10. Ethical Review of University Research

Overview

Provides a framework that includes mechanisms and standards for ethical review of research projects undertaken in the University.

Scope

Applies to all employees and students of the UAEU and to all research carried out at the University facilities or under UAEU name elsewhere.

Objective

The University is committed to the maintenance of the highest ethical standards in the preparation, implementation and dissemination of research. This Policy gives effect to that commitment.

Policy

1. The University regards maintenance of high ethical standards in research as a central and critical responsibility, and will take greatest care to ensure that the ethics and integrity of research are beyond question, as the individual has a responsibility not only to him/herself but also to society. The Policy will be interpreted in a manner that is consistent with the University commitment to the highest standards of professional conduct.
2. Members of the academic community have the responsibility to act in accordance with the UAE law, in addition to cultural norms as well as UAEU codes of practice, Policies, and standards of professionalism.
3. The University will establish a Research Ethics Review Board (RERB) that is responsible for conducting ethical review of research proposals requiring such a review. The RERB will also investigate allegations of scientific/behavioral misconduct, referred to it by the APR.

Procedures of Policy No. (10) - Ethical Review of University Research

1. University Research Ethics Review Board

a) Governance:
   (i) The Chair and Vice Chair of the Board are appointed by the Vice Chancellor, based on the recommendation of the APR, and approval of the Provost.
   (ii) The other members of the Board are appointed by the APR.
   (iii) The Chair of the Board reports to the APR.
   (iv) The Chairs of the Board Committees are appointed by the Chair of the RERB.
   (v) The Chairs of the Board Committees report to the Chair of the RERB.

b) Structure of the RERB-Committees:
   (i) The Research Ethics Review Board will form and oversee four committees as follows:
      - Human Medical Research Ethics Committee (HM-REC): This committee will review and process approval of relevant research projects submitted by the faculty researchers at related colleges and affiliated and contracted Hospitals.
      - The Social Sciences Research Ethics Committee (SS-REC): This committee will review and process approval of relevant research projects submitted by the faculty researchers at related colleges.
      - Hazardous and Bio-Hazardous Materials/Processes Research Ethics Committee (HAZ-REC): This committee will review and process approval of research projects involving the use of hazardous and bio-hazardous materials or processes submitted by the faculty researchers at related colleges.
      - Animal Research Ethics Committee (A-REC): This committee will review and process approval of research projects involving animals by the faculty researchers at related colleges.
   (ii) The Chair of each Committee can transfer a submitted research project to another committee if deemed necessary.

c) Responsibility:
   (i) The RERB-Committees have the responsibility for the ethical review of research proposals including but not restricted to the following:
      - Research involving humans and human-derived materials;
      - Research involving genetic modification that can potentially have a health risk;
      - Research involving hazardous materials and processes;
      - Research involving animals and animal-derived materials;
   (ii) The research proposals involving the use of established, characterized and commercially available human and animal cell lines are not subject to review by the RERB committee
   (iii) The RERB-Committees will develop the mechanism and process for ethical review, and as required implementation of the projects undertaken at or by the UAE University, and dissemination of their outcomes.
   (iv) The RERB-Committees will have discretion on behalf of the University and in light of ethical considerations, to disallow the proposed research or to require modifications as appropriate.
   (v) The RERB committee will establish a common code of practice regarding animal husbandry and sacrifice to be used by all UAEU researchers whose work involves animal use.

d) Membership of the RERB:

Eleven (11) members as follows:

- Nine faculty members with relevant academic qualifications and research experience including
  1- Chair
  2- Vice Chair
  3- Chair of the Human Medical Research Ethics Committee (HM-REC)
  4- Chair of the Social Sciences Research Ethics Committee (SS-REC)
  5- Chair of the Hazardous and Bio-Hazardous Materials/Processes Research Ethics Committee (HAZ-REC)
  6- Chair of the Animal Research Ethics Committee (A-REC)
  7- Three more faculty members with relevant academic qualifications and research experience.
- A person with knowledge of, and current experience in, the professional care, counseling or treatment of people;
- A lawyer or a person with a different kind of law-related background;

The RERB may assign a staff secretary with no right of voting.

2. Ethical Review of University Research

a) When a research proposal is required to be ethically assessed either by a funding organization or from within the UAEU, as stated in above, it is referred to a Committee of the Board.

b) Principal Investigators are responsible for submitting research projects to the RERB whenever this is required according to the classification specified above. Submissions to the RERB require prior approval of the respective Department Chair and notification to the Assistant Dean and Office of APR. No funding or agreements shall be provided or entered into until such projects obtain approval from the RERB relevant Committee.

c) Each RERB-Committee conducts its review process and approval according to international best practices. The review process should normally take no more than four weeks. The Chair of each RERB-Committee will notify the Principal Investigator, the Department Chair, the Assistant Dean for Research, and the Office of APR in writing, about the Committee's decision on approval.

d) Each RERB-Committee may request copies of research manuscripts before submission by the Principal Investigator for publication.

e) The Principal Investigator should keep a file for each project approved by the RERB including the research proposal, application for approval, all communications, a copy of the approval letter, and the final report for a minimum period of five years from the date of publication, unless a different length of time is approved by the APR.

f) The Chair of each RERB-Committee will report on the activity of the Committee to the RERB at every RERB meeting.

g) The RERB will have regular meetings four times a year, in addition to any ad-hoc meeting requested by any member of the RERB, the Chair, or the APR.

h) The RERB will submit an annual report to the APR.

