the Board of Directors on 6 December 2013 highlights **research ethics and research integrity** as critical elements of the University's research enterprise. The present document presents the ethics and integrity aspects of the research policy as the context for the establishment of a Research Ethics Committee. The relevant section of the University's research policy is highlighted in the present document as a basis for the formulation of the functions and terms of reference for the Research Ethics Committee. The University acknowledges the support received from the European and Developing Countries Clinical Trials Partnership (EDCTP), and the Medical Research Council of Zimbabwe (MRCZ) in the establishment of the Research Ethics Committee.

1.1 The principle of research ethics

The University recognizes, and stresses, the comprehensive application of the principle of research ethics in all disciplines of study, and all areas of research. As a method of investigation in the search for knowledge, and the application of knowledge, research at Africa University shall be guided by a set of globally recognized research ethics principles. The University is committed to protecting the rights, dignity, health, safety and privacy of members of the community who participate in research; to minimise pain in animals in research; and to safeguard the integrity of the physical environment. The University is committed to promote access to the benefits of research by making research data available for utilization by members of the research community, policy makers, practitioners and other stakeholders.

The University research policy has been developed to ensure that research conducted at Africa University is of the highest ethical standard. Accordingly, ethical considerations shall constitute a principal basis for the design and execution of research projects.

The policy stresses the following ethics principles to guide research practice at the University:

- (i) In research involving human participants, particularly in most health-related research, there shall be particular commitment to the protection of the rights, interests, dignity, health, safety and privacy of the participants. Care shall be taken to minimise or avoid risk of harm, pain, discomfort, or negative impact of whatever form, on the part of the human participants in the research. The principle of informed consent shall be respected;
- (ii) In research targeting communities and groups within communities, the socio-cultural value systems and sensitivities of the communities and groups shall be recognized and protected;
- (iii) In research involving animals care shall be taken to minimise pain in the animals;
- (iv) In research involving, or expected to have an impact on, the physical environment, care

- shall be taken to protect the sustainability of the environment;
- (v) In research targeting institutions, organizations and other similar entities, the protection of the interests and values of such entities shall be ensured;
- (vi) Furthermore, research must observe standards of respect and protection of the interests of other researchers and the potential beneficiaries of the particular research.

1.2 Responsible conduct of research

The University shall establish procedures, mechanisms and institutional codes of practice in research, that provide an environment for the upholding of the principles of responsible conduct of research where academic staff, researchers and students:

- (i) Conduct and manage research with honesty and integrity;
- (ii) Appropriately acknowledge the role of others in research;
- (iii) Communicate research results responsibly;
- (iv) Train, mentor, support and appropriately attribute research trainees
- (v) Demonstrate good stewardship of public and institutional resources used to conduct research.

1.3 Research integrity

The University is committed to promoting the highest standards of responsible research through a culture of ethics in research. Accordingly a research project shall be deemed to meet high standards if it satisfies the following requirements, in addition to the other requirements of a good research project:

- (i) Complies with the guidelines on research ethics outlined above;
- (ii) Does not reflect any of the following characteristics of unethical research and research misconduct:
 - (a) Fabrication of data
 - (b) Falsification of research
 - (c) Plagiarism
 - (d) Abuse of confidentiality
 - (e) Failure to acknowledge contributors to research
 - (f) Breach of the interests of human and animal research subjects
 - (g) Failure to report, or covering up, incidents of research misconduct
 - (h) Misappropriation and misuse of research resources;
 - (i) Accepting improper rewards such as: gifts, fees and honoraria for being involved in research
 - (j) Informal sharing in royalties resulting from the commercialization of the results of a project in which one is not a recognised participant.

1.4 Academic conflict of interest

A conflict of interest occurs when there is a divergence between an individual's participation in a research project being influenced by personal interest, and his or her professional obligations to the University, so that the individual's professional actions might be negatively influenced by considerations of personal advantage to be derived from the research project.

The University considers it improper for a researcher's actions or decisions in the course of his or her University duties to be determined or influenced by considerations of personal financial or other benefit.

Members of the academic staff, researchers and students engaged in research shall declare any conflict of interest occasioned by their participation in a research project. Such conflict of interest shall be considered by the University Research Committee, who shall either clear or prohibit the person concerned from undertaking or participating in the research.

