**1. Introduction**

Abu Dhabi University recognizes its ethical and legal responsibilities to provide a mechanism to protect individuals and animals involved as subjects in research conducted under the auspices of the University. Research is defined as the attempt to derive generalizable or transferable new knowledge to answer or refine relevant questions by scientifically sound methods. Generalizable means the findings can be reliably extrapolated from the study to a broader population and/or applied to settings or contexts other than those in which they were tested. Transferable means the findings can be assumed to be applicable to a similar context or setting.

All research involving human participants or animal subjects is reviewed, prior to the initiation of the research, through the procedures set forth by the University and directed by the Institutional Review Board (IRB). University faculty, staff, and students conducting research involving human participants or animal subjects are responsible for complying with this policy. Failure to submit an ethics application for any research project involving human participants or animal subjects is a violation of Abu Dhabi University policy. The IRB reserves the authority to suspend or terminate approval of research that is not being conducted in accordance with this policy.

**2. IRB Membership**

2.1 The IRB is a faculty committee that is appointed by the Provost. Faculty considered for membership must have an established record of conducting research with human participants or animal subjects and have published the results of such research in high quality outputs.

2.2 A second committee comprised of the current IRB Chair, the Associate Provost and the Deans of all colleges determines the faculty to be recommended to the

Provost to fill the seven voting positions of the IRB. The committee making the recommendations to the Provost should consider the nominees as a whole and ensure that the IRB maintains a balance of disciplinary specializations and College representation.

2.3 The term of office is two years, renewable by the Provost. The Associate Provost serves as ex-officio, non-voting member. The Chair is appointed by the Provost and reports directly to the Associate Provost.

**3. Human and Animal Subjects Research Ethics Training**

3.1 The IRB Chairperson, IRB members, IRB administrator, Principal Investigators and student researchers are required to complete certified human and animal subjects research ethics training as appropriate to their specific role. The IRB Chairperson must complete the training prior to taking up the position as Chair. IRB members must complete the training within one month of appointment to the IRB. The IRB administrator must complete the training within one month of appointment to the administrator role. Principal Investigators and student researchers must complete the training prior to final approval of ethics applications.

**4. Administration**

4.1 The Provost is the university official responsible for carrying out or delegating executive functions. The executive functions include developing and modifying policies to conform to laws and regulations; providing continuing education for personnel with respect to the policy; and providing administrative support and legal assistance to the IRB.

**5. Procedures**

5.1 Researchers must submit an application for ethics approval to the IRB for all research involving human participants or animal subjects. The application must describe the proposed research in enough detail that the potential adverse effects and benefits to human participants or animal subjects can be evaluated. The IRB forms and procedures provide a means for researchers, subjects, the University and the community to communicate clearly and responsibly about the risks and benefits of research involving human participants or animal subjects. Copies of all IRB forms and corresponding documentation will be available through the Office of Research and Sponsored Programs.

**6. Guiding principles**

IRB reviews of ethics applications will consider the three fundamental ethical principles for conducting research involving human participants or animal subjects:

6.1 Respect for persons: Protecting the privacy, autonomy and dignity of all people and treating them with courtesy and respect and allowing for informed consent. Participants must be given sufficient information to make an informed decision about participation in the research and retain the right to withdraw their consent at any time during the process of research without a given reason and without facing adverse consequences.

6.2 Beneficence and non-maleficence: Upholding the principle of ‘do no harm’ while maximizing benefits for the research project and minimizing risks to the research participants.

6.3 Justice: Ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly such that there is a fair distribution of costs and benefits to potential research participants.

**7. Review process**

7.1 The review process uses the concept of minimal risk to decide the type of review warranted. Minimum risk means that the risks of harm anticipated from the proposed research are not greater than those ordinarily encountered in daily life or during performance of routine physical or psychological tests. Risks to participants and subjects are minimized by using procedures which are consistent with sound research design and, whenever appropriate, using procedures already being performed on participants for diagnostic, evaluative or other relevant purposes.

7.2 Research proposals submitted to the IRB are classified as requiring full review, requiring expedited review or being exempt from review. Researchers may propose the level of review they believe is appropriate, however the IRB Chairperson, in consultation with committee members if necessary, determines the level of review required.

**8. Full Review**

8.1 A Full Review is required for research proposals that involve more than minimal risk or that involve vulnerable populations or address sensitive topics. Examples of proposals requiring full review include the following: procedures that may result in threats to dignity, physical or emotional injury, legal liability or arrest or damage to financial or social standing; procedures that may result in participants experiencing stress beyond that of an everyday nature; procedures that pose physical danger to animal subjects; procedures that involve physically invasive methods; procedures that involve researchers manipulating participants’ behavior, attitudes or beliefs; projects that involve intentional deception such that misleading or untruthful information will be provided to participants; human genetic and stem cell research involving identified samples; procedures which would have negative impact upon pregnancy of a participant and/or a fetus; research with vulnerable populations such as children, prisoners, people with intellectual or physical impairments or people with a mental illness; research with participants who are highly dependent on medical care, unconscious or otherwise unable to consent; research intended or likely to study, expose or discover illegal activity; clinical trials or health related interventions involving the use of a substance, device or procedure which has not been registered or approved for use for this purpose in the UAE; research that is culturally or politically sensitive.