3. Standard Protocol for Checking Ethical Considerations

a) Principal Investigators will routinely check their projects to ensure they are meeting ethical requirements. Checklists will serve as an aide-memoire prior to seeking approval from the Board, as part of standard procedure aimed at ensuring compliance with research governance requirements. This can be facilitated by standardizing database "fields" that contain information about any research project.

b) The following checklist is to be included in the application forms for approval from the responsible RERB-Committee. It is intended to act as a comprehensive stimulus to ethical considerations throughout a project. Such a checklist prompts the making of clear statements of intent, mechanisms of approach and consideration of potential hazards arising from research in a manner that can be understood by the public and research professionals alike. While some of the items appear to be beyond the scope of ethics alone, any matter that may affect the success of research is of ethical interest if it may expose participants to exploitation or risk.

(i) Project Title: This offers a quick reference for any interested party and indicates the broad sphere of interest.

(ii) Expected Duration: This indicates the commitment required of subjects, and time to be given by researchers.

(iii) Identity of Field Researchers and Organizational Base: This contains names, positions, qualifications and functions of those involved in the proposed research, of all holders of responsible positions, and of all persons who might be in direct contact with research subjects according to the UAE law. It offers an overview of competence, together with a chain of responsibility and accountability.

(iv) Purpose of Study: This cites aims and objectives that may indicate hypothesis testing, policy evaluation, and any potential "value" added to the subject group and/or society in general.

(v) Source(s) of Funding: This names the organization(s), individual(s) or group(s) providing the funding for the study.

(vi) Scientific Background: This offers a rationale for conducting the study.

(vii) Design of the Study: This contains a brief description of what will be done, of how subjects are expected to participate, and of what will be required of them. All procedural matters will be clarified here, including data analysis methods and procedures; time commitments; and data-collection settings.

(viii) Potential Benefits and Hazards: This identifies any risks to the subjects entailed by involvement in the research; any potential physical, psychological or disclosure dangers that can be anticipated; and any potential benefit or harm to the subjects or society from their participation or from the project as a whole. It also outlines procedures for the care and protection of subjects (e.g. insurance, medical coverage), and for the control of any information gained from them or about them.

(ix) Recruitment Procedures: This contains information on whether participation will be purely voluntary, or whether any subjects will be in any sense "obliged" to participate, as in the case of students or patients. If participation is in any sense compulsory, there must be adequate provision for indicating any potential consequences of non-compliance to subjects; if it is strictly voluntary, there must be adequate provision for an entitlement to withdraw consent, and if applicable, an indication of a date when that entitlement expires.

(x) Informed Consent: This specifies the procedure for obtaining informed consent according to the following principles:
- Where appropriate, consent of participants must be requested in terms easily comprehensible to lay persons. Consent will be given in writing and ideally also communicated orally.
- An information sheet setting out factors relevant to the interests of participants in the study must be written in like terms and handed to them in advance of seeking consent. They must be allowed to retain this sheet.

(xi) Data Protection: This will illustrate by what means the project will comply with the requirements of current data protection legislation, and how this compliance will be disclosed to participating subjects and those monitoring the research procedure. It will include information on proposed data storage arrangements, degrees of security, etc., and whether any material facts have been withheld (and when, or if, such facts will be disclosed).

(xii) Confidentiality and Anonymity: This will list the steps taken to safeguard the confidentiality of records and will disclose the circumstances under which any potential identifying information about the subject must be revealed.

(xiii) Monitoring of the Research: This will outline the organizational procedures for monitoring the project.

(xiv) Dissemination of Findings: This will address the anticipated use of the data, forms of publication, dissemination of findings, etc.

4. Research Misconduct

Procedures for dealing with allegations of research misconduct and unethical behavior related to research are generally implemented as follows:

a) Notification from Individuals should be submitted to the respective College Dean for initial investigation. If warranted, colleges may submit the allegations with their findings to the APR, who may refer the case to the RERB for a full investigation. Notification from the APR Office or DVCAA Office may be submitted directly to the RERB.

b) The RERB forms a subcommittee for investigation. The subcommittee's decision will be reported to the RERB.

c) In case the RERB does not agree with the recommendation of the subcommittee, the RERB may form another subcommittee for investigation.

d) The RERB Chair will report the outcome of the RERB's deliberation to the APR who will forward the RERB's report to the Vice Chancellor, through the Provost, for the appropriate action in accordance with the UAEU policies.