AIU AMERICAN INTERNATIONAL UNIVERSITY الجامعة الأمريكية الدولية	Policy Main Title	Research Ethics and Human Subjects Protection Policy	Effective Date	14/06/2026
	Policy Subject	Research	Last Review date	
	Policy Number	RES-002	Next Review date	14/06/2029
	Responsible Entity	Assistant VP Research	Approved By	President

Overview

Research ethics governance exists for one reason: to ensure that the pursuit of knowledge does not come at the cost of the rights, welfare, safety, and dignity of the people and animals who participate in or are affected by research. This is not a regulatory obligation that institutions tolerate; it is a foundational commitment of the scientific and scholarly enterprise. AIU's commitment to research and scholarly activity under RES-001 is only credible if it is matched by an equally serious commitment to ensuring that research at AIU is conducted with the highest ethical standards.

The international framework for research ethics has been shaped by events that should never be forgotten. The Nuremberg Code (1947), adopted in direct response to atrocities committed in the name of medical research, established informed consent as a non-negotiable foundation of ethical human research. The Declaration of Helsinki (first adopted 1964, most recently revised 2013 by the World Medical Association) extended that framework into a comprehensive set of principles governing biomedical research with human participants. The Belmont Report (1979) added the philosophical framework of respect for persons, beneficence, and justice. The CIOMS International Ethical Guidelines for Health-Related Research Involving Humans (2016) provide the most directly applicable international framework for institutions operating outside the United States in contexts without a domestic equivalent of the US Common Rule.

AIU's adoption of a research ethics policy aligned with the Declaration of Helsinki (2013) and the CIOMS Guidelines (2016) is not simply accreditation requirement: it is the exercise of institutional responsibility.

This policy covers both human subjects research and animal research because these are ethically related domains, both involve the use of living beings for the advancement of knowledge, both require that the benefit of the research be weighed against the risks to participants, and both require institutional oversight through a qualified independent review body. AIU adopts the integrated approach, with the Research Ethics Committee having jurisdiction over both domains, engaging specialist expertise as required for animal research protocols.

Scope

This policy applies to all research and scholarly activity conducted under AIU's auspices that involves: living human participants; data, specimens, or records from which living human beings could be identified; living animals; or any combination of the above. It applies to all faculty, staff, students, researchers, and contractors who conduct such research at AIU or under AIU's institutional sponsorship, regardless of whether the research is funded by AIU's internal Research Fund, by an external grant, or is unfunded. It applies to research conducted at AIU's facilities, at external facilities under collaborative arrangements with AIU, and to online and remote research activities conducted by AIU researchers. It does not apply to research involving solely publicly available, fully de-identified data or to research on anonymous survey responses where no identifiable information is collected

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Purpose

The purposes of this policy are to:

- Establish the Research Ethics Committee (REC) as AIU's standing institutional body responsible for review and approval of research involving human participants and animals
- Define the three-tier review framework (Exempt, Expedited, Full Board) through which research proposals are categorized and reviewed
- Establish the foundational ethical principles governing all research involving human participants at AIU, consistent with the Declaration of Helsinki (2013) and the CIOMS International Ethical Guidelines (2016)
- Establish the animal welfare standards governing research involving animals at AIU, consistent with the 3Rs framework (Replace, Reduce, Refine) as the internationally accepted benchmark
- Define the requirements for informed consent in research involving human participants, including the specific requirements for research involving vulnerable populations
- Establish the requirements for research data protection and confidentiality
- Define the protocol deviation and adverse event reporting requirements
- Establish the annual assessment and reporting cycle through which the REC's performance and institutional research ethics compliance are evaluated
- Demonstrate compliance with honest and ethical institutional operations and ethical conduct of scholarly activity as a component of research quality

Abbreviations and Definitions

Research Ethics Committee: AIU's standing institutional body responsible for the independent ethical review and approval of research involving human participants and animals. Functionally equivalent to an Institutional Review Board (IRB) as used in US institutions and an Independent Ethics Committee (IEC) as used in clinical research under ICH Good Clinical Practice guidelines.

