4.b. Research Ethics and Institutional Review Board (IRB)

Subject	Research and Scholarly Activities	***Effective From***	Sep - 2011
Policy #	4.b.	***Latest Revision***	Nov - 2026
Title of The Policy	Research Ethics and Institutional Review Board (IRB)	***Next Review***	Dec - 2027
Responsible Entity	Deanship of Scientific Research & Graduate Studies	***Policy Pages***	9

Definitions	• AAU - Al Ain University • IRB- Institutional Review Board (AAU Research Ethics Committee) • REC- Research Ethics Committee • DoH - Department of Health (Abu Dhabi) • ADHRTC - Abu Dhabi Health Research and Technology Committee • Minimal Risk: Research in which the probability and magnitude of harm or discomfort anticipated for participants are not greater than those ordinarily encountered in daily life or during routine activities. • Identifiable or Private Human Data: Information about an individual that directly identifies the person, can reasonably be linked to the person, or concerns information that the individual would reasonably expect to remain private. • Vulnerable Participants: Individuals or groups who may have difficulty making a fully informed and voluntary decision to participate in research, or who may be at greater risk of being pressured or harmed because of their circumstances. • Routine Review: Ethical review of research involving no more than minimal risk and no significant ethical concerns, conducted by the IRB Chair and the relevant committee member(s) without requiring review by the full committee. • Full Committee Review: Ethical review by the AAU IRB at a convened meeting for research involving significant ethical concerns or risks, such as greater than minimal risk, sensitive issues, significant deception, vulnerable participants requiring additional protections, or substantial ethical complexity.
Purpose	This policy establishes a clear process for determining and obtaining the ethical approvals and permissions required before AAU faculty members and researchers commence research activities. It also promotes the conduct of research in accordance with ethical standards and requirements.
Scope	This policy applies to AAU research projects conducted by faculty, undergraduate students, and graduate students involving human participants and/or identifiable or private human data. Research involving human participants or data in a health/clinical context shall follow the applicable ethical review requirements of the Department of Health (DoH), Abu Dhabi Health Research and Technology Committee (ADHRTC), or other relevant

<table>
<tr><td></td><td>Research Ethics Committee (REC)/IRB, as applicable. Research involving animals is outside the scope of this policy and requires approval from the appropriate animal research ethics committee and relevant UAE authority, as applicable.</td></tr>
<tr><td>Statement</td><td>AAU is committed to ensuring that research involving human participants and/or identifiable or private human data is conducted in accordance with applicable UAE laws and regulations, recognized ethical principles, and University policies. Such research shall protect the rights, dignity, safety, privacy, and confidentiality of participants and shall undergo the appropriate ethical review and approval before the research begins.</td></tr>
<tr><td>Procedures</td><td>1. Ethical Review Requirements
• Research involving human participants or identifiable or private human data requires ethical review through the applicable pathway, as outlined in the table below.
• Where AAU IRB review is applicable, researchers shall submit the AAU Research Ethics Application Form (Form A).
• Data collection shall not begin until all required ethical approvals and organization/site permissions have been obtained.
• Where AAU IRB review applies, the AAU IRB shall determine the appropriate level of review (routine review or full committee review) based on the submitted application.
• Research that does not involve human participants or identifiable or private human data does not require ethical review. However, where such research requires access to non-public organizational documents, records, databases, or other information, authorization from the relevant organization shall be obtained before access or use. Such authorization does not constitute ethical approval.
• Research conducted in a clinical or healthcare context that does not fall withn a DoH/ADHRTC review category shall be submitted to the applicable REC/IRB, such as the AAU lRB or the relevant healthcare institution REC/IRB, as applicable.
2. Ethical Review Pathways
<table>
<tr><td>Case</td><td>Research Situation</td><td>Required route</td></tr>
<tr><td>1</td><td>No human participants and no identifiable or private human data</td><td>No ethical review required. No Form A required. Obtain organization/site authorization where required.</td></tr>
<tr><td>2</td><td>Human participants or identifiable/private human data - non-health context</td><td>Submit AAU Research Ethics Application Form (Form A). AAU IRB determines routine or full committee review.</td></tr>
<tr><td>3</td><td>Human participants or data — health/clinical context falling within a DoH/ADHRTC review category</td><td>Follow the applicable DoH/ADHRTC ethical review process and obtain healthcare site authorization where</td></tr>
</table>
</td></tr>
</table>

	(e.g., multicenter studies, clinical trials, industry-sponsored studies, significant-risk human research, genetic/genomic research, or other categories specified by DoH).	required.
4	Human participants or data - health/clinical context not falling within a DoH/ADHRTC review category	Submit to the applicable REC/IRB (AAU IRB or relevant healthcare institution REC/IRB, as applicable) and obtain healthcare site authorization where required.