1.5 Conflict of commitment

Any conflict of commitment between the normal duties of an academic staff member or researcher and his or her commitments in a research project shall be reported to the University Research Committee, who shall make a decision on the matter and advise the staff member concerned. In the case of a student experiencing conflict of commitment between his or her studies and his or her involvement in a research project, the student and his or her adviser shall report the matter to the Dean of the Faculty concerned, for the Faculty Board to make a decision and guide the student accordingly. Should the student's involvement in a research project affect his or her semester or final examination the Dean shall request special approval from Senate.

2. Africa University Research Ethics Committee

As capacity to achieve the objectives of the University's policy with regard to research ethics and research integrity, the University hereby establishes a Research Ethics Committee (AUREC) whose operation shall be guided by international principles, international best practice and African traditional ethical values.

Details of the Research Ethics Committee regarding its functions, terms of reference, membership and operation are outlined as follows:

2.1 Authority and Status of the Research Ethics Committee

- (i) AUREC is established in accordance with international guidelines and standards regarding research ethics committees, also known as Institutional Review Boards, as an independent committee of Africa University accountable to the Vice Chancellor;
- (ii) AUREC is established as *an autonomous entity* in terms of its functions and decisions

relating to research protocols submitted to it; and shall operate independently of the academic and administrative structures of the University in the exercise of these functions;

- (iii) AUREC is recognized by the Medical Research Council of Zimbabwe, the national entity responsible for safeguarding ethical principles in research; and the national authorities have duly authorised AUREC to operate in a designated geographical area and at specified levels of research ethics review;
- (iv) Africa University Senate delegates to AUREC authority to review, approve and reject research protocols;
- (v) AUREC's jurisdiction for the exercise of the authority delegated to it is defined as follows:
 - (a) All faculty, staff and students of Africa University who conduct research or submit their protocols for review;
 - (b) Investigators from related institutions who wish to carry out research at Africa University or in collaboration with Africa University staff, or independently of Africa University;
- (vi) Africa University management may not override any decision taken by AUREC concerning a research protocol submitted to it for review;
- (vii) Africa University reserves the right to deny the implementation of AUREC-approved research protocols originating from or intended to be conducted at the University, for reasons other than research ethics. Such reasons may be administrative, programmatic, philosophical, or resource-based in nature.
- (viii) AUREC shall submit reports on its work to the Vice Chancellor through the Office of Research and Outreach Programmes. The Vice Chancellor shall subsequently share the reports with Senate, and seek Senate's consideration of issues raised in the reports that require action by the University;
- (ix) AUREC shall have an obligation to report regularly to the national authority responsible for monitoring ethics compliance in research projects;
- (x) Any assets acquired by AUREC will be owned by and registered in the name of Africa University.

2.2 Relationship with the Medical Research Council of Zimbabwe

- (i) AUREC shall conduct its work in compliance with research ethics guidelines, policies, rules, regulations and procedures established by the Medical Research Council of Zimbabwe (MRCZ) which functions as the National Research Ethics Committee, and which monitors and supervises the work of institutional research ethics committees;
- (ii) Through accreditation actions, MRCZ shall designate AUREC's geographical jurisdiction and level(s) of the research proposals that AUREC shall be authorized to review;
- (iii) AUREC shall comply with the reporting, and other information sharing requirements, with the MRCZ.

2.3 Composition and membership of AUREC

- (i) AUREC shall consist of a chairperson, a deputy chairperson and a minimum of seven (7), and not more than fifteen (15) members, appointed by the Vice Chancellor after consultation with Senate through the Research Committee;

[The initial members of AUREC were appointed by the Vice Chancellor after consultations with the interdisciplinary Project Implementing Committee of the grant-supported project established to set up a Research Ethics Committee at the University]

- (ii) The chairperson and deputy chairperson shall be appointed from the staff of Africa University that will have been appointed members of AUREC;
- (iii) The majority of the members of AUREC must be appointed from the staff of Africa University; and a minimum of three (3) members must be appointed from outside the University;
- (iv) The membership of AUREC must reflect the following qualifications, experience and interests:
 - (a) At least one member must have broad expertise in the scientific research methodology, health science research, and medicine.
 - (b) At least one member must demonstrate knowledge of the principles of ethics.
 - (c) At least one member must be a lawyer in a relevant field
 - (d) At least one member must be a specialist in animal science.
 - (e) At least one member must be a community representative who has no affiliation with the institution, who does not necessarily have to have any prior scientific expertise but may be a layperson that represents the interests and concerns of ordinary members of the community.
 - (f) AUREC must have adequate gender representation.
 - (g) AUREC must have a mix of both the younger and the older age groups.