8.2 The research proposal is considered by all members of the IRB. Researchers may be required to meet with the IRB regarding their proposal. The IRB has the authority to approve, require modifications to secure approval of, or reject the application.

**9. Expedited Review**

9.1 An Expedited Review occurs when the research proposal does not require full review, involves no more than everyday risks to human participants or animal subjects, does not include intentional deception, does not involve vulnerable populations, does not address sensitive topics, does not collect data through physically invasive methods and includes appropriate informed consent procedures.

9.2 At least two members of the IRB, designated by the Chairperson, review the proposal. The IRB has the authority to approve, require modifications to secure approval of, or reject the application.

**10. Exemption from Review**

10.1 An Exemption from Review may be granted for research proposals that are of very low risk. Examples of such research include: research conducted in educational settings involving normal educational practices; research collecting anonymous data; research involving the collection or study of existing publicly available or anonymized data; taste and food quality evaluation and consumer acceptance studies.

10.2 One IRB member, designated by the Chairperson, reviews the proposal. The IRB has the authority to approve, require modifications to secure approval of, or reject the application.

**11. Time frame for Decision**

11.1 All reviews will normally be completed within 5-15 business days of receipt in the Office of Research and Sponsored Programs.

**12. IRB Reports**

12.1 Researchers are required to submit annual reports throughout the period of IRB approval. Researchers are required to submit a final report within one month of the conclusion of the approved research project.

**13. Proposed amendment to the IRB form:**

13.1 Include a series of questions that help determine which level of review is required.

**14. Student Research**

14.1 Student research activities are governed by both the requirements of good research and the regulations of the Abu Dhabi University IRB. Projects whose primary purpose is educational but which also are encompassed by the definition of research in the introduction, fall within the scope of this policy. If the project meets the criteria for expedited or full review above, it must be submitted to the IRB. It is the responsibility of faculty supervisors to ensure that the student conforms to this policy. Supervisors must indicate their approval of the IRB application prior to its submission to the IRB.

**15. Procedures for Appeal**

15.1 In the event a proposal is not approved at the exempt or expedited level, the researcher may request a full review of the protocol by the IRB.

16.1 The Principal Investigator has the primary responsibility for protection of individual participants or animal subjects. It is the Investigator's responsibility to comply with this policy. The IRB is the only body authorized to take action when a researcher is in noncompliance. 16.1.1 Failure to apply for ethics review to the IRB for research involving human participants or animal subjects;

16.1.2 Failure to conduct the research according to the approved protocol as it relates to the protection of human participants and animal subjects;

16.1.3 Failure to immediately notify the IRB when research activity results in an unexpected adverse impact on participants or subjects; and,

16.1.4 Failure to submit the required annual and/or final reports to the IRB in a timely manner.

16.2 Allegations of noncompliance (either written or oral) should be directed to the Chairperson of the IRB. The IRB will investigate allegations of noncompliance, maintaining confidentiality in all matters. Only voting members will participate in the investigation. In the event that allegations are substantiated, the IRB will terminate approval of the research, if applicable, and recommend to the Associate Provost that the research be terminated. These decisions will be communicated to the researcher and the appropriate funding agency, if applicable, by the Associate Provost. A decision to terminate research may be appealed to the IRB within 15 days of notification.

**Procedures for Noncompliance**

Noncompliance includes:

**16. Research at ADU by Investigators from Other Institutions** 16.2 Researchers who are not affiliated with ADU may recruit ADU faculty members, staff members, or students as participants if approval has been granted by another IRB. Although such studies do not require the involvement of the ADU IRB, approval by instructors, academic unit administrators, or deans may be necessary. Faculty members or administrators who approve such studies should verify that the research protocol has received IRB approval. The applicant must submit the below to the IRB committee to get approval: 16.2.1 A copy of the approved application from the other institution.

16.2.2 Evidence that the study has ethics approval (i.e. the approval letter).

16.2.3 The approved participant information sheet and consent form

16.2.4 Submit information about the committee that approved the study, especially if it has been approved by a non-UAE institution.

**18. Benefits**

Application of this policy is a key enabler for faculty conducting human participant or animal subject research, and for supporting requests by external researchers to conduct human participant or animal subject research at Abu Dhabi University. Consequently, efficient and effective application of this policy makes a significant contribution to the university’s research performance.

**19. Implementation**

Any researcher wishing to conduct human participant or animal subject research must comply with this policy’s requirements, with its implementation managed by the Chair and committee members of the Institutional Review Board for Human Participant and Animal Subject Research Committee, reporting to the Research Innovation and Impact Committee.

**20. Roles and responsibilities**

The Chair of the Institutional Review Board for Human Participant and Animal Subject Research Committee is primarily responsible for managing the implementation and operation of this policy and will, as a standing member of the Research, Innovation and Impact Committee, monitor and report the ongoing implementation of this policy.

**Exceptions**

The Chancellor reserves the right to decide on any situation/circumstances outside the conditions stated in this policy.

Footnotes: Allegations of Research Misconduct Policy University Research Support Policy; Conflict of Interest Policy.