جامعة أبوظبي
ABU DHABI UNIVERSITY

APPLICATION FORM
Institutional Review Board – IRB

☐ Review (Expedited or Full Board) Complete all sections

Please read the IRB application Guidelines and attached the below documents (mandatory)

- Research Proposal
- Questionnaire
- Consent form

1 PROJECT INFORMATION

Project Title:

Date of Request:

2 PRINCIPAL INVESTIGATOR (PI)

Name and Degree(s):

Department/Center:

Mailing Address:

Email: Phone #: Fax:

University Affiliation:

☐ Professor

☐ Associate Professor

☐ Assistant Professor

☐ Instructor

☐ Other: Please specify.

3 CO-INVESTIGATORS (CO-I)

- A Co-I is anyone who has responsibility for the project's design, implementation, data collection, data analysis, or who has contact with study participants**.**
- If the project involves medical procedures or patient care that the PI is not certified or licensed to conduct, a responsible physician or other certified or licensed professional must be included as a Co-I. The application must include a copy of supporting documentation for this individual (CV, license, board certification etc).

Name Affiliation Department Email/Tel/Fax

4 SUMMARY OF PROJECT

Please include a summary answer for each of the questions. Use as much space as necessary **AND** attach a copy of the study proposal or project.

If you attach a copy of the **full** proposal, place page and paragraph numbers from the proposal next to each question in this section to show precisely where information pertaining to each question can be found. Please note that information should be consistent throughout all relevant documents.

How will study results be used?

What is the hypothesis?

Describe study procedures and methodologies.

What are the participant selection criteria?

Describe the steps that will be taken to ensure the confidentiality of the participants and data.

5 STUDY DURATION

What is the expected duration of the study through data analysis? (Attach a timeline, if applicable)

What is the expected date that recruitment will begin? (Must be after the submission date)

6 DATA SOURCES AND USES

a) Please check all the ways that you will obtain data: (Copies of written and oral questions must be provided for ADU IRB review. The questions must be approved prior to implementation.)

☐ Interviews ☐ Questionnaires/Surveys

☐ Focus Groups ☐ Public Records

☐ Medical Records ☐ Biological Specimens

☐ Registries ☐ Other *(please describe)*

b) How will the data be used? (Check all that apply)

☐ Dissertation ☐ Publication/journal article

☐ Thesis ☐ Undergraduate honors project

☐ Results released to participants/parents ☐ Results released to employer or school *(please describe)*

☐ Results released to agency or organization *(Please describe)*

☐ Conferences/presentations ☐ Other *(please describe):*

7 PROJECT FUNDING

How is the research project funded?

- ☐ Research is **not funded**
- ☐ Funding decision is pending
- ☐ Research is **funded**

A copy of the grant application **must** be provided prior to IRB approval

8 STUDY SITES

Where will the study be conducted? (Check all that apply)

☐ On campus (Please indicate building(s) and room number (s) if known)

☐ Off campus (Please provide location and letter of permission, where applicable)

9 INTERNATIONAL RESEARCH

a) Does this study include an international site? ☐ Yes (list country)

☐ No

b) If this is an international study, please provide a statement including the following items:

- The investigator's familiarity with the culture in which the study is taking place.
- Cultural norms relevant to the project and how this study may affect an individual's standing in his/her community.
- The standard of health care in the community if relevant, how the proposed research procedures will differ, and a plan for the continuation of care once the research is complete.

10 RESEARCH PARTICIPANT INFORMATION

a) What are the inclusion criteria? (Use an expended list and attach a secondary sheet with explanation, where applicable. If you attach a

secondary sheet, reference on which page the information can be found.)

b) What are the exclusion criteria?

c) Please explain recruitment procedures in detail. (A copy of the recruitment materials must be attached.)

d) What is the expected duration of participation of each individual? (total and at each session)

e) What is the expected number of individuals to be screened for enrollment?

f) What is the maximum number of individuals to be enrolled? (This includes individuals who drop out)

g) If the following criteria are important to the program, please describe

What is the approximate number of:
Males Females

Indicate the age range of the participants that you plan to enroll in your study. to

What is the race of participants?

h) Does the study target any of the following participants?
☐ Yes (please check all that apply) ☐ No

- ☐ Children (under 18)
- ☐ Pregnant women
- ☐ Mentally Challenged
- ☐ Economically disadvantaged
- ☐ Prisoners or detainees
- ☐ Persons at high risk of becoming detained or imprisoned
- ☐ Fetuses
- ☐ Patients, if yes – what is the status of their health?
- ☐ Participants who have low-literacy (describe the means used to ensure the participants' understanding of the research)

☐ Non-English speakers (describe the means used to ensure the participants' understanding of the research)

i) If any of the above categories have been checked, please state how you will protect the rights and privacy of these individuals.

11 COMPENSATION

a) Will any type of compensation be used? (e.g. money, gift, raffle, etc.)

☐ Yes (Please describe the kind of compensation):

☐ No

b) Explain why the compensation is reasonable in relation to the of and burden on participants.

c) Is compensation for participation in the study or completion of the study? (Note: participants must be free to quit at any time without penalty).

☐ Participation ☐ Completion

d) If some or all participants are economically disadvantaged, explain how the compensation is provided in such a way that participants can refuse the request to participate?

12 RISKS AND BENEFITS

Please reference the proposal, where applicable and answer the questions below.

a) What are potential risks to participants?

b) What steps will the investigators take to reduce risks?

c) What are any potential benefits to participants?

d) Please note how the results of the study will affect the health and welfare of the general public.

e) What are the costs, if any, to participants? (This should be mentioned in the consent form):

13 CONFIDENTIALITY

Describe the specific steps you will take to ensure the confidentiality of the participants and data.

a) How will you safeguard data that includes potentially identifying information (e.g. coding)?

b) When will identifiers be separated or removed from the data?

c) Where on campus will you store the data and media and ensure its security (videotapes and/or audiotapes)?

d) How long do you plan to retain the data?

e) How will you dispose of the data?

f) Is a certificate of confidentiality required? ☐ Yes ☐ No

14 INFORMED CONSENT

Describe the procedures you will use to obtain and document informed consent and assent. Attach copies of the forms that you will use. Fully justify any request for a waiver of written consent or parental consent for minors.

15 CONFLICT OF INTEREST

Does the investigator or key personnel have a potential conflict of interest in this study?

☐ Yes ☐ No (If yes, please describe and disclose in the consent form)

16 REQUIRED SIGNATURES

By signing this application form:

- I agree to accept responsibility for any impact to the rights and welfare of the human subjects involved with this study as a result of my research.
- I believe that the benefits outweigh the risks to the participants in this study.
- I have read Abu Dhabi University IRB policy and guidelines and I agree to comply with them.
- I certify that, to the best of my knowledge, I am in compliance with ADU's IRB policies and its related guidelines.

Principal Investigator Date

Attach a copy of the PI's CV unless one is already on file.

Dean Date Print Dean Name

(If the PI is the Dean, the application must be signed by another authorized Department/ School/College level Administrator)

If you have any queries on this form, please contact your Faculty Ethics Coordinator or visit the website at ……

Please email or send this form to the appropriate Faculty Ethics Coordinator at: irb@adu.ac.ae

For office use only:

The appropriate Ethics Committee has considered the ethical aspects of this proposal. The committee recommends that the program/project be:

☐ Approved

☐ Deferred (for reasons attached)

☐ Not approved (for reasons attached)

Name of Committee Member:	
Signed:	
Date:	

Reviewer comments: