جامعة نيويورك أبوظبي

NYU | ABU DHABI

APPLICATION FOR REVIEW BY THE NEW YORK UNIVERSITY ABU DHABI INSTITUTIONAL REVIEW BOARD (NYUAD IRB)

Principal Investigator (PI) or Faculty Sponsor

First name: Last name:

Division:

Work phone: Home phone:

PI mailing address:

Email address: PI NYUAD ID:

☐ NYUAD Faculty ☐ Other NYUAD ☐ Non-NYUAD

Co-investigator

First, last name: Institutional affiliation (if not NYUAD):

NYUAD Division: Role in Research:

Additional investigators (First, last name) **Role in Research**

Student Investigators (First, Last name) NYUAD ID:

Project Title:

Are you requesting **Exempt Status**? *(See page 3 for definition.)*

☐ Yes ☐ No *If yes, fill out Request for Exempt Status on page 3.*

OR, Are you requesting **Expedited Status**?

☐ Yes ☐ No *If yes, complete expedited checklist*

OR, Are you requesting **Full Board Review?**

☐ Yes ☐ No

Investigator's Agreement

I agree to use procedures with respect to safeguarding human subjects in this activity that conform to federal, state, local and University policy. If significant change in investigative procedure involving human subjects is called for during the activity covered by this Application, I shall seek prior approval for such change from the IRB and agree to follow the advice of the IRB. If this activity is a continuation or renewal of an ongoing program, I affirm that the procedures followed during the current period conform to this policy.

PI/Faculty Sponsor signature: Date:

Student Investigator signature: Date:

Has this study been **previously approved** by any IRB or Research Ethics Committee?

☐ Yes ☐ No

If yes, please provide:

Name of IRB/Committee:

Approval date:

Name of project as approved:

Have procedures changed since the most recent IRB review?

☐ Yes ☐ No *If yes, provide details as part of this Application as appropriate.*

Will data be collected from or about any of the following protected populations? *(Check all that apply.)* **Note:** There are additional protections and procedures required for the use of protected populations as subjects in research. Additional questions should be directed to the IRB staff at 02-628-4313 or IRBnyuad@nyu.edu.

☐ Minors (under 18 years of age) *If checked, specify age range:*

☐ Individuals with impaired decision-making capacity

☐ Individuals who are economically or educationally disadvantaged

☐ Pregnant women

☐ Fetuses

Will the project involve any of the following? *(Check all that apply.)*

☐ Deception (research in which subjects are purposely led to have false beliefs or assumptions)

☐ More than minimal risk to subjects (i.e., risk greater than that of everyday life)

☐ Investigational new drug or device exemption *If checked, include IND/DE/510(k) information.*

If the Investigator is a student, indicate if the project is a:

☐ Thesis ☐ Capstone ☐ Class project ☐ Other *(please specify):*

Is the application for a Pilot Study?

☐ Yes ☐ No

Research Funding: Indicate <u>all</u> sources of funding (submitted, pending and/or awarded) that may/will support the proposed project

☐ Investigators' internal research funds

☐ NYUAD competitive or other research program (e.g. REF)

☐ U.S. Federal Funding (non-NYUAD)

☐ Other external funding (non-NYUAD)

Please state name of **funding agency**, **organization** or **NYUAD program**?

What is the status of the request for funding?

☐ Submission planned in near future ☐ Submitted & Pending

☐ Initial award ☐ Continuation award ☐ Renewal award

If already awarded, what is the award or grant number?

What is the title of the project as it appears in the submission for funding or award?

REQUEST FOR EXEMPT STATUS FROM FULL HUMAN SUBJECTS COMMITTEE REVIEW

Certain categories of research deemed very low risk under Federal regulations may be granted Exempt Status once the appropriate review has been conducted by the IRB. If Exempt Status is granted, the study will not require continuing or other review unless procedures are revised which deviate from those originally approved by the IRB.