Human Participants Research: Any systematic investigation designed to develop or contribute to generalizable knowledge that involves living human beings as subjects, including: collection of data, biospecimens, or records through interaction with individuals; research using data derived from individual persons; observational research; survey and interview research; educational and psychological research; and quality improvement activities designed to contribute to generalizable knowledge.

Informed Consent: The voluntary, affirmative agreement of a competent individual to participate in research, given after they have received and understood adequate information about the purpose, procedures, risks, potential benefits, alternatives, and their rights as a research participant. Informed consent is a process, not merely the signing of a form. Where a participant cannot give their own consent (minors, cognitively impaired individuals), consent from a legally authorized representative is required, together with assent from the participant where they are capable of expressing a preference.

Minimal Risk: The probability and magnitude of harm anticipated in the proposed research is not greater, in and of itself, than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests. Minimal risk is the threshold that determines whether Exempt or Expedited review (rather than Full Board review) is applicable.

Vulnerable Population: A group of individuals whose circumstances may limit their ability to exercise autonomous decision-making about research participation, including minors, individuals with cognitive impairments, prisoners, pregnant women, individuals experiencing significant financial hardship, students in a dependent relationship with the researcher, and any other population that the REC determines warrants additional protections in a specific research context.

Institutional Assurance: The formal undertaking by AIU that research conducted under its auspices will be governed by this policy and the ethical standards it incorporates. The institutional assurance is the basis on which AIU researchers can represent to external funders, journals, and collaborating institutions that their research was conducted with institutional ethics oversight.

3Rs Framework: The internationally accepted framework for the ethical use of animals in research: Replace (use non-animal alternatives wherever scientifically feasible); Reduce (use the minimum number of animals necessary to achieve statistically valid results); Refine (design procedures to minimize pain, distress, and suffering).

Protocol Deviation: Any change to, or departure from, an approved research protocol that occurs without prior REC approval. A protocol deviation may be: minor (not expected to affect participants' safety or the integrity of data) or major (has or could have affected participants' safety or the integrity of data). Both categories must be reported to the REC; major deviations require immediate reporting.

Adverse Event: Any unexpected, undesirable experience that affects a research participant or that creates significant risk to participants or others during the conduct of an approved research protocol. Adverse events must be reported to the REC within the timeline specified in Article 9 of this policy.

Declaration of Helsinki: The World Medical Association's (WMA) foundational statement of ethical principles for medical research involving human subjects. First adopted in 1964 and most recently revised in 2013. The Declaration is the primary international reference for human subjects research ethics at institutions.

CIOMS Guidelines: The International Ethical Guidelines for Health-Related Research Involving Humans, published by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization.

Policy

Article 1: Governing Principles

All research involving human participants or animals conducted at AIU or under AIU's institutional sponsorship is governed by the following principles, derived from the Declaration of Helsinki (2013), the CIOMS Guidelines (2016), the Belmont Report (1979), and the 3Rs Framework for animal research:

a. Respect for persons: Every research participant is an autonomous individual whose right to self-determination must be honored. Informed consent is the institutional expression of that right. Where a participant cannot exercise autonomous consent, their interests are protected by requiring consent from a legally authorized representative and assent from the participant where possible. The obligation of respect for persons is not diminished when research is conducted remotely, online, or with secondary data.

b. Beneficence: Research must be designed to produce benefits, to the individual, to the community, or to knowledge, that are proportionate to and justify the risks it imposes on participants. The

REC evaluates the risk-benefit ratio of every protocol it reviews. Research that imposes significant risk on participants in order to generate knowledge of minimal value does not satisfy this principle.

