Ethical Considerations in Research

2022 - 2023

Research Ethics Policy

A. Code of Responsible Research Conduct at the UKF

Overview

The UKF is highly committed to the code of responsible research practice and fully adheres to international standards of research integrity. Its policy on responsible research conduct follows the most upstanding principles of the code of good practice and gives clear instructions and guidance on responsible research conduct. It also has clear rules and procedures for handling and correcting misconduct in research practice.

Scope

This policy applies to: (1) all UKF faculty, graduate and undergraduate students, and researchers who are involved in research at the UKF; (2) all administrators and research assistants who participate in any research activity within or under the auspices of UKF; and (3) all technical staff and employees working in animal care facilities. This policy should be read and applied in conjunction with the UKF's policy on protecting human subjects and its policy on the care and use of animals.

Policy Purpose

This policy aims to ensure that all UKF researchers, administrators, and technical staff know the code of responsible research conduct. They act according to it, and their failure to observe this code may result in the suspension of research activity and other counteractive measures. This policy also aims at maintaining the highest standards of integrity and professionalism in conducting research, managing research data and materials, publishing research outputs, exploiting research results, and other matters about research in all its aspects at UKF, in addition to specifying the procedures for reporting allegations or breaches of the code of responsible research conduct and for dealing with those allegations.

Policy Statement

The UKF's policy on Responsible Research Conduct will set out its commitment to research integrity and its expectations of the highest standards of compliance with the code of research ethics by its researchers, regardless of the sources of their funding, their area of research, and whether they are members of research groups or lone researchers.

In addition to its being in total harmony with the UKF's mission to encourage innovative and world- class research in terms of institutional compliance, this policy sets out the obligations on researchers and administrators to observe the standards of good practice in all aspects of their work, including the way research is planned, funded and conducted, as well as the way research outputs are recorded, disseminated, applied and exploited. This policy also guides on ways of dealing with

situations involving misconduct in research.

Definitions

The following terms shall have the meaning assigned to them unless the context indicates otherwise:

- Allegation: an allegation that a researcher has breached the Code of Responsible Research Conduct.
- Code of Responsible Research Conduct: the code of ethical integrity in research sets out this policy.
- Complainant: a person who has made an allegation of research misconduct against a researcher or a staff member.
- Conflict of Interest: a situation in which a researcher or staff member is in a position to derive personal benefit from actions or decisions made in their official capacity.
- Plagiarism: the practice of taking someone else's work or ideas and passing them off as one's own.
- Research Misconduct: breach of the ethical code of responsible research conduct by a researcher or a staff member.
- Violation of Ethical Integrity: breach of the ethical code of responsible research conduct by a researcher or a staff member.

Procedures
Principles of Responsible Research Conduct

All UKF researchers, administrators, and technical staff involved in research activities conducted at the University or under its auspices must act according to the following principles:

1- Responsibility: responsibility for performing or completing assigned or willingly chosen research tasks and accountability to superiors for the implementation of such tasks.
2- Honesty: Integrity in presenting research goals, practices, and findings; conducting research, reporting on research methods and procedures; managing research data and materials, publishing research outputs and exploiting research results; using and acknowledging the work of other researchers; as well as making justifiable claims based on research findings.
3- Transparency and open communication: mean clarity in presenting the methods of research data collection; analyzing and interpreting data; giving access to research findings; discussing the work with other researchers; and communicating the work to other researchers and to the general public.
4- Good Governance: good management practices by providing an appropriate

research management framework through which quality research is encouraged and evaluated with safety, confidentiality, risk management, and compliance with the international standards of responsible research conduct.

5- Objectivity: impartiality and independence in making decisions about research funding, research management, interpretation of research results, publications of research findings, communication of results to the general public, and investigation of research misconduct.

6- Respect and Care: humane concern for participants involved in research, including humans, animals, the environment and objects of cultural or historical value.

7- Care for future generations: the preparation and training of young researchers through the adoption of high standards of mentoring and supervision within a constructive and supportive environment.

8- Fairness: scientific integrity and justice in providing correct references and giving the right attribution to the work of other researchers and in treating colleagues with truthfulness and honesty.

B. Standards of Responsible Research Conduct

The code of responsible research conduct at UKF is meant to help individual researchers and research groups to undertake and accomplish research projects in a transparent, trustworthy and reliable manner. UKF maintains the highest standards of Research Integrity in all stages of research activity, including research planning and conduct, research data management, publications, authorship, collaborative research and conflicts of interest.

1. Compliance with Policies

All UKF researchers, administrators and technical staff should be familiar with the University policies and procedures regulating the research process, including policies regulating the ethical review of the use of human subjects and animals; policies regulating research management, reporting, publication and exploitation of results; as well as policies governing the investigation of misconduct in research.

2. Research Planning and Conduct

- UKF advocates responsible planning and conduct of research to ensure transparency and credibility of research activities in all disciplines. Thus, individual researchers and research groups must justify their research plans and implementation following the standard practice within the discipline in question.
- UKF is responsible for ensuring that rules are put in place for handling research plans in all fields of inquiry as well as procedures for any required approvals or permissions for research activities.
- Principal Investigators (PIs) must be reasonable in ensuring the truthfulness and completeness of the information that is contained in applications for funding. It is

the PI's responsibility to ensure that the planned research is vigorous and adequately funded.