Note that only the IRB may grant Exempt Status. Therefore, applications for Exempt Status must include the completed remainder of the application in addition to the information requested below.

Exempt status may be claimed under the following categories. **Please check all that apply.**

☐ **1.** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices, instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education.

☐ **2**. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (c) Identifiable information is recorded and there is risk of harm if results are disclosed but the IRB conducts a limited review and determines exemption after adequate safeguards are put in place.

☐ **3.** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection **and at least one of the following criteria is met**: **(a)** The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **(b)** Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or **(c)** Identifiable information is recorded and there is risk of harm if results are disclosed but the IRB conducts a limited review and determines exemption after adequate safeguards are put in place. [For details on conditions and limitations, see **Revised Exemption Categories**]

☐ **4.** Secondary research uses of identifiable private information or identifiable biospecimens, **if at least one of the following criteria is met**: (a) The identifiable private information or identifiable biospecimens are publicly available; (b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (c) The research involves only information collection and analysis involving the investigator's use of identifiable health information for the purposes of "health care operations" or for "public health activities and purposes"; or (d) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities [For further details, see **Revised Exemption Categories**]

☐ **5**. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. For further details, see **Revised Exemption Categories**]

☐ **6.** Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

I. PURPOSE OF STUDY

Please describe the purpose of your proposed research, making clear the question the research is attempting to address. Avoid the use of technical terms or discipline specific language. Your explanation must be clear to those unfamiliar with your field. References are unnecessary.

II. USE OF SECONDARY DATA AND PRE-EXISTING DATA SETS

Please complete this section if your investigation involves obtaining, using, studying or analyzing data or specimens, about/from individuals, that were not collected for the currently proposed research and are already in existence (e.g. using information/samples from data or tissue repositories or other secondary sources)

Is the data **publicly available** from its source? ☐ Yes ☐ No

Is the data **private/proprietary**? ☐ Yes ☐ No
Please identify source or provider:

Describe in detail the nature of data/specimens that you wish to acquire. What are the main data collection points that are of interest to this research?

Are you (investigator/recipient of data) able to link the specimens/data directly to identifiable living individuals either directly or indirectly through a code or through data combination? (e.g. statistical identification of households is possible using village names in combination with the household data)

(Coded: An individual's identifiable information such as name has been replaced by a code, such as a number, letter or combination thereof, and there is a key to link the code to the identifiable information of that individual. Please explain:

Has the data provider/owner requested a data usage agreement?

III. SUBJECT SELECTION AND RECRUITMENT

Note: If your research **ONLY** involves use of pre-existing data sets or secondary data and does not involve interaction/ intervention with individuals to collect any new data, please skip to **CONFIDENTIALITY** Section**:**

Part 1

Selection of subjects must be equitable, scientifically justifiable, and, in the case of protected populations such as children, prisoners, pregnant women, or disabled persons, should reflect their special needs. In addition, investigators should be sensitive to the use of educationally and economically disadvantaged persons as subjects. If you are excluding women, children, or minorities or other specific populations from your subject pool, you must include a scientific justification for such exclusion.
Investigators are advised to consult with IRB staff prior to planning studies with regulated access to special populations such as prisoners or the disabled. In addition, investigators are strongly discouraged from proposing recruitment that involves their own classrooms/students, clients, patients, or similar groups, in order to avoid any potential for coercion.

Please answer the following questions:

a. What is the maximum sample size (maximum number of subjects to be included?)

b. What are your criteria for inclusion of potential subjects (e.g., age range, country of birth or native language, medical status, grade in school, membership in a particular organization, marital or parental status)?

c. What are the criteria for subject exclusion (e.g., age range, country of birth or native language, medical status, grade in school, membership in a particular organization, marital or parental status)?

d. How will investigators ensure that the criteria for subject exclusion is met?

Part 2

Describe in detail how the subjects will be recruited. Investigators should make every attempt to use indirect recruitment methods (i.e., methods in which the investigator does not make direct contact with potential subjects but rather makes information available on the opportunity to participate and how