c. Non-maleficence: Researchers have an obligation to do no harm. Where harm is unavoidable, it must be minimized. This obligation applies with particular force to research involving vulnerable populations and to animal research, where the participant cannot evaluate or consent to the risks they face.
d. Justice: The benefits and burdens of research must be distributed fairly. Vulnerable or disadvantaged populations must not bear a disproportionate share of the risks of research that will primarily benefit others. Selection of research participants must be based on scientific criteria, not convenience or the relative powerlessness of a particular group.
e. Scientific validity: Research that is scientifically invalid, poorly designed, using inappropriate methods, or incapable of generating reliable knowledge, cannot be ethically justified, because it exposes participants to risk without the compensating possibility of producing genuine benefit. The REC evaluates the scientific soundness of every protocol as an ethical question, not merely a methodological one.
f. Transparency and honesty: Researchers must represent their research accurately to participants, to the REC, and to the scientific community. Deception is permitted in limited circumstances where it is scientifically necessary and where adequate debriefing provisions are in place, and then only with explicit REC approval.
g. Independence of the REC: The Research Ethics Committee must exercise its review function free from institutional, political, commercial, or collegial pressure. The REC's determination on any protocol is a professional ethical judgment, not a service to researchers. The AVPR supports the REC's independence and does not direct its decisions.

Article 2: The Research Ethics Committee

AIU establishes the Research Ethics Committee (REC) as a standing institutional body with the authority and responsibility to review, approve, conditionally approve, require modification of, or reject research protocols involving human participants and animals. The REC has the following governance characteristics:

Member Category	Number	Qualifications and Selection
Core Members (Permanent)		
REC Chair	1	Senior faculty member (Associate Professor or above); demonstrated research ethics expertise; no active grant applications before the REC; appointed by the AVPR for a

		two-year renewable term; may not be the Director of Research and Grants
Faculty Members from AIU Schools	At least 3	Full-time faculty representing at minimum three different Schools; appointed by AVPR for two-year staggered terms to ensure continuity; members with expertise in biomedical, social science, and humanities/education research are prioritized
External Member ethics, law, or community	At least 1	Individual not affiliated with AIU as a faculty member or administrator; expertise in ethics, law, or community representation; demonstrates no conflict of interest with AIU's research program; appointed by President on recommendation of AVPR for a two-year term. Required by international REC/IRB standards including the Declaration of Helsinki and the Belmont Report framework
Non-Scientist / Lay Member	At least 1	Individual whose primary area of expertise is in a non-scientific domain; provides the perspective of research participants; may overlap with the external member appointment where the external member satisfies both criteria. Required by international IRB standards
Resource Persons (not standing members attend by invitation)		
Legal Counsel	As required	Engaged by the Director of Research and Grants for applications with significant legal complexity, including research involving personal health data under Kuwait data protection law or research with potential dual-use implications
Animal Care Expert	As required	Engaged for Full Board Review of animal research protocols; must hold relevant veterinary or animal welfare qualifications

Subject Matter Expert	As required	Engaged for applications requiring specialized disciplinary knowledge not represented among standing members; serves as reviewer only, not a voting member

2.1 Independence and Conflict of Interest

The REC exercises its functions independently of the research interests of any individual researcher, School, or external funder. Every REC member completes a Conflict of Interest Declaration before reviewing any protocol. A member with a conflict of interest in a specific protocol, including prior collaboration with the PI, supervisory relationship with student researchers, or financial interest in the research, is recused from that protocol's review and does not vote. The REC Chair confirms recusal decisions; where the Chair has a conflict, the AVPR designates an alternate chair for that protocol.

2.2 Quorum and Decision-Making

A quorum for REC decisions consists of the REC Chair and at least three voting members, provided that the quorum includes at least one non-scientist or lay member and at least one member without an active research relationship with the applicant. Full Board Review decisions require a quorum of at least five members. Decisions are made by majority vote of members present and eligible to vote. The REC Chair has a casting vote in the event of a tie. All decisions are communicated to researchers in writing with a statement of reasons within the standard timelines in Article 4.

2.3 Reporting Line

The REC Chair reports to the AVPR. The REC's annual report is submitted to the AVPR, who presents a summary to the President. The REC does not report to the Director of Research and Grants on substantive ethical review matters, the Director of Research and Grants provides administrative support and coordination but exercises no authority over the REC's determinations.