- All UKF researchers must maintain high standards of responsible research conduct, promoting intellectual integrity and scholarly rigor. Researchers must:
  - Respect the rights of all individuals or parties involved in their research
  - Manage conflicts of interest in a way that prevents personal advantage from violating ethical standards
  - Follow proper practices for safety and security
  - Cite research publications fairly and accurately
  - Observe and respect the policies adopted by their research sponsors, whether their research is internally or externally funded
  - Keep clear and accurate records of the procedures followed and of the results obtained from their research works.
- The VCAA must approve all reporting obligations related to collaboration with external partners.

3. Ethical Issues

- All ethical matters must be taken into consideration before any research work begins. For research activities involving human participants, the University's policies and procedures on the protection of human subjects must be observed.
- For any research that involves patients, samples, tissue or data, the approval of the Research Ethics Committee (REC) must be obtained before the beginning of the research. Researchers must accordingly discuss any research that involves human subjects, human tissue or data with the REC chair.
- Research involving animal subjects must obtain the approval of the Animal Care and Use Committee (ACUC) before the beginning of the research activity and must consider the possibility of reducing, replacing or refining animal involvement.
- Any other ethical considerations pertaining to the environment or the use of sensitive economic or social data must be taken into account.

4. Data Management

The UKF maintains the highest standards of responsible handling and storage of research data. For any research conducted at UKF:

- All basic material and data derived from research carried out at UKF must be stored at the University and made available on demand.
- All protocols and plans for experiments or studies, notes, laboratory registers, data, and basic material must be stored for at least three years after the completion of the research project and must be accessible, provided that this does not conflict with other regulations.
- All basic research material and data obtained from research carried out at UKF belongs to the University and can only be displaced under permission of the concerned department, college or institute.
- Disposable research material must be disposed of in a safe and secure manner with due consideration of the involved ethical and environmental issues.

5. Dissemination and Publication of Research Results

Dissemination and publication of research results is a significant part of research and this process must be truthful, transparent and accurate.

- The UKF is responsible for promoting ethically-compliant publication and dissemination of research findings
- The UKF is responsible for protecting the confidentiality of research findings before and through the publication process
- UKF researchers are obliged under the code of responsible research conduct to:
  - Openly and honestly communicate and disseminate their research and results to other researchers and the general public through refereed publication.
  - Ensure that published reports and statistics about their research activities are complete, accurate and explicit.
  - Cite other works pertaining to their research properly and truthfully when communicating their research findings.
  - Disclose the research support and the financial aid they get from funding bodies truthfully and accurately
  - Acknowledge the work of students or staff members during the research phase honestly and accurately

6. Intellectual Property and Commercialization

- All UKF researchers must be aware of and take appropriate steps to protect any intellectual property (IP) arising from their work.
- The UKF supports the development and exploitation of IP belonging to it through its planned IP office using any means deemed appropriate for the University's interest, its researchers, and administrative staff and as part of its contribution to the local, regional and international communities.
- All UKF researchers must be aware of the University's IP and commercialization policy and procedures, which include rights to any kind of IP and any income that may be generated from their research work.

7. Authorship

The UKF acknowledges that accurate attribution of authorship is a significant element of responsible research conduct.

- Authors should acknowledge the efforts of all those who have contributed to their work as well as the funding agencies behind a project. They should also acknowledge the sources of funding for their research in their publications (research, books, reports, patents and others).
- Attribution of authorship, co-authorship and responsibility must be based on the ethics of research integrity. This requires that authors must fulfill the following requirements:
  - Contribution to the conception or the research work, or the acquisition, analysis and interpretation of data;

- Drafting the work or reviewing it for important scientific content;
- Acceptance of accountability for all aspects of the work; and iv- Resolution of all ethical issues related to the work.

 All authors are responsible for the content of the published work. Even so, the responsibility of

 each author should be evaluated in relation to their role in the research and in relation to their area of expertise.

 Unacceptable authorship offered to individuals who do not meet the requirements for authorship is considered a breach of the code of responsible research conduct.

 Research works submitted for publication to UKF journals must abide by the publication policy and procedures of the UKF Scientific Publishing Unit, including the double-blind peer review of manuscripts and the declarations on the conflicts of interest.

 Disputes on authorship shall be dealt with and resolved by a special committee appointed by the VCAA.

8. Conflicts of Interest

- All research activities at UKF must be conducted in a responsible manner and free from any possible influence arising from personal interest or advantage.
- All UKF researchers are obliged to disclose any conflict of interest that has a potential influence on grant applications, the appointment of research assistants, research investigations, publication, media reports, or any other process/aspect related to the research activity.
- In circumstances where a conflict of interest is seen or anticipated to occur, the researcher must provide sufficient information to the VCAA so as to allow for a proper examination of the matter.
- In circumstances where student supervisors or research trainees identify an actual or a potential conflict of interest, either on personal or professional grounds, they must provide sufficient information to the VCAA to allow for a proper examination of the matter.
- Researchers must obey all the instructions given by the VCAA regarding the existing or potential conflict of interest.