2.4 AUREC Functions and Terms of Reference

The central function of AUREC shall be to ensure that all research conducted on human beings, animals and the environment under the auspices of Africa University and related institutions meets the highest scientific and ethical standards. This is in order to safeguard

the dignity, rights, safety and well-being of all actual or potential research participants, and of animals, as well as the protection of the sustainability of the environment.

- (i) AUREC shall have responsibility for:
 - (a) Conducting independent, rigorous and timely reviews of the compliance to ethical principles of the research proposals submitted to it;

- (b) Ensuring that all research protocols have a favourable risk: benefit ratio for research participants; and respect the rights, dignity, and autonomy of research participants and equitably distribute the benefits and burdens of research;
 - (c) Monitoring on-going research studies at Africa University and /or relevant institutions to ensure that ethical standards are maintained throughout the course of the research;
 - (d) Recommending policies and procedures governing ethical conduct of human participant, animal research, as well as research involving the environment;
 - (e) Acting as a resource on matters of research ethics for Africa University and other relevant institutions.
- (ii) AUREC shall exercise the following authority over research protocols presented to it:
- (a) Approve research protocols it deems as complying with research ethics principles;
 - (b) Suggest modifications to research protocols;
 - (c) Reject research protocols for non-compliance with ethics requirements;
 - (d) Monitor implementation of approved research projects;
 - (e) Suspend, or terminate, a research project being implemented that is deemed not to comply with any ethical requirement.

2.5 Appointment and Terms of Service of Members of AUREC

- (i) The Vice Chancellor shall appoint members of AUREC upon recommendation of the Research Committee by way of a letter to each member;
- (ii) The Vice Chancellor reserves the right not to appoint a particular person recommended by the Research Committee;
- (iii) Appointments shall be made in individual capacity, on the basis of specified areas of expertise, professional experience and interest, and availability to serve on the committee,
- (iv) Upon appointment members shall sign a pledge of 'Privacy and Confidentiality';
- (v) AUREC membership shall be for a term of three (3) years renewable once upon mutual agreement, provided that the initial appointments shall be for one term with five (5) of the members being reappointed for a further one term;
- (vi) Renewal of appointments to the committee shall be staggered to ensure that continuing members of the committee constitute at least one-third of the membership at any given time;
- (vii) As an interim arrangement, pending mobilization of resources for AUREC operations, members will be called upon to offer their services without being paid a sitting allowance.

2.6 Responsibilities and commitments of AUREC Members

Within the framework of AUREC's functions and terms of reference the responsibilities and commitments of members of AUREC include the following:

- (i) Reviewing research protocols, reports and other relevant documents;
- (ii) Monitoring implementation of approved and on-going studies;

- (iii) Attending AUREC meetings regularly and participating fully and actively in deliberations during meetings;
- (iv) Participating in the necessary continuing education activities for AUREC members;
- (v) Maintaining the confidentiality of documents and deliberations in AUREC meetings;
- (vi) Declaring any conflict of interest, as provided for elsewhere in this policy document.

2.7 AUREC members' conflict of interest

Members of AUREC shall declare any financial, professional, social or other conflict of interest, with regard to any protocol submitted to the committee; withdraw from the process involving the review of the particular protocol and must not be involved in the decision concerning the protocol...

2.8 Termination of Appointment to AUREC

Members of AUREC shall exercise their functions and responsibilities guided by the principles of integrity, ethical conduct and high professional standards. Non-compliance with these principles would compromise the integrity of AUREC and the University, and may therefore constitute a basis for removal from membership of the committee. Generally, a member's appointment to AUREC shall expire at the end of the term of appointment specified in the letter of appointment, or in the letter extending the appointment. The Vice Chancellor can terminate a member's appointment for other reasons, such as the following:

- (i) Upon a member writing to the Vice Chancellor giving one-month notice to resign from AUREC;
- (ii) Upon AUREC's recommendation in the event a member is unable to participate in the committee's proceedings for a period exceeding one year;
- (iii) Upon AUREC's recommendation in the case of a member being absent from four consecutive meetings without apology, or a member being absent from six consecutive meetings with apology, or when a member is unable to attend a total of two-thirds of the meetings of the committee in a year;
- (iv) Upon AUREC's advice in the event of a member committing an act of misconduct (such as breach of confidentiality, not declaring a conflict of interest regarding a research protocol . . .);
- (v) Upon AUREC's recommendation in the case of a member becoming physically or mentally incapacitated;
- (vi) Other appropriate reasons as may be advanced by AUREC, the Research Committee and Senate.

