Policy Title	Rules and Regulations of Research Involving Human Subjects
Responsible AIU Office (Higher Management/Directorate)	Office of Research Integrity and Assurance (ORIA)
Policy Owner (Executive Department/Office)	Office of the Vice President for Research
Pertinent Dates	This policy will become effective upon the date of approval by the Vice President for Academic Affairs and University President

I. SCOPE OF POLICY

Alamein International University is committed to performing research with humans in an ethical manner that is compliant with regulatory requirements. This policy sets forth the principles and responsibilities for research projects involving human subjects.

This policy covers all faculty, staff, and students (both graduate and undergraduate) intending to conduct research using living individuals or pre-existing data containing identifiable private information about living people. This policy applies to research funded by any source as well as unfunded research.

II. DEFINITIONS

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Systematic investigation is defined as an attempt to answer research questions using a methodological approach, incorporating data collection (both quantitative and qualitative) and data analysis, and permitting conclusions to be drawn.
"Interaction" includes communication or interpersonal contact between an investigator and a research subject.

"Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It also includes

information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for the acquisition of the information to constitute research involving human subjects.

III. POLICY STATEMENT

AIU is committed to the ethical conduct of research, and strives to adhere to the highest ethical standards for the protection of human subjects, consistent with the principles of the Nuremberg Code and the Belmont Report.
This policy applies to all research involving human subjects performed by or under the direction of University faculty, staff, students or other trainees in connection with their University affiliations; or involving use of non-public individually identifiable information created or maintained by the University; in University facilities or using University resources.

IV. RESPONSIBILITIES

A. President and Vice President for Research

In instances of an IRB finding of serious and/or continuing noncompliance the President and Vice President for Research is the ultimate decision maker about University administrative actions.

B. Assistant Vice President, Office of Research Integrity and Assurance

The Assistant Vice President, Office of Research Integrity and Assurance directs the Office of Research Integrity and Assurance, establishes who may determine a human subjects research project to be exempt, and manages allegations of research being conducted contrary to this policy. The Assistant Vice President is the Institutional Signatory Official. The Assistant Vice President appoints and removes IRB members, approves and cancels authorization agreements for the IRB, and provides support for the IRB. In instances of an IRB finding of serious and/or continuing noncompliance, the Assistant Vice President, Office of Research Integrity and Assurance will provide recommendations for administrative actions to the Vice President for Research and Provost.
The Assistant Vice President, ORIA is to determine in consultation with the Vice President for Research if an approval from an additional Egyptian government agency, such as for example the Egyptian Drug Agency, is needed before conducting the proposed research.

C. Institutional Review Board (IRB)

The Institutional Review Board reviews all covered research (through expedited and full board procedures specified in the Standard Operating Procedures). The IRB will approve covered research only if it meets the following requirements:

risks to subjects are minimized
risks are reasonable in relation to anticipated benefits
selection of subjects is equitable
informed consent is obtained or appropriately waived from all prospective subjects
subjects' privacy is protected and the confidentiality of data is maintained

appropriate safeguards are incorporated for any vulnerable subjects.
The Institutional Review Board may approve protocols, require modifications to secure approval, disapprove protocols, and suspend or terminate approval of research. Any suspension or termination of approval due to serious and/or continuing noncompliance shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and the Assistant Vice President, Office of Research Integrity and Assurance.

The board also conducts continuing reviews of approved research, reviews proposed amendments, adverse events, protocol deviations, and matters of non-compliance.

Neither the IRB nor ORIA has the authority to take disciplinary action against any individual relating to noncompliance. Findings of noncompliance that are neither serious nor continuing will be referred to appropriate administrative units, as described in the Noncompliance/Deviation SOP.

D. IRB staff in the Office of Research Integrity and Assurance (ORIA)

The IRB staff in the ORIA office administratively manage the human subjects protection program. This involves serving as a resource for education and information, developing and distributing SOPs, maintaining communication mechanisms such as the website, providing guidance and feedback to investigators, providing administrative support to the IRB, researchers, and administration, and conducting quality assurance activities.

E. Individuals Conducting Research

All individuals conducting research with human subjects have an obligation to follow protocols as described to the IRB, ensure all subjects enrolled in research provide informed consent (unless altered or waived), and report protocol deviations and unanticipated problems to the IRB/IRB staff in the ORIA office. All projects must have a Principal Investigator ultimately responsible for the design, conduct, and reporting of the project and responsible for oversight of the research tea

V. POLICY STANDARDS AND PROCEDURES

All research activities involving humans as subjects must provide for the safety, health and welfare of every individual. Additionally, all legal rights, including the right to privacy, must not be infringed. The direct or potential benefits to the subject or the importance of the knowledge to be gained must outweigh the potential risks to the individual. No human subject can participate in a research project until the IRB has approved the research protocol and written informed consent has been obtained from the subject. All activities related to research should adhere to Egyptian laws and regulations including (prime minister decree number 927 for the year 2022) or whatever latest revisions substituting it.