9. Handling Research Misconduct

Research misconduct is commonly defined as deliberate fabrication, falsification, or plagiarism in proposing, conducting, reviewing, or describing research results.

 The UKF is highly committed to the international standards of research integrity and condemns all types of research misconduct in all phases of the research activity. It also holds seriously any information that reports suspicion of research misconduct and handles allegations in the most serious and timely way.

 The UKF encourages all its researchers, administrators, and technical staff to report any suspicions on the violation of the code of responsible research conduct of research, so that the case may be investigated immediately.

 All allegations must be addressed appropriately and presented to the office of

the VCAA in written form.

- Upon receipt of the information on suspicious research misconduct, the VCAA forms a Review Committee (RC) as expeditiously as possible to investigate the suspected violation of research integrity.
- Any investigation of research misconduct allegations conducted by the RC at UKF must be impartial, thorough, and fair.
- The RC may interview any person it thinks is suitable to describe the circumstances of the case honestly.
- The Committee may choose to reject the case and stop the investigation process if no sufficient or explicit evidence is provided in support of the allegation(s).
- The person(s) who is/are the subject of an allegation must be treated fairly and be given the opportunity to respond to allegations in writing.
- If a given allegation of research misconduct is proven to be well-founded and supported with solid evidence, the researcher or the staff member will be penalized according to the degree of violation.
- A person who raises suspicion of research misconduct in good faith may not be punished or intimidated, and the University must protect the complainant against this.
- If it turns out that the complainant was in bad faith, s/he may be charged with breach of responsible research conduct.
- In handling allegations, the RC must ensure that all parties involved in the case receive prompt, thorough, and fair treatment.

Human Subjects Use Policy and Procedures

Overview

The UKF's research policy on the Use of Human Subjects reflects an institutional-wide concern with ethical issues involved in all research activities. It is supervised by the office of the Vice Chancellor for Research, and Graduate Studies (VCAA), and its implementation involves executive officers, research review committees, and other entities that are responsible for protecting the
rights and welfare of participants in research conducted by UKF's Researchers. According to this policy, all researchers and administrative staff involved in research must adhere to the ethical principles of responsible research conduct to protect the dignity, rights and welfare of research participants. As such, a research ethics committee must review all research involving human beings to ensure that the appropriate ethical standards are being upheld. This policy should be read and applied in conjunction with UKF's executive research bylaws.

Scope

This policy applies to all research involving human subjects conducted by: (1) all UKF faculty, graduate and undergraduate students, and visiting faculty (hereafter referred to as researchers) who take part in research at UKF; (2) all administrators and research assistants who participate in any research activity that involves human subjects.

Policy Purpose

This policy aims to ensure that all UKF researchers, administrators, and technical staff are aware of the code of responsible research conduct, that they act according to it, and that their failure to observe this code may result in the suspension of research activity and other counteractive measures. This policy also aims at maintaining the highest standards of integrity and professionalism in conducting research, managing research data and materials, publishing research outputs, exploiting research results and other matters about research in all its aspects at UKF, in addition to specifying the procedures for reporting allegations or breaches of the code of responsible research conduct and for dealing with those allegations.

Policy Statement

It is the policy of UKF that no research activity involving human subjects be conducted until it has been reviewed and approved by the VCAA. All research proposals involving human subjects must first be submitted to the Research Ethics Committee (REC) for the VCAA' review and approval. In addition, the UKF requires training on the protection of human subjects and the related ethical principles for all types of research activities involving human subject research, regardless of whether or not researchers or research groups have obtained consent for the funding of their projects. Protecting participants from any kind of risk is the ethical responsibility of each faculty member, student or research assistant who is involved, either directly or indirectly, in conducting research at UKF. Principal Investigators must also require that each member of the research group carries out all research activities in accordance with the ethical principles of research. As per this policy, the VCAA has the absolute authority to suspend or terminate research that is not being conducted in accordance with the UKF policy requirements or that has been associated with any kind of harm to human subjects. Investigators whose research does not abide by university policies may not obtain the REC review or approval for other research activities involving human subjects until the compliance issues have been cleared. This policy also requires that the REC report violations of university policies to the VCAA.

Definitions

The following terms shall have the meaning assigned to them unless the context indicates:

- Research stands for systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to human knowledge.
- Human Subjects: human subjects are defined as individuals about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information."
- Intervention: intervention means: (1) physical procedures by which data are gathered and (2) manipulations of the subject or the subject's environment for research purposes.

- Interaction: Interaction means communication or interpersonal contact between Investigator and subject.
- Private information: private information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.
- Informed Consent: Informed Consent is a voluntary agreement to participate in research. It is not merely a form that is signed but is a process in which the subject has an understanding of the research and its risks. Informed consent is essential before enrolling a participant and ongoing once registered.
- VCAA university or another funding organization and the research project/group leader supported by the grant. Each Principal Investigator is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization, for the ethical conduct of the project or program, including the submission of all required reports.