3. AAU IRB Review

• Initial Review: Where AAU IRB review applies, the IRB Chair and the IRB member representing the applicant's college shall review the AAU Research Ethics Application Form (Form A) and determine the appropriate review route.

• Routine Review: Routine review may be used where the study presents no more than minimal risk and does not involve complex ethical concerns. The IRB Chair and the IRB member representing the applicant's college may recommend approval, request revisions, or refer the application for full committee review.

• Full Committee Review: Full committee review shall be required where the study presents greater than minimal risk or involves complex etnical concerns, such as vulnerable participants requiring additional safeguards, sensitive or potentially harmful personal information, significant deception, or legal or ethical complexity. The IRB committee shall assess whether risks have been minimized, appropriate safeguards are in place, and the remaining risks are reasonable in relation to the anticipated benefits of the research. The IRB committee may approve, request revisions, or not approve the application.

• External Ethical Review: Where the AAU IRB determines that review by an external ethics authority is required, the final AAU IRB decision shall indicate the applicable external review requirement. The researcher shall obtain the required external ethical approval before commencing data collection.

4. Decision and Documentation

• The IRB decision shall be documented using the AAU IRB Decision Form (Form B). The final decision may approve the research, not approve the research, or refer the research to an appropriate external ethics review authority.

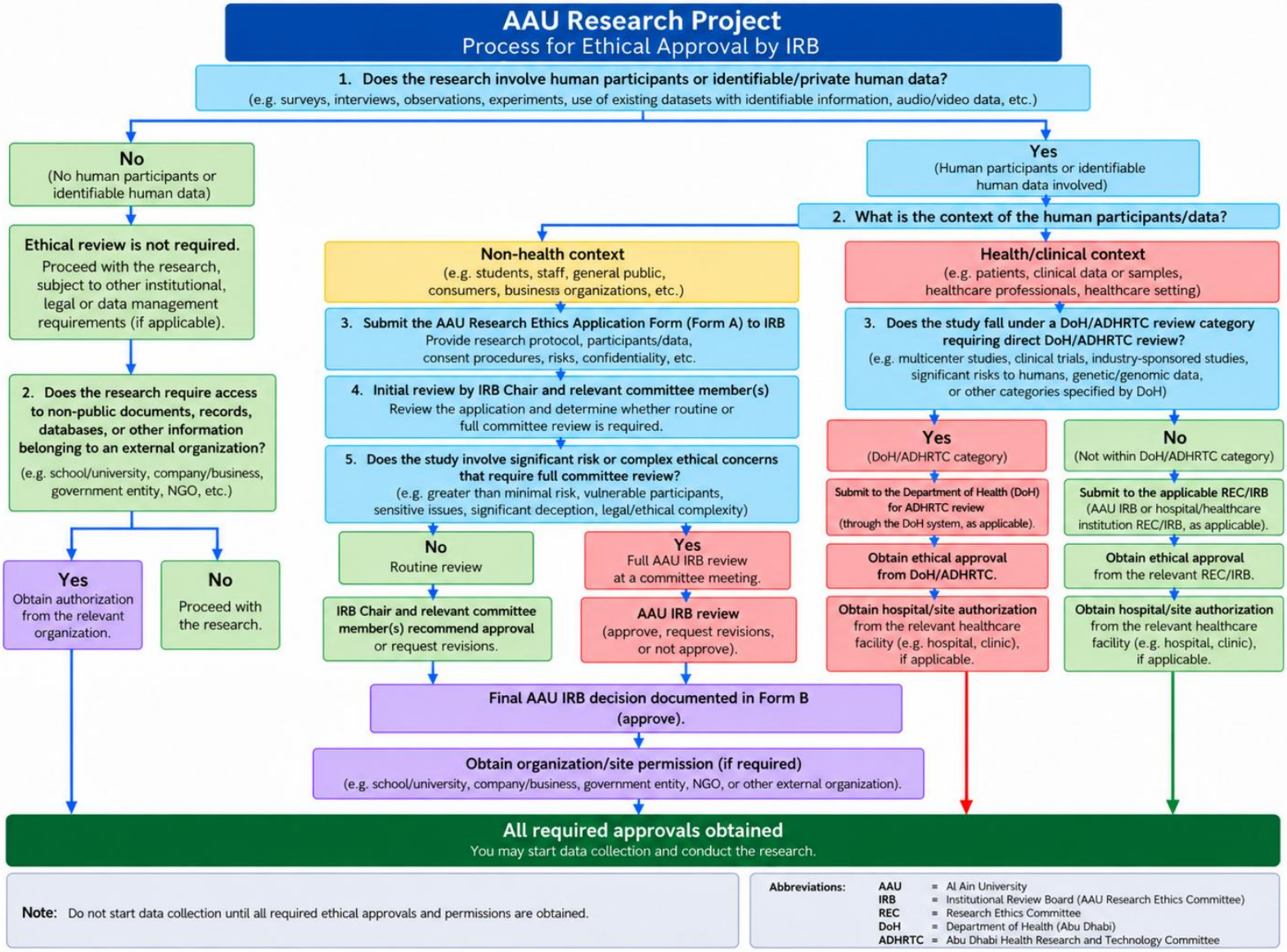
• The IRB Chair's signature on Form B constitutes the official AAU IRB approval of the research.