The Principal Investigator has the obligation of safeguarding information obtained as part of a research project. Principal Investigators are responsible for the IRB application, training for the research protocol, research activities, supervision of human subjects, and reporting any changes to the IRB, as well as unanticipated consequences from the research.

At a minimum, all human subjects research performed at the AIU or using its resources will meet the following requirements:

RESPECT FOR PERSONS

A. Research protocols must say how subjects will be recruited.
B. Subjects must freely agree to participate after receiving complete information about the research and its risks, potential benefits and alternatives.
C. Subjects must fully understand their rights including the right to discontinue at any time without loss of otherwise available benefits.
D. Vulnerable populations (fetuses, children, prisoners, those without decisional capacity, and those with economic or educational vulnerability) must receive special consideration and protection.

MINIMIZING RISKS AND AVOIDING UNREASONABLE RISKS

A. Research may not expose subjects to unreasonable risk of harm (whether physical, psychological, social, legal or economic in nature).
B. The probability and magnitude of possible harm must be reasonable in relation to the anticipated direct or indirect benefits of participation in any research project.
C. Identifiable risks that practicably could be avoided without undermining legitimate research objectives must be eliminated.
D. Sound research designs that minimize risks and maximize benefits of participation must be used.

EQUITABLE RECRUITMENT AND SELECTION OF SUBJECTS

A. Research protocols must promote equitable recruitment and selection of subjects, as applicable, with the overall goal of ensuring fair distribution of the burdens and benefits of research. Subjects should be selected for participation for reasons directly related to the questions under study.
B. Subjects must not be induced to participate in research projects by means or under circumstances that may overcome the voluntary nature of their participation. Enrollment into a study may never be the product of coercion or undue influence.

INVESTIGATOR QUALIFICATIONS AND RESPONSIBILITIES

A. Research must be performed or closely supervised by individuals qualified by training and/or experience to minimize risks and otherwise protect subjects. When research is performed by students, supervising faculty members are responsible to ensure that the students are qualified to conduct the research and to safeguard subject rights and welfare.
B. Primary responsibility for research with human subjects is vested in the principal investigator conducting a study. This includes responsibility to comply with the laws, regulations, and institutional policies that regulate research. Others engaged in the conduct of the research such as co-investigators and research staff share this responsibility. The PI must assure that all study team members are appropriately trained to the protocol or study procedures.
C. Investigators must follow institutional policy for initial submission and approval of proposals, continuing review, amendment to the study, and reporting of unanticipated problems and adverse events. Investigators are responsible for informing IRBs of existing knowledge of any risks

involved in participating in a study at the time of initial review and for apprising IRBs of any new risks identified during the course of the study.

D. Investigators must explain to subjects, prior to their participation in research projects, the objectives of the research, the procedures to be followed, the risks and potential benefits of participation, and alternatives to participation; as well as funding sources and conflicts of interest, where applicable. individuals may participate as a subject only after voluntarily consenting to participation and must be made aware of their right to withdraw without risking benefits or services to which they otherwise would be entitled. In addition, in most cases, investigators will obtain the assent of subjects, such as minors or mentally incapacitated individuals, before participation. Investigators are responsible for ascertaining that subjects consenting or assenting to research actually comprehend the information provided to them before enrolling them in studies and that subjects are aware of their right to ask questions about the research before, during and after participation. IRBs may waive some of these consent requirements only in limited circumstances.
E. Investigators must respect the privacy of subjects participating in their protocols and implement safeguards to protect the confidentiality of data gathered for the research.

Training

AIU requires completion of training determined by ORIA on the protection of human subjects and the ethical principles of research for all human subject research, regardless of whether or not investigators have received funding to support their project. This training is mandatory for all faculty, staff, and students who conduct/supervise research involving human subjects whether on campus or off-campus, whether funded or unfunded.

Conflict of Interest:

Conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. This definition applies to any IRB member or his/her immediate family member (within the second degree of affinity or third degree of consanguinity). An IRB member who has a conflict of interest, or a perceived conflict of interest, in any research application must recuse himself or herself from the vote and must disclose the conflict of interest. If a quorum is present without the recused member, a vote can proceed. Otherwise, an alternate IRB member must be present to proceed to a vote. No individual conducting and/or supervising a specific project can participate in IRB review of the proposal, except to provide information.