Procedures

The following Procedures shall be used to implement the main purpose and principles of the above policy.

A. General Procedures

- The UKF recognizes the ethical principles, considerations, and concerns expressed in the federal laws of the UAE and the bylaws of the Ministry of Health.
- All research activities conducted under the auspices of UKF, including collaborative research conducted with one or more public or private entity, in which human subjects are involved, must be reviewed and approved by the VCAA after being submitted to and reviewed by the University's REC.
- In conducting collaborative research projects involving more than one institution, each institution is responsible for protecting the rights and welfare of human subjects and for complying with applicable bylaws and regulations of the UKF.
- The VCAA has the responsibility and authority to appoint the chair and members of the REC and also has the power to engage in agreements with other institutions, such as universities or hospitals, to form a joint review committee if required.
- Any research project, conducted individually or within a research group that involves human subjects must obtain an informed consent signed by the concerned subject after their review of the terms of the agreement (this is not applicable to some research activities which are retrospective record reviews or study on old anonymous archival human tissues. other forms of research (such as deception research) can only be conducted with a waiver of consent. this will be up to the REC to decide upon).

B. Conditions and Procedures for Recruiting Human Subjects

- Favorable Risk-Benefit Ratio. The REC should ensure that all risks (physical, psychological, social, financial…etc) have been identified by the researchers and that every attempt was made to reduce those risks.
- The REC should also evaluate the actual and potential benefits, which will be received by the research subjects, including monetary and other incentives, and make sure those are neither inappropriate nor exaggerated.
- Fair Selection of Research Participants. The REC should ensure that no particular group of people or a particular community is chosen to carry the burden of the research. The REC should ensure that both the benefits and the burden of research are distributed equally unless there is scientific reasoning to consider otherwise.
- Protection of the Participants' Privacy and Confidentiality. The REC must ensure that researchers have guaranteed decency and privacy for the research participants whilst those are engaged in the research.
- The REC must see strong measures that would maintain the confidentiality of the research participants' data during and after the conduct of the research.
- To ensure privacy and to protect the rights of participants, investigators may not directly contact a potential participant identified by private sources, such as private clinics, schools or businesses, before s/he submits a written and signed permission to the identifying source.
- Recruitment of subjects must be equitable and include racial, ethnic, educational, socio- economic, and gender diversity appropriate to the condition that is studied.
- Recruiting methods will be planned to make sure that vulnerable subjects are not systematically selected due to ease of availability or manipulability.
- Recruitment should result in the selection of appropriate participants reflecting the question under study and not involving participants who will not benefit from the future applications of the research.
- The REC will consider the medical, employment, and educational status of participants, as well as available financial, emotional, and community resources, when determining whether participants can be recruited fairly, informed adequately and properly compensated.

C. Procedures for Informed Consent

The REC must ensure that research participants are:

- Competent in understanding the information presented to them regarding their research involvement, and They are completely free to make choices about their participation without being coerced into it. In order to achieve this, the informed consent must contain the following essential items:
    - Be in the research participants' native language. The burden of accurately and formally translating the informed consent should be on the researchers.
    - Be written in a simple, yet professional language (i.e., equivalent to 5th or 6th school grade level). The form should be free from any linguistic and

structure errors.

- The title should clearly state the words "research", or "study" if in English and the equivalent word if other languages are used.
- The names, titles and contact details of the researchers.
- The purpose of the research.
- The research site and how privacy will be guaranteed.
- A statement on how the confidentiality of the collected data will be safeguarded.
- The participants' expected time commitment and the overall duration of the research project.
- The exact procedures in which the participant will be involved in. This should preferably be written in a bullet point format. The use of photos and diagrams, which would simplify this engagement is strongly encouraged.
- The risks and discomfort which the participant will need to bear during the research, and after its completion (if relevant).
- Benefits (if any) that the participant will get out of their participation. This could be financial, free consultations, free blood tests…etc.
- A statement about voluntary participation, and the right to withdraw at any time without any consequences to this decision.
- Whether there will be an insurance to cover damages as a result of this research, and/or to compensate for injury.
- Contact details of a third party to contact in case of concerns of complaints. Usually, this third party is the chair of the REC.
- A statement about any unforeseeable risks.
- The circumstances under which the research would be terminated.
- At all times, a copy of the Informed Consent must be retained with the research participant.

D. Special Circumstances Related to the Informed Consent

1- Surrogate consent: There are situations in which informed consent is obtained from the legally- authorized representative instead of the research participants. Those situations include:

- Persons below the legal age
- Persons who are mentally or cognitively incompetent
- Persons with deprived freedom (such as prisoners)

In those cases, the REC must ensure that the researchers have taken into consideration the participants' Assent, which means that the participant is comfortable with the research procedures, and is not showing any form of resistance or discontent.

2- Consent Waiver

In some studies, obtaining the consent is not possible or is impractical. In those cases, the REC may waive the informed consent as a requirement. The following are examples of such situations:

Emergency settings, in which consent or surrogate consent is not possible.

- Retrospective studies, such as record review and analysis of leftover samples.

- Deception studies
- Observational studies on a huge number of people.