• Routine reviews should normally be completed within a maximum of two weeks, and full committee reviews within three weeks, following receipt of a complete application. University holidays and semester breaks shall not be counted in these timelines. For full committee review, more than half of the IRB members shall constitute a quorum, and decisions shall be made by majority vote of the members present.

	• For approved research, Form B shall identify the approved project/proposal version, review type, and approval date. • The completed AAU IRB Decision/Approval Form (Form B) shall be issued to the Principal Investigator (PI) as the official notification of the IRB decision, with a copy retained by the AAU IRB. 5. Researcher Responsibilities • Complete and submit the AAU Research Ethics Application Form (Form A) with the required research project information and supporting documents (e.g., research proposal/protocol, survey/questionnaire, interview/focus-group guide, participant information sheet, and informed consent form), as applicable. • Obtain organization/site authorization, where required, after obtaining the applicable ethical approval. • Obtain informed consent, where applicable. • Protect participant privacy, confidentiality, and research data. • Do not begin data collection until all required ethical approvals and organization/site permissions have been obtained. • Researchers shall promptly report any harmful or unexpected incidents or emerging risks that may affect participants to the AAU IRB and obtain IRB approval for significant amendments before implementation. 6. AAU Institutional Review Board (IRB) Composition • The AAU Institutional Review Board (IRB) shall consist of the IRB Chair (Dean of Scientific Research and Graduate Studies) and members representing the University's colleges. • IRB members should have appropriate research experience and familiarity with research ethics relevant to their academic discipline. • The IRB Chair, in consultation with relevant IRB member(s) where necessary, shall determine the appropriate review route. For routine review, the application shall normally be reviewed by the IRB Chair and the IRB member representing the applicant's college. Where full committee review is required, the application shall be considered by the full IRB committee in accordance with this policy. • The IRB is responsible for assessing ethical issues and participant protections, requesting revisions where necessary, and making decisions on research applications in accordance with this policy. • Members of the Scientific Research and Graduate Studies Council may also serve on the IRB. However, the IRB shall exercise independent judgment in all ethical review decisions. Any IRB member, including the Chair, who has a conflict of interest in a research application shall not participate in its review or decision.
Recent Changes	**October 2026** 1. The Definitions section of key terms related to this policy has been expanded to include related terms. 2. Expanded Policy Scope: Extended the policy beyond clinical and in-vivo

	research to cover research across all University disciplines, including studies involving human participants and private human data. 3. Clarified Review and Approval Procedures: Established clearer ethical review pathways, requirements, and responsibilities for different types of research. 4. Renamed the policy as the Research Ethics and Institutional Review Board (IRB) Policy, defined its composition and responsibilities. 5. Revised Application and Decision Forms: Updated the forms to clarify the required research information and introduced two separate forms: one for researchers to submit ethical review applications (Form A) and another for the IRB to document review decisions (Form B), including routine or full committee review. 6. A flowchart has been created to illustrate the process and pathway for determining the ethical review requirements. 7. Replaced outdated references to the Health Authority – Abu Dhabi (HAAD) with the Department of Health – Abu Dhabi (DoH) and removed non-functioning links.

Deanship of Scientific Research and Graduate Studies



Note: Do not start data collection until all required ethical approvals and permissions are obtained.

Abbreviations:

AAU	=	Al Ain University
IRB	=	Institutional Review Board (AAU Research Ethics Committee)
REC	=	Research Ethics Committee
DoH	=	Department of Health (Abu Dhabi)
ADHRTC	=	Abu Dhabi Health Research and Technology Committee

جامعة العين
AL AIN UNIVERSITY

Deanship of Scientific Research and Graduate Studies
Form A: AAU Research Ethics Application Form

This form is for AAU research involving human participants and/or identifiable or private human data that falls under AAU IRB ethical review. The AAU IRB will determine the appropriate ethical review route. Please complete the form with the required information about the research project.

