Application for Ethical Clearance

A detailed research proposal should be appended to this application for the IRB review to be effective and for a quick response. The protocol described herein must provide background information on the research study and its importance along with the recruitment, research methods, and procedure. The IRB will verify that:

1. Informed consent is taken from every participant/subject or his/her legal representative,
2. Risk-to-benefit ratio and minimization of risks on participants/subjects have been addressed,
3. Each subject/participant has an equal chance of selection,
4. Participation is voluntary and no coercion was used on participants, and
5. Data collection is private, confidential, and protected. Researchers involved in the study must monitor the safety of the participants/subjects. Additional protection should be given to vulnerable populations such as children, prisoners, people living with disabilities, etc.

Review Level ☐ Full ☐ Expedited ☐ Exempted

If "Exempted", please select the condition that applies to your research study and please only fill Section I: A.:

☐ No human/animal participation in this research.

☐ Oral History projects insofar as (i) they collect and use information about specific individuals themselves, (ii) they do not collect nor use identifiable information about living individuals to produce generalizable knowledge, and (iii) they are not conceived to inform policy.

If "Expedited", please select the condition that applies to your research study:

☐ Research on a medical device that uses a cleared/approved medical device in accordance with its cleared/approved labeling.

☐ Research study uses finger stick, heel-stick, or ear stick for blood sample collection (for adults, not more than 450mL (milliliter) per 8-week period and not more than twice per week. For children or participants below 50kg (kilogram), not more than 50mL or 3mL per kg per 8-week period and not more than twice per week).

☐ Research study involving non-invasive collections of biological specimens such as buccal swabs, nail clipping, etc.

☐ Research study involving already collected materials/data.

☐ Research study in which data is collected from recordings made for research purposes.

☐ Research study on group characteristics or behavioral study not involving manipulating/stressing the subject behavior.

☐ Research study using questionnaires, surveys, interviews, netnography, focus group discussions, participant observations, oral history, or quality assurance procedures. This should pose a low risk to the research population and should not be on vulnerable populations as described in *Section III D.*

Completed forms should be submitted electronically to the Center for Research and Development (CRD) at CRD@auib.edu.iq

Section I: Investigators

A: Principal investigator

Project Title:				
Proposed Study Dates:	Start Date:	sfdsf	End Date:	
Principal Investigator (PI):	Name:	dsfd	Department:	
	Academic Position:	sfssfd	Type of Research:	
	Mobile:		Email:	

B: Co-investigators

List all Co-Investigators below, including those from other institutions with attached IRB and relevant forms:				
Name	Academic Position	University/ College	Department	Email
1.				
2.				
3.				

Date of CITI completion? (Attach a copy of CITI certification for all investigators, if available):

SECTION II – Indicate funding sources

Internal/external funding source		
Has funding been obtained?	☐ YES (complete below)	☐ NO (skip below)
Funding Source:		
Grant details:		

Section III: Description of the project

A: Project summary (500 words max) Purpose, significance, research questions, background, hypothesis, and aims)

B: Research design, methods, and procedures (500 words max) Please include the research design, methodologies, location/s (on/off campus), and procedures, recruitment including data collection and follow-up procedures, if relevant

C: Details of potential subjects (demographics)	
Proposed sample size	
Proposed age group	
Proposed study population (details)	
Inclusion criteria	
Exclusion criteria	
Other	

D: Will vulnerable subjects be used? (If yes, please state how they should be protected ☐ YES ☐ NO

Please state if vulnerable subjects will be used?			
Children	☐ YES ☐ NO	Refugees / Internally Displaced People	☐ YES ☐ NO
Prisoners	☐ YES ☐ NO	Non-English speakers	☐ YES ☐ NO
Vulnerable Minorities	☐ YES ☐ NO	People with a physical/cognitive disability	☐ YES ☐ NO
Terminally ill subjects	☐ YES ☐ NO	People over the age of 60	☐ YES ☐ NO
Military /Law Enforcement/Regulatory Authorities	☐ YES ☐ NO	AUIB Students	☐ YES ☐ NO
Pregnant women	☐ YES ☐ NO	Neonates	☐ YES ☐ NO
Please provide clear reasons for the inclusion of any group from the above and provide details of the precautions that will be adopted to protect the above-selected group:			

Section IV: Research risks and benefits

A: Risk management procedures Please state any potential risks			
Physical	YES ☐ NO ☐	Emotional	YES ☐ NO ☐
Psychological	YES ☐ NO ☐	Employment	YES ☐ NO ☐
Legal	YES ☐ NO ☐	Personal	YES ☐ NO ☐
Please state any other potential risks and the proposed methods to minimize such risks.			

Section V: Data safety

A: State all data collection, storage, and security methods. Please provide a monitoring plan, destruction of data, and nondisclosure agreement among co-investigators

Section VI: Conflict of interest

A: Possible conflict of interest ☐ YES ☐ NO If yes, provide details about any type of financial interest and compensation, clashes of sponsorship, and previous association with anyone involved with this project.

Section VII: Attach all relevant documentation

I have attached all instruments, including surveys, questionnaires, etc.	☐ YES ☐ NA
I have attached all consent forms.	☐ YES ☐ NA
I have attached all recruitment instruments/advertisements.	☐ YES ☐ NA
I have attached any other IRB approval from any external institutions.	☐ YES ☐ NA
I have attached all necessary CITI certificates	☐ YES ☐ NA
I have attached full grant documents	☐ YES ☐ NA
I have attached any other relevant documents	☐ YES ☐ NA

Section VIII: Decision of the IRB

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Date application submitted		Date committee approved	
Date of revisions		Approval #	
Proposal meets ethical clearance requirements?		YES ☐	Revisions required ☐
Comments on revisions from the IRB committee:			