Waiving consent must always be viewed as an exceptional situation. Researchers should, therefore, present a strong justification for requesting a waiver. A waiver must only be granted if the research being applied for is classified as minimal risk. In case of deception studies, and whenever possible, consent must be sought from the participants after the completion of the study.

3- The Process of Informed Consent

At all times, informed consent needs to be viewed as a process, not an event. In some cases, the REC might request evidence from the researchers of an ongoing process of giving information to research participants to ensure a complete understandability of their research involvement. This is particularly important in multi-phase studies, drug trials, and other interventional studies. It is also important when the research participants are considered vulnerable.

Informed Consent Form versus Information Sheet

Signing of the informed consent would contradict the principle of anonymity when research participation ought to be anonymous. This is commonly the case with questionnaire-based survey studies. In those cases, the submission of the questionnaire is -in itself- an indication of acceptance, and there would be no need for a signed informed consent. Nevertheless, an information sheet, containing the same information as those in the informed consent, should be prepared and be given to research participants.

E. REC Review of Research Involving Human Subjects

- The REC is assigned the task of reviewing, approving, disapproving or requiring changes in research or related activities involving human subjects, including their tissues or their data, in accordance with applicable bylaws and regulations of the UKF.
- The REC is entitled to suggest suspension or termination of the approval of research that is not being conducted following the UKF-related bylaws, that has deviated from the format on which it was approved or that has caused unpredicted serious harm to human subjects.
- The VCAA, after reviewing the report submitted by the REC, has full authority to take a decision regarding the disapproval, deferral, suspension or termination of a research study that has caused harm to human subjects.
- The REC might upon its discretion, request from the Principal Investigator or the individual researcher who is using a human subject the informed consent signed by the concerned subject.
- The REC shall notify the Principal Investigator or the individual researcher in writing of its decision to approve or disapprove the proposed research activity or the changes required to obtain final approval of the research activity. If the REC decides to disapprove a research activity, it shall specify in its written notification the reasons for its decision and give the Investigator an opportunity

to respond in writing. Any suspension or termination of approval will be reported promptly to the Investigator.

- The REC shall conduct ongoing reviews of research covered by this rule at least once per year, and shall have authority to observe or have a third party observe the consent process and the conduct of research.
- Special attention should be put on reviewing research projects which target vulnerable populations, such as children, prisoners, disadvantaged persons…etc. Researchers must present strong justifications when those vulnerable populations are specifically targeted.

F. Criteria for the Approval of Research

To approve research covered by this rule, the REC shall determine that all of the following requirements are satisfied:

- Risks to subjects are reduced to a minimum: (i) by adopting procedures that are consistent with sound research conduct and which do not expose subjects to risk, and (ii), whenever appropriate, by adopting procedures already being performed on the subjects for diagnostic or treatment purposes.
- In assessing risks and benefits, the REC should consider only those risks and benefits that may result from the research (as differentiated from risks and benefits of therapies that subjects would receive even if not participating in the research).
- In reviewing the proposed use of human subjects, the REC should take into consideration the purposes of the research and the setting in which the research will be conducted and should be aware of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent shall be sought from each prospective subject and shall be documented in accordance with the adopted regulations.
- The Investigator must be committed to the protection of the privacy of subjects as specified in the confidentiality section in the application form s/he signs before submission.
- The right for an appeal: researchers will be notified, in the decision letter, that if they are not satisfied with the decision of the REC, they can write to the VCAA within 30 days of receiving the REC decision letter.

G. Participant Compensation

- Compensation for participation in a research study is to be considered by investigators and the REC as a recruitment incentive rather than a benefit.
- Participants may be compensated on an hourly-basis scheme or as a package after the signature of the informed consent.
- Payments must not been so big as to encourage participants to accept risks that they would not otherwise undertake.

H. Reporting Noncompliance

Reports or allegations of noncompliance with the UKF regulations concerning research involving human subjects, the REC requirements, and this policy may be submitted to the REC chair or directly to the office of the VCAA. Reports may also be made online via email to the REC chair or the VCAA. The processing of reports or allegations of noncompliance will be conducted according to the UKF regulations and the research executive bylaws.

I- Animal Care and Use Policy and Procedures Overview

The UKF's research policy on Animal Care and Use is strictly committed to the international ethical standards of animal use, care and welfare. It complies with the UAE Federal Law No. 16 of 2007 regarding animal protection. This policy is supervised by the Vice Chancellor for Academic Affairs (VCAA) office. Its implementation involves executive officers, research review committees, and other entities responsible for protecting and using animals humanely in any research activity involving animal subjects. According to this policy, all researchers, administrators, and managers of animal care facilities are required to promote and protect animal welfare in a way that complies with the ethical standards of animal use and care. Therefore, all research activities involving animal subjects must be reviewed by the Animal Care and Use Committee (ACUC) to ensure that convenient ethical standards are being maintained.

Scope

This policy applies to all research activities involving animals conducted by:
(1) all UKF faculty, graduate and undergraduate students, and researchers who are involved in research at the UKF;
(2) all administrators and research assistants who participate in any research activity that involves animals; and
(3) all employees of animal care facilities owned by the University of Khorfakkan. This policy should be read and applied in conjunction with the UKF's research executive bylaws.