A. Project Information

Project Title:				
Principal Investigator (PI):	**Name:**		**College:**	
	Title:		**Highest Degree:**	
	Telephone:		**Email:**	
	Student	☐ Yes ☐ NO		

Co-Investigators including those from other institutions:				
Name	**Responsibility for the Research Project**	**Highest Degree**	**College/University/ Country**	**Email**

Funding Source	☐ None ☐ Internal ☐ External: _____
Expected Duration	Start: _____ End: _____

B. Research Summary

Objectives	Describe the objectives of the research.
Methodology and Participants/Data	Method(s): ☐ Survey/Questionnaire ☐ Interview ☐ Focus Group ☐ Observation ☐ Experiment ☐ Existing Identifiable/Private Data ☐ Other: _____
	Briefly describe the research design, study setting, data collection procedures, participant group or data to be used, expected number of participants/records, and how participants will be recruited, where applicable.
Vulnerable Participants *(e.g., children/minors, persons with disabilities, or individuals with impaired decision-making capacity)*	☐ No ☐ Yes — identify and explain safeguards:

C. Informed Consent

Consent method: ☐ Written ☐ Electronic ☐ Verbal ☐ Not applicable — provide justification below

Consent Process	Explain how informed consent will be obtained. If “Not applicable” is selected, explain why consent is not required.

D. Risks and Sensitive Issues

Risks	Describe any potential physical, psychological, social/cultural, professional, financial, privacy, or other risks. If none are anticipated, state “None.”
Risk Mitigation	Explain how identified risks will be minimized and managed. If no risks are identified, state “Not applicable.”

E. Privacy, Confidentiality and Data Management

Privacy / Confidentiality	Explain how participant privacy and confidentiality will be protected. State where/how data will be stored, protected, and who will have access.
Data Sharing	☐ No ☐ Yes — explain what data will be shared, with whom, and under what safeguards: _____

F. Organization/Site Authorization and Supporting Documents

Organization/site authorization required? ☐ No ☐ Yes Organization/Site:

_____

Attach as applicable: ☐ Research proposal/protocol ☐ Survey/questionnaire ☐ Interview/focus-group guide ☐ Participant information sheet ☐ Informed consent form ☐ Other: _____

G. Principal Investigator Declaration

I confirm that the information provided is complete and accurate. I will obtain all required ethical approvals and organization/site permissions before data collection, obtain informed consent where applicable, protect participant privacy, confidentiality and research data, and conduct the study in accordance with the approved project and documents.

Principal Investigator	Name: Signature:
Date	

H. Internal IRB Review — For IRB Use Only

Project No.	AAU-IRB-COB-2026-**001**
Review Route	☐ Routine Review ☐ Full Committee Review
Initial Review	☐ Recommend Approval ☐ Revisions Required ☐ Refer to Full Committee Review
Comments / Revisions	
IRB Member Representing Applicant’s College	Name: Signature:
IRB Chair	Name: Signature:
Review Date	

Deanship of Scientific Research and Graduate Studies
Form B: AAU IRB Decision Form

This is the official notification of the AAU Institutional Review Board (IRB) decision. It is issued to the Principal Investigator (PI), with a copy retained by the AAU IRB.

A. Project Information

Project No.	AAU-IRB-COB-2026-**001**
Research Title	
Principal Investigator (PI)	Name: College:
Co-Investigator(s)	Name/ Institution / Email:
Funding Source	☐ None ☐ Internal ☐ External:
Approved Project / Proposal	Version: _____ Date: _____

B. IRB Review Information

IRB Review Type	☐ Routine Review ☐ Full Committee Review
IRB Review Date	

C. Final IRB Decision

Decision	☐ Approved ☐ Not Approved ☐ Referred to an External Ethical Review Authority Comments:
External Authority (if referred)	☐ DoH/ADHRTC ☐ Other External Authority:_____
If Approved **IRB Approval Date**	
IRB Approval Valid Until	

D. Approval Statement — For Approved Research Only

Where **"Approved"** is selected above, the AAU Institutional Review Board (AAU-IRB) approves the project/version identified in this form. The research shall be conducted in accordance with the approved project and supporting documents. Informed consent shall be obtained where applicable. Participant privacy, confidentiality, and research data shall be protected. Required organization/site authorization shall be obtained before data collection.

E. IRB Authorization

IRB Chair	Name: Signature:
Date	
Stamp	