Article 3: Scope of Required Review

The following categories of research require REC review before commencement. No AIU researcher, faculty member, student, or contractor may commence research falling into these categories without a valid REC approval letter or documented Exempt determination:

- Any research involving living human participants, including surveys, interviews, observations, questionnaires, focus groups, and experimental interventions
- Any research involving data, records, or specimens collected from living human beings in a form that could be used to identify the individuals
- Any research involving secondary analysis of existing datasets that contain identifiable human data, even where the researcher did not collect the original data
- Any research involving living animals

- Any research involving human genetic material, biospecimens, or health records
- Any research where deception of participants is proposed
- Any quality improvement, program evaluation, or needs assessment activity that is intended to contribute to generalizable knowledge (as distinct from evaluation conducted solely for internal institutional improvement that will not be published or shared externally)

The following research activities are not within the scope of required REC review, provided they meet the stated conditions:

- Research involving solely publicly available, fully de-identified data where no living individual could be identified from the data
- Case studies, journalistic activities, and artistic works that do not constitute systematic investigation designed to develop generalizable knowledge
- Routine educational testing, survey research, or observation of public behavior where researchers do not participate in the activities being observed and where participants' responses or identities would not reasonably place them at risk

Where a researcher is uncertain whether their proposed activity requires REC review, they contact the Director of Research and Grants for a pre-submission consultation. The Director of Research and Grants provides a written determination, which the researcher retains as documentation. This determination does not substitute for a formal REC Exempt determination where Exempt review is required.

Article 4: Three-Tier Review Framework

AIU's REC applies a three-tier review framework. The tier determines the intensity of review and the timeline:

Review Category	Criteria: Research Qualifies for This Category When	Typical Processing Time
Exempt Review	The research presents no more than minimal risk to participants AND falls within one or more of the following categories: (1) Research involving educational practices in established educational settings; (2) Surveys, interviews, or observations where responses are recorded anonymously and no sensitive topics are involved; (3) Research on existing data, documents, or records that are publicly available or de-identified; (4) Research involving the collection or study of existing data, specimens, or diagnostic specimens in a manner such that subjects cannot be identified	10 working days from complete submission

Expedited Review	The research presents no more than minimal risk to participants AND involves procedures that present no more than minimal risk and are listed in one or more of the following categories: (1) Collection of data using non-invasive procedures routinely employed in professional practice; (2) Collection of data through verbal or written responses to surveys or interviews where responses may be recorded in identifiable form but the risk of harm is low; (3) Research involving observational methods in settings where the researcher does not participate in activities being observed; (4) Analysis of existing data or biospecimens that contain identifiable information but the research team is experienced and the privacy safeguards are robust	15 working days from complete submission
Full Board Review	The research does not qualify for Exempt or Expedited Review, including: (1) Research involving more than minimal risk to participants; (2) Research involving vulnerable populations, minors, pregnant women, prisoners, individuals with cognitive impairments, students in a dependent relationship with the researcher, economically disadvantaged individuals; (3) Research involving sensitive topics, sexual behavior, substance use, illegal activity, mental health, significant personal distress; (4) Research involving deception where participants are not fully informed of all aspects of the research; (5) Research involving biospecimens, genetic information, or health records; (6) Research involving animals; (7) Any research where the REC Chair determines that Full Board Review is warranted	30 working days from complete submission — subject to meeting schedule

Article 5: Informed Consent Requirements

5.1 General Requirements

Informed consent is required for all research involving human participants, except where the REC grants a specific waiver of consent in accordance with Article 5.3. Consent must be obtained before any research activities begin. The consent process is the researcher's responsibility. Consent obtained under duress,

coercion, or undue influence is not valid. The following elements must be present in all informed consent processes:

a. A clear statement that the study involves research and an explanation of the purpose of the research
b. A description of the procedures involved and the expected duration of the participant's involvement
c. A description of any foreseeable risks or discomforts to the participant
d. A description of the potential benefits to the participant or to others that may reasonably be expected from the research
e. A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the participant, where applicable
f. A statement describing the extent to which confidentiality of the records identifying the participant will be maintained
g. A clear statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty
h. Contact information for the researcher and for the REC, so that the participant may ask questions about the research or their rights as a participant