Policy Purpose

The purpose of this policy is to ensure the protection and welfare of animals that may be involved in any research or teaching activity carried out under the auspices of the UKF. Given that the use of animals in research and teaching is an important component of the work of the UKF colleges and institutes, namely the medical and health colleges as well as the Research Institute of Medical and Health Sciences, the University is committed to ensuring that animals users among researchers and students act in strict accordance with the standards and guidelines specified in the UAE Federal Law No. 16 of 2007 regarding animal protection as well as the University of Khorfakkan ethical standards. The policy will outline the ethical principles that govern Animal care in research and testing, the expectations relating to Animal care and Animal ethics as well as the consequences of non- compliance with the policy.

Policy Statement

The University of Khorfakkan is committed to the highest ethical standards of animal care and use. This policy outlines: (1) the responsibilities and duties of the Animal Care and Use Committee, (2) the animal care and use protocol procedures that ensure compliance with the UAE Federal Law No. 16of 2007 regarding animal protection as well as the UKF's standards of responsible research conduct, (3) the animal use protocol procedures, (4) reporting noncompliance, (5) inspection of animal facility and (5) the roles and responsibilities of researchers who are involved in the use and care of animals in research and testing. The VCAA, upon recommendation of the Animal Care and Use Committee, has the absolute authority to suspend or terminate research that is not being conducted in accordance with the UKF policy requirements or that has been associated with any abusive use of animals.

Definitions

The following terms shall have the meaning assigned to them unless the context indicates otherwise:

- Animals: the term 'animal' refers to all non-human living vertebrates and higher invertebrates that feed on organic matter and have specialized sense organs and a nervous system enabling them to respond to stimuli.
- Animal Facility: any buildings, rooms, areas, enclosed spaces or vehicles used for animal confinement, transportation, preservation, reproduction, experimental procedures or surgery.
- Animal Use Protocol: a predefined written procedural method of conducting research experiments using animal subjects.
- Animal Use Violations: any unauthorized or non-compliant animal use is considered an animal use violation.
- Attending Veterinarian: is a person has received training and/or experience in the care and management of the species being observed; and who has direct or delegated authority for activities involving animals at an animal use and care facility.
- Major Survival Surgery: a surgery that "penetrates and exposes a body cavity or produces considerable impairment of physical or physiological functions."
- Principal Investigator: is usually defined as the holder of a research grant administered by a university or another funding organization and the leader of the research project/group supported by the grant. Each Principal Investigator is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization, for the ethical conduct of the project or program, including the submission of all required reports.

Procedures

The following Procedures shall be used to implement the primary purpose and principles and of the above policy.

A. The Animal Care and Use Committee (ACUC)

The responsibilities of the Animal Care and Use Committee (ACUC) regarding all animal activities at the UKF include:

- Defining and communicating guidelines for research involving animals in accordance with the International Animal Welfare Acts and that the protocol is consistent with the Guide for the Care and Use of Laboratory Animals. The Committee shall propose a standard guide for the use and care of animals and coordinate with the Ministry of Health in UAE for procedures and protocols set up for animal care and use.
- Continuously visit the Animal Facility (at least semiannually) to ensure that the facility is suitable for animal care and use according to international standards.
- Ensure all research involving animals complies with the standard Public Health Service.
- Reviewing emerging issues involving the care and use of animals at the facility.
- Reviewing and approving, requiring modifications, or withholding approval of proposed major changes regarding the ongoing use of animals at the facility.
- Monitoring all animal activities for compliance with ACUC recommendations and with the UKF policy and procedures for animal care by any appropriate means, including direct observation of the processes of animal activities or appointment of a third party to perform such observation.
- Suspending or terminate animal activities if they are non-compliant with the ACUC's requirements, if they involve major violations of the approved Animal Use Protocol, or if they have been associated with any harm or suffering caused to animal subjects.
- Following up all issues needed to get accreditation of the animal facility from the corresponding government agencies including Sharjah Municipality and the Ministry of Health.
- Coordinating if needed with the Research and Ethics Committee regarding issues that involve animal subjects.

B. Animal Use Protocol Procedures

<u>The Animal Use Protocol (AUP)</u>

- A typical Animal Use Protocol (AUP) should include information about: the research project; a list of species, sources and numbers; rational for the species and number of animals; description of the use; surgical procedures; minimization of pain; veterinary care; care and use facilities; as well as funding resources.
- Animal users must submit a written AUP to the ACUC for review and approval prior to implementing the protocol. The protocol must be consistent with the UKF

bylaws and with the UAE federal law on animal use and care requirements.

- The Principal Investigator is the responsible party for all activities included in and related to the AUP.
- AUPs that are already approved are subject to review at any time by the ACUC at the request of any of its members, the attending veterinarian (hereafter AV) and the VCAA.
- Any UKF researcher intending to conduct research involving animal subjects at another institution must submit an AUP describing the project to the ACUC. The latter shall review the protocol to ensure that it is consistent with the UKF bylaws and with the UAE federal Law on animal care standards. The Committee may then approve the protocol in principle before it gets the approval of the host institution's animal care committee or its equivalent.