2.9 Meetings of AUREC

- (i) The chairperson, deputy chairperson and the secretary to the Committee shall prepare a schedule of regular meetings of AUREC; the schedule shall be presented to a meeting of the full Committee for discussion and adoption;

- (ii) AUREC shall hold its regular meetings at least once every three months; and the chairperson is authorised to convene additional meetings as need arises;
- (iii) In order for a meeting of the full Committee to proceed more than half the total membership of AUREC must be present;
- (iv) In the absence of the chairperson the deputy chairperson shall chair a particular meeting. Should both the chairperson and deputy chairperson be absent any of the other members of AUREC may chair the meeting, preferably following prior consultation with the committee chairperson, or by decision of the members present;
- (v) A meeting of the full AUREC may recommend to the Vice Chancellor the removal from the Committee of a member who has been absent from a total of two-thirds of the meetings held in a year, who has been absent from four consecutive meetings without apology, or who has been absent from six consecutive meetings with apology.

2.10 AUREC Standard Operating Procedures

AUREC, in compliance with Africa University, national and international guidelines, shall establish the following Standard Operating Procedures (SOPs) to guide operations in all aspects of its work:

- (i) Preparation and updating of the SOPs;
- (ii) AUREC administration processes;
- (iii) Confidentiality and conflict of interest;
- (iv) Management of protocol submissions to AUREC;
- (v) Procedures for initial review of protocols;
- (vi) Expedited review;
- (vii) Annual continuing review;
- (viii) Protocol follow up and review;
- (ix) Audit and inspection;
- (x) Emergency meetings;
- (xi) Handling of participant's complaints and queries;
- (xii) Glossary - completion, distribution and filing of verbal and written
Communication with investigators, sponsors, volunteer subjects, institutes and MRCZ;
- (xiii) Maintenance of study files;
- (xiv) Storage of inactive study files;
- (xv) Archiving study files;
- (xvi) Handling non-compliance;
- (xvii) Management of protocol amendments;
- (xviii) Handling seriously adverse events;
- (xix) Protocol termination processes;
- (xx) Training and continuing professional development.

2.11 Administrative Arrangements

The University is committed to ensuring that AUREC is provided with the necessary facilities and resources for its efficient operation. AUREC's operational and administrative

requirements shall be ensured through the Office of Research and Outreach Programmes (OROP). A Research Ethics Programme Officer attached to OROP will serve as Secretary to AUREC. He/she will function as AUREC technical and administrative manager, and as a non-voting member of the Committee.

The AUREC secretariat to be serviced by the University Administration will provide the required technical and administrative services to support the work of the Committee. In close collaboration with the chairperson, deputy chairperson and members of the Committee the secretariat shall exercise the following core functions, in addition to other relevant responsibilities:

- (i) Preparing and organising AUREC meetings and related activities;
- (ii) Preparing minutes and maintaining up-to-date records of AUREC meetings and other activities;
- (iii) Managing correspondence on behalf of AUREC;
- (iv) Receiving research protocols, distributing them to AUREC members and maintaining an efficient system for tracking the circulation of the files;
- (v) Managing on-going training for AUREC members, the University community and external groups;
- (vi) Maintaining a collection of reference documents, and a database, on research ethics;
- (vii) Managing the preparation, up-dating and distribution of AUREC Standard Operating Procedures (SOPs).

2.12 Local and International Standards and Guidelines

AUREC shall be guided in its work by norms and standards on research ethics established by the competent national bodies and by international professional agencies, with particular reference to the following:

- (i) Africa University Research Policy;
- (ii) Guidelines of the Medical Research Council of Zimbabwe;
- (iii) Policies and guidelines of the Research Council of Zimbabwe;
- (iv) Guidelines on Good Clinical Practice of the Medicines Control Council of Zimbabwe;
- (v) The Helsinki Declaration;
- (vi) Guidelines of the Council for International Organisations of Medical Sciences (CIOMS);
- (vii)** Medical Research Council of Zimbabwe Guidelines for Conducting Research and Good Clinical Practice;
- (viii)** The Helsinki Declaration;
- (ix)** The Belmont Report;
- (x)** The Nuffield Report
- (xi)** Guidelines of the International Conference on Harmonisation-Good Clinical Practice (ICH-E6-GCP).



AFRICA
UNIVERSITY®
A United Methodist-Related Institution

Office of Research and Outreach Programmes

Telephone: +263 (0) 20 60588; +263 (0) 20 61611/61618/66968 - Ext. 1064

E-mail: adviser@africau.edu; researchsec@africau.edu