5.2 Vulnerable Populations

Where research involves vulnerable populations, the additional protections specified in the following table apply:

Vulnerable Population Category	**Principal Risk Requiring Mitigation**	**Required Additional Protections**
Minors (under 18)	Limited legal capacity to provide informed consent; power differential with adult researcher; potential for undue influence by parents or guardians	Parental or guardian consent required in addition to minor assent for children aged 7 and above; assent forms must be age-appropriate; REC must confirm that research cannot be conducted with adults; Full Board Review required
Students in a dependent relationship with the researcher	Undue influence arising from the researcher's authority over the student's grades, degree progress, or employment	Participation must be genuinely voluntary with no academic penalty for non-participation; wherever possible, data collection is managed by a researcher not in authority over the

		participants; Expedited or Full Board Review required
Individuals with cognitive impairments	Diminished capacity to provide meaningful informed consent; potential for exploitation	Assessment of decision-making capacity required before enrolment; consent obtained from legally authorised representative; participant assent also sought; Full Board Review required
Pregnant women and foetuses	Risk to the fetus; potential for pressure on the woman during pregnancy	Research must present no more than minimal risk to the fetus; consent process must acknowledge pregnant status without stigma; Full Board Review required
Economically disadvantaged individuals	Risk that compensation or other benefits create undue inducement to participate against the person's genuine interests	Compensation must be fair and proportionate, not so large as to constitute undue inducement; REC evaluates compensation levels; Expedited or Full Board Review required
AIU faculty in research conducted by AIU colleagues	Collegial pressure or hierarchical relationships may compromise voluntariness	Participation must be genuinely voluntary; anonymity preserved where possible; disclosure to the REC of the relationship between researcher and potential participants

5.3 Waiver or Modification of Consent

The REC may waive or modify the requirement for written informed consent only where all of the following conditions are satisfied:

a. The research involves no more than minimal risk to the participants
b. The waiver or modification will not adversely affect the rights and welfare of the participants
c. The research could not practicably be carried out without the waiver or modification
d. Where appropriate, the participants will be provided with additional pertinent information after their participation (debriefing)

Waivers of consent for research involving deception are subject to additional conditions: the deception must be scientifically necessary (i.e. knowledge of the true purpose would invalidate the research), participants must be debriefed at the conclusion of their involvement, and participants must be given the opportunity to withdraw their data after debriefing. Research that involves deceptive procedures always requires at minimum Expedited Review and typically Full Board Review.

Article 6: Data Protection and Confidentiality

Research involving personal data is also governed by ADM-002 (Privacy and Personal Data Protection Policy). The following provisions specific to the research context apply under this policy:

a. Research data that could be used to identify individual participants must be stored securely, with access limited to authorized members of the research team. Data security measures must be specified in the REC application and approved before data collection begins.
b. Where research data is stored electronically, the data security measures must comply with ADM-003 (Information Systems and Technology Governance Policy), including data classification as Confidential or Restricted under the four-tier framework and appropriate encryption requirements.
c. Identifiable research data must not be entered into public AI tools, consistent with ACA-006 (Artificial Intelligence Use Policy) Article 6. Where AI tools are used in data analysis, the CIO must confirm that the tool meets the data protection requirements for the classification level of the data before use.
d. Research data must be retained for the minimum period required by applicable funder requirements, Kuwait law, and institutional policy, and then securely destroyed. The minimum retention period for research data at AIU is five years from the conclusion of the project. Data that is the basis of published research must be retained for the duration of the reasonable accountability period for that publication.
e. Where research involves personal health information, the additional obligations in Kuwait Law No. 25 of 1981 on the Organization of Medical Professions (as amended) and any applicable Ministry of Health regulations apply. The researcher must confirm compliance with these obligations in the REC application.
f. Research participants have the right to withdraw their data from the study at any time before the data is irreversibly anonymized or published. The researcher must explain this right in the consent process and must have a mechanism in place for participants to exercise it.