Animal Use Protocol Application

- The AUP application is an official document that the ACUC approves. Any form modifications must be reviewed and approved by the ACUC to ensure compliance with the protocol requirements.
- Laboratory Animal Use Protocol: use for any laboratory-related species such as mice, rats, rabbits, etc.

Submission the Animal Use Protocol

- The PI submits the AUP to the ACUC coordinator after having completed the required forms (animal use request form, survival surgery form or observation form, etc.).
- As stated above (A.1.a.), The AUP must contain a list of animal users, animal species and their number as well as a brief description or explanation of the proposed work and any potential animal welfare issues for consideration, such as ways of minimizing discomfort (e.g.anesthesia), appropriate, sedation, used medication, etc.

c. Criteria for the AUP Approval

In order for an AUP to be approved by the ACUC it needs to comply with the UKF policy and procedures for animal care and needs to meet the following criteria:

- All animal activities must avoid or minimize discomfort and pain as much as possible.
- Activities that may cause more than minor pain or discomfort to the used animals must be conducted with proper sedation, analgesia, or anesthesia.
- Animals that would otherwise experience severe pain or distress that cannot be relieved shall be painlessly killed at the end of or during the procedure if appropriate.
- The living conditions of animals and their transportation method must be appropriate for their species and contribute to their health and comfort.
- The feeding and non-medical care of the used animals shall be supervised by a veterinarian or other expert trained and experienced in the proper care, treatment and use of the species being maintained or studied.
- Medical care for the used animals must be available and given when needed by a practiced veterinarian or trained researcher.
- All personnel performing procedures on the used animals must be qualified and

trained in those procedures.

D. The ACUC Review of the AUP Procedures

- Each member of the ACUC may obtain a copy of the protocol. Suppose no member calls for full committee review. In that case, the AV and at least one member of the ACUC, designated by the committee coordinator, shall review the submitted protocol research and have the authority to approve, require modifications to the proposal or request full committee review of the AUP.
- The detailed method of review for a submitted protocol shall be documented in the meeting minutes, in addition to the outcome of the review.
- The approval date is the date when the ACUC agrees on the project. Any animal work conducted before this date will be reported to the director of the VCAA as a serious noncompliance with the UKF policy and procedures for animal use and care.
- If a full committee review is requested, approval of the protocol shall be granted only after a convened meeting of a majority of the ACUC and with the approval vote of a majority of the present quorum. The present quorum may vote to request modifications or disapprove the project. No member may participate in the review of a research project in which s/he has a conflicting interest except to provide the information requested by the ACUC.
- The ACUC may also invite consultants to help in the review of complicated issues. Consultants are not eligible to approve or disapprove any activity or vote with the ACUC unless they are also members of the Committee.
- All protocols involving major survival surgery on animals must receive full committee review.
- Approved protocols shall receive a final approval number from the ACUC coordinator
- An approval letter from the ACUC coordinator and the approved AUP shall be sent to the PI within three days after the committee meeting.

- If the AUP is disapproved, the PI shall receive a notification letter of the ACUC's decision and the recommended resubmission modifications.

E. Suspension of the AUP

- The ACUC has the authority to suspend the activity of an approved AUP if notified about non- compliance by the AV or any authorized party.
- Suspension of the AUP activity must be discussed and voted on in a full committee meeting and requires a majority vote of the present quorum.
- Immediately after the ACUC suspension of AUP activity, the ACUC coordinator shall inform the VCAA and the PI of the suspension and the reasons on the basis of which the decision has been taken.
- Recommended remedial actions may be outlined by the ACUC and sent to the IP in the notification letter.
- The IP must then notify the funding department or the funding agency of the suspension and the corrective actions to be taken.

- The IP does not have the right to reject the ACUC suspension of the AUP activity.

F. Reporting Noncompliance

- The ACUC shall post the email addresses of its members, its office locations and the phone numbers of its coordinator as well as the AV on the research portal of the UKF website for reporting of complaints and violations in all UKF animal facilities.
- Any individual who notices that an animal is subject to maltreatment or that there is a possible violation of the ACUC policy is urged to report allegations of noncompliance and policy violations to the ACUC coordinator, the AV or any member of the Committee.
- A report on noncompliance may be communicated either orally or in writing and must include a description of the violation, the time and date of the violation, the exact location, the species of animal involved, and any other details relevant to the complaint.
- Noncompliance reports sent directly to the ACUC members will be forwarded to the committee coordinator for an initial investigation. The latter may either choose to conduct the investigation or assign it to the AV.
- If the AV is involved in the noncompliance issue, the ACUC coordinator shall assign the task to an appropriate person to investigate the allegations.
- If the AV is not the subject of the complaint and s/he receives a noncompliance report, s/he may conduct an initial investigation and forward the results to the ACUC coordinator.
- Any person who reports a violation of the UKF policy and procedures for animal use and care is protected by the University regulations from any retaliation.
- The confidentiality of the noncompliance report must be respected by all parties involved.