Informed Consent:

A subject's informed consent must be obtained through methods that are consistent with the Egyptian law or its latest amendment(prime minister decree number 927 for the year 2022). An individual does not abdicate any rights by consenting to serve as a research subject. A human subject has the right to withdraw from a research project at any time or can refuse to participate; in either case, the subject must not experience any loss of benefits for withdrawing from a research project. Further, a human subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information, and to be free from undue embarrassment, discomfort, anxiety or harassment. Consent must be voluntary and must be given without coercion or undue influence. This includes provisions for payments or other incentives to participate in a research study. The information provided to the subject or to the subject's legally authorized representative must be in simple, easily understood

language. If the human subject does not understand Arabic, the informed consent must be presented in the appropriate language.
Informed consent cannot waive or limit a human subject's legal rights, including any release of the institution or its agents from liability for negligence. Requirements and guidelines for informed consent can be obtained from the ORIA website.

Exempted Research

All qualifying research with human subjects, as defined in this document, must be reviewed by the IRB. A Principal Investigator cannot claim exempt status in order to bypass IRB review. The IRB is responsible for determining whether a research project falls within one of the exempted categories as defined in this document,

Expedited Review

Certain research projects may be eligible for expedited review. In making this determination, the research protocol will be reviewed by the IRB chair and/or experienced IRB members selected by the chair. All members of the IRB will be advised on research proposals that have been approved under expedited review at each IRB committee meeting.

Full Review Research

Full review research protocols that include any protected populations must be reviewed by the full IRB committee. Protected populations include prisoners, children (unless the study is normal educational practice), employees, terminally ill subjects, AIDS/HIV subjects, human fetuses, and neonates. The IRB committee may reject the application, accept the application with minor revisions, or request significant changes with the request for an additional full committee review.

IRB Membership

In keeping with the university Regulations, the AIU IRB must:

1- have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted under the authority of the AIU IRB. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. Since the IRB may review research that involves vulnerable categories of subjects (such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantage persons) consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

2- include at least one member who is qualified as a scientist and one member who is qualified as a non-scientist. A non-scientist member are required for quorum at all meetings convened with the full IRB.

3- include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

4- ensure that no members will participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The IRB may at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available in the IRB membership. These individuals may not vote with the IRB.
Other considerations: The IRB can have as many members as necessary for it to perform its duties effectively. The appointing authority should ensure that it does not become so large that its management becomes cumbersome.

The chair of the IRB should be a highly respected individual from within the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community falls primarily on the shoulders of this individual. The IRB must be and must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources. The chair may designate other IRB members to perform duties, as appropriate, such as reviews, signature authority, or other IRB functions.
The IRB members and the chair are appointed by the Vice President of Research. IRB members who are faculty should be tenured, so as to avoid pressure or influence from more senior faculty or administrators. Due to the level of experience and relevant expertise needed to perform IRB duties, there are no term limits for IRB members, and they will continue to serve as long as they demonstrate knowledge of regulations, an understanding of the application of the ethical principles, and have time available to devote to the associated responsibilities. The Vice President of Research will conduct annual reviews of the chair, IRB members, and IRB composition and will determine and seek action if a conclusion is made that a member's participation should be discontinued. If it is necessary to add new or replace exiting members, several methods are used to identify candidates: the existing members may be asked to provide recommendations; faculty with expertise in areas specific to the types of projects reviewed may be contacted directly; open calls will be announced via campus websites and distributed emails; interested persons may contact the Vice President of Research to express interest; or the Vice President of Research may identify and recruit potential members.
The IRB should meet at least once per quarter during the academic year.

VI. FORMS/INSTRUCTIONS (if applicable)

IRB Application Forms by Protocol Type
Expedited/Full Board
Exempt
Not Human Subjects Research
Informed Consent Templates

VII. APPENDICES (if applicable)

[This section includes any additional relevant information or documents in attached appendices.]

VIII. RELATED POLICIES

1. Research Ethics and Scientific Integrity Policy
2. Experimental Animal Care and Use Policy
3. Rules and Regulations of Research Involving Human Subjects

VIV. CONTACT INFORMATION

[Lists relevant position titles and/or offices who may be contacted by University community members for any questions about the policy.]

Triggered by:	Name	Date	Sig.
Created by:	Name	Date	Sig.
Revised by:	Name	Date	Sig.
Approved by:	Name	Date	Sig.

Benchmarks

California Polytechnic State University Policy for the Use of Human Subjects in Research
https://research.calpoly.edu/HS-policy

George Mason University Standard Operating Procedures for research with humans
https://universitypolicy.gmu.edu/policies/research-involving-human-subjects/

Northeastern University Policy on Human Subjects Research
https://research.northeastern.edu/app/uploads/sites/4/2019/05/Policy_on_Human_Subjects_Research.pdf

Stephen Austin University Guiding Principles to the Ethical Use of Human Research Subjects
https://www.sfasu.edu/researchcompliance/103.asp

University of Michigan Policy for Research with Human Participants
https://spg.umich.edu/policy/303.05

قرار رئيس مجلس الوزراء رقم ٩٢٧ لسنة ٢٠٢٢ باصدار اللائحة التنفيذية لقانون تنظيم البحوث الطبية الإكلينيكية.
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