Article 7: Animal Research Requirements

AIU currently has limited capacity for animal research and anticipates that most animal research involving AIU faculty will be conducted at collaborating institutional facilities. Regardless of whether the research is conducted at AIU or at an external facility, AIU's Research Ethics Committee must review and approve any animal research protocol involving an AIU-affiliated researcher. The following standards govern all such research:

Standard	Requirement at AIU
3Rs Mandatory Application	All proposals involving animals must demonstrate consideration of the 3Rs before the REC will approve a protocol: Replace (has the researcher considered whether the scientific objective can be achieved without animal subjects, using cell cultures, computer models, or other alternatives?); Reduce (is the number of animals proposed the minimum statistically adequate to address the research question?); Refine (have the procedures been designed to minimize pain, distress, and suffering to the greatest extent consistent with the scientific objectives?)
Species and strain justification	The researcher must justify in the application why the specific species, strain, and number of animals selected are scientifically necessary for the research objectives. A general statement that 'animals are needed' is not sufficient. The REC evaluates whether the choice of species is appropriate and whether the number proposed is consistent with the 3Rs principle of reduction
Sourcing and procurement	Animals used in AIU-affiliated research must be sourced from suppliers who can demonstrate compliance with relevant animal welfare standards. Where research is conducted at an external facility under a collaborative agreement, the researcher must confirm that the facility's animal care program meets standards equivalent to AIU's requirements under this policy
Pain and distress minimization	Researchers must employ the most humane methods available consistent with the scientific objective. Procedures likely to cause pain or distress must include a plan for pain management. Where pain cannot be avoided, the researcher must justify why it is necessary and demonstrate that the level of pain is the minimum required
Anesthesia and analgesia	Appropriate anesthesia must be used for all surgical procedures. Analgesia must be used post-procedure unless there is a specific scientific justification for its omission, approved by the REC. The use of these agents must follow current veterinary guidelines. Paralytic agents must not be used without anesthesia

Housing and care	Animals in AIU-affiliated research must be maintained in housing that meets their physiological and behavioral needs, including appropriate space, environmental enrichment, social housing where species-appropriate, and veterinary care. Where research is conducted at an external facility, the researcher confirms compliance in the ethics application
Euthanasia	Where euthanasia is required, the method must be the most humane available consistent with the scientific objective and must follow guidelines established by recognized veterinary authorities. The method must be included in the approved protocol; unapproved euthanasia methods constitute a protocol deviation requiring immediate REC notification

Article 8: Review Process and Application Requirements

A researcher who wishes to conduct research requiring REC review submits a complete application package to the Office of Research and Grants, which coordinates receipt, completeness checking, and forwarding to the REC Chair. The application package must include the following components, as applicable to the nature of the research:

a. Research protocol: A full description of the research objectives, methods, participant selection criteria (including inclusion and exclusion criteria), procedures, data collection instruments, analysis plan, and any risks to participants
b. Informed consent forms and participant information sheets, in the language or languages of the target participant population
c. Recruitment materials, including any advertisements, social media posts, or scripts for telephone or online recruitment
d. Data management plan: how identifiable data will be collected, stored, protected, and eventually disposed of
e. Conflict of interest disclosure: a declaration by the PI and all co-investigators of any financial, professional, or personal interest in the research outcome
f. For research involving vulnerable populations: the specific additional protections to be implemented as required by Article 5.2
g. For animal research: a completed 3Rs justification and all elements required by the animal welfare standards in Article 7
h. For research involving secondary data: documentation of the original data collection approval or the basis for de-identification
i. For research at an external facility: confirmation of the external facility's ethics approvals and the researcher's standing at the facility

Incomplete applications are returned to the researcher within five working days of submission with a written statement of the missing elements. The review timeline does not begin until a complete application has been received. The REC Chair determines the appropriate review category and assigns the application for review. The REC communicates its decision, approval, conditional approval, request for modification, or rejection, to the researcher and the Director of Research and Grants in writing within the timelines in Article 4.