G. Investigating Noncompliance

a. <u>Initial Investigation by the AV or Any Assignee</u>

H. The AV or Assignee will evaluate the noncompliance report to determine whether there is sufficient information to make further investigations.

I. If evidence of animal mistreatment is found, the AV or assignee will take the necessary action, which may include temporary suspension of the use of animals by the individual(s) involved in the reported complaint.

- The AV or assignee shall submit the findings and recommendations to the ACUC coordinator.
- The ACUC coordinator shall consider the findings and recommendations for further action.

b. <u>Action Following Initial Investigation</u>

- If no violation is found, the ACUC coordinator shall inform the reporting person, the AV and the person who is the subject of the complaint in writing of the decision that no further action will be made.

- If the investigation reveals that there is a minor violation, such as inappropriate sedation or unnecessary increase in the number of animals used or failure to implement the suggested modifications on the initial protocol, the ACUC coordinator will inform the complainant and the person who is the subject of the complaint and their PI in writing of the findings and the suggested remedial actions required to be completed within a specified time frame.
- The ACUC Coordinator shall be responsible for checking if the remedial actions are implemented within the set time limit.
- If the investigation reveals that there is a major violation such as the inhuman treatment or neglect of animals, the use of animals without an approved AUP protocol, disregard for animal pain and suffering, offensive euthanasia, improper surgical techniques or improper experimental treatments, the ACUC coordinator shall report the violation to the VCAA who will report and inform the PI in a timely manner. After that, the following actions will be taken:
    - The ACUC coordinator calls for a meeting of the Committee to discuss the violation. A quorum of the IACUC must be present.
    - The ACUC shall review the noncompliance report and the findings and recommendations of the AV or the assignee and ask for additional information if need be.
    - The reporting person may be requested to meet with the ACUC. If s/he cannot attend s/he may submit a written statement to the ACUC coordinator prior to the meeting.
    - The individual(s) who is/are the subject of the complaint shall be sent a written description of the subject of the complaint through their PI and shall be given the chance to meet with the ACUC to respond to the complaint.
    - By majority vote of the present quorum, the ACUC will determine whether or not mistreatment of animals or policy noncompliance has occurred and make a decision.
    - The ACUC will then decide either to reprimand the person accused of noncompliance or suspend the protocol and its decision shall be immediately binding.
    - The ACUC coordinator will keep records of complaints, violations, investigations, and decisions for future reference if necessary.

i- **Facility Inspection**

- As stated by this policy, the ACUC is required to inspect the UKF physical facilities, including labs, study areas and areas where surgical manipulations are conducted, at least once every 6 months.
- The inspection team shall consist of at least two ACUC members, the AV, a representative from the UAE Ministry or Health or the Municipality of Sharjah, and a representative from the UKF compliance office.
- A report of the facility inspection findings and recommendations for correction must be reviewed and approved by the ACUC and deadlines for correction shall be specified and sent to the facility supervisor and the compliance office. A copy of the final report must be forwarded to the VCAA if needed.

- A checklist that is reviewed semiannually by the ACUC shall be used as a guide for the inspection team to ensure compliance with all institutional guidelines.
- One week before the inspection, the ACUC coordinator should provide the inspection team members with a copy of the previous facility inspection findings for reference.
- Major deficiencies, such as those that represent a threat to animal health or safety, discovered during facility inspections must be reported promptly to the VCAA. The VCAA is responsible for taking all necessary actions needed to maintain the upmost international standards utilized for animal care and use.
- Corrected deficiencies must be sent to the ACUC before the deadline specified in the in the final inspection report.
- Failure to implement the recommended actions for deficiency correction will end up in immediate suspension of all the activities in the facility until proper correction is made.

10.3.1 General Provisions

Under these guidelines, Regulations for scientific research shall be issued at the University, which indicate the details and conditions pertaining to these guidelines. The University shall ensure that scientific research projects are not in conflict with the teachings of Islam, public morals, and the legal requirements of the Emirate of Sharjah and the UAE. Issues related to intellectual property and research ethics shall be dealt with through the University Research Board. Researchers should observe scientific honesty and abide by the University Guidelines and Regulations for scientific research. It is the responsibility of the Chancellor, the Dean and the Research Board to implement these guidelines. The University Research Board shall decide on any matter not provided for in the Guidelines or any problem that may arise as a result of the application provided that such matters are reviewed regularly.

10.3.2 Preparation and Supervision of Theses/Dissertations

Master's theses and doctorate dissertations shall be written in either Arabic or English in accordance with the policy of the concerned academic department and shall include the abstract in the alternative language.

- Professors and associate professors shall supervise theses and dissertations. In exceptional cases approved by the college dean, associate professors may supervise master's theses.
- Individuals with outstanding experience and academic and scientific competence who are not members of the faculty may conduct supervision by decision of the Deans Council.
- A co-supervisor from outside the department of specialization may be appointed when the need arises. The maximum number of theses/dissertations that may be supervised at any time is four for the full professor, three for the associate professor, and two for the assistant professor. The Council may increase the number when necessary.

The University may replace the theses/dissertation supervisor when necessary.