REC approval is valid for one year from the date of the approval letter. Research that extends beyond one year requires annual renewal. Renewal applications are submitted to the REC at least 30 working days before the current approval expires and include a progress report on the research and confirmation that no unanticipated risks or problems have emerged.

Article 9: Protocol Deviations and Adverse Event Reporting

Approved protocols must be followed precisely. Where deviations occur or adverse events arise, the following reporting requirements apply:

a. Minor protocol deviation (not expected to affect participant safety or data integrity): The PI submits a written Protocol Deviation Report to the REC within 10 working days of the deviation occurring or being discovered. The REC Chair reviews and files the report; no retrospective approval is needed for a genuine minor deviation.
b. Major protocol deviation (has or may have affected participant safety or the integrity of data): The PI notifies the REC Chair by email within 24 hours of the deviation occurring or being discovered, followed by a full written Major Protocol Deviation Report within five working days. The REC Chair may convene an emergency session to determine whether the approval should be suspended or modified.
c. Adverse event: Any unexpected, undesirable event affecting a research participant must be reported to the REC Chair within 24 hours of the PI becoming aware of it. If the adverse event constitutes a serious risk to participant welfare, the PI must take immediate protective action (including suspending data collection if necessary) and notify the REC Chair simultaneously. The REC convenes within five working days to determine the appropriate institutional response.
d. Serious adverse events, major protocol deviations, and any suspension of an approved protocol are reported by the REC Chair to the AVPR and Director of Research and Grants within 48 hours of the REC's determination. The AVPR determines whether any external reporting obligations apply (to funders, collaborating institutions, or Kuwait health authorities).
e. A summary of all protocol deviations and adverse events in the preceding academic year is included in the Annual REC Report.

Article 10: Research Ethics Training

Research ethics is not self-evident and cannot be assumed. All researchers, faculty, graduate students, and other personnel who conduct research involving human participants or animals at AIU must complete

research ethics training before commencing research activities and must complete refresher training every three years thereafter. The following provisions govern training:

a. The Director of Research and Grants, in coordination with the REC Chair, designs or procures an appropriate research ethics training module covering: the principles in this policy; the Declaration of Helsinki and CIOMS Guidelines; informed consent in practice; recognition and reporting of protocol deviations and adverse events; data protection in research; and the 3Rs framework for animal research. Training content is reviewed and updated with each triennial policy review.
b. Completion of research ethics training is a condition for submission of a REC application. Where a researcher has not completed current training, the application is returned without substantive review until training completion is confirmed.
c. The Director of Research and Grants maintains training completion records and provides completion certificates for researchers who need to demonstrate compliance to external funders or collaborating institutions.
d. Researchers who have completed equivalent training at a recognized research institution within the preceding three years may request credit for that training from the REC Chair, who determines whether the external training satisfies AIU's requirements. The decision is documented in the research file.

Article 11: Assessment and Annual Reporting

The REC's performance and AIU's research ethics compliance are assessed annually using the following Key Performance Indicators:

KPI	Measurement	Target
REC protocol review turnaround	Average number of working days from complete submission to REC decision, by review category	Exempt: 10 days; Expedited: 15 days; Full Board: 30 days; achieved in >=90% of cases in each category
Research ethics compliance rate	Percentage of research projects active at AIU in any year that have a current, valid REC approval or a documented Exempt determination	100% of active human participants research and animal research with a valid REC record by Year 2
Protocol deviation reporting rate	Number of protocol deviations reported to the REC per year versus number estimated based on active protocols	Positive reporting culture confirmed through periodic researcher survey; zero instances of post-hoc identification of

	(deviation under-reporting is a research integrity concern)	unreported deviations in external audits
Annual REC training completion	Percentage of active researchers (faculty and graduate students engaged in research involving human participants or animals) who have completed the current-year research ethics training module	>=90% completion per year
Conflict of interest disclosure completeness	Percentage of REC applications that include a completed conflict of interest disclosure section	100% applications without a complete COI disclosure are returned to the researcher before substantive review
Annual REC Report	Whether the Annual REC Report was produced and submitted to the AVPR by 31 October	100% annual compliance

The REC Chair produces the Annual REC Report by 31 October each year, covering the preceding academic year. The Report is submitted to the AVPR, who presents a summary to the President. The Director of Research and Grants incorporates research ethics compliance data in the Annual Research Report (RES-001) and the Annual Institutional Effectiveness Report (IE-002). The Annual REC Report includes:

- Number of applications received by review category and School
- Number of approvals, conditional approvals, modifications requested, and rejections
- Protocol deviations and adverse events: number, category, and outcomes (de-identified)
- Research ethics training completion rates
- Any significant research ethics concerns identified during the year
- Recommendations for policy or process improvements
- The REC Chair's assessment of the quality and robustness of AIU's research ethics governance

Procedures

Research Ethics Review Application Process

1. The researcher completes the REC Application Form (available from the Office of Research and Grants website) and assembles the required application package as specified in Article 8.

2. The completed application package is submitted electronically to the Office of Research and Grants. The Office acknowledges receipt within two working days and checks the application for completeness within five working days. Incomplete applications are returned to the researcher with a written statement of missing elements; the review timeline begins upon receipt of the complete package.
3. The Director of Research and Grants forwards the complete package to the REC Chair, who determines the appropriate review category (Exempt, Expedited, or Full Board) within five working days of receiving the complete package and assigns the application for review.
4. For Exempt review: The REC Chair (or a designated REC member) conducts the review and issues a determination within 10 working days of the Exempt determination.
5. For Expedited review: The REC Chair and at least one other REC member conduct the review and issue a determination within 15 working days.
6. For Full Board review: The Director of Research and Grants schedules the application for the next available full REC meeting and notifies the researcher of the expected decision date. The full REC reviews the application and issues a determination within 30 working days of the complete submission.
7. The REC's written determination (Approval, Conditional Approval, Request for Modification, or Rejection) is sent to the researcher and copied to the Director of Research and Grants within five working days of the REC's decision. Conditional Approval and Request for Modification determinations specify the required changes; the researcher must resubmit a revised protocol for confirmation before commencing the research.
8. The Director of Research and Grants records the application outcome in the Research Activity Register and notifies the PI of the one-year approval validity and renewal requirements.

Protocol Amendment Process

1. A researcher who wishes to modify an approved protocol before the modification is implemented submits a Protocol Amendment Application to the Office of Research and Grants. The Application describes the proposed change, the reason for the change, and the researcher's assessment of whether the change affects participant safety or data integrity.
2. The REC Chair reviews the Amendment Application and determines the appropriate level of review, where the change is minor and does not affect participant safety or research scope, the Chair may approve the amendment administratively. Where the change is substantive (new procedures, new participant population, change to consent process, significant change to risk profile), the amendment undergoes Expedited or Full Board review as appropriate.
3. No protocol amendment is implemented before written confirmation of approval has been received from the REC.
4. Approved amendments are added to the approved protocol file and the Research Activity Register. The revised approval letter specifies any changes to the conditions of approval.

AIU AMERICAN INTERNATIONAL UNIVERSITY الجامعة الأمريكية الدولية	Policy Main Title	Research Ethics and Human Subjects Protection Policy	Effective Date	14/06/2026
	Policy Subject	Research	Last Review date	
	Policy Number	RES-002	Next Review date	14/06/2029
	Responsible Entity	Assistant VP Research	Approved By	President

President Signature	Signature: _____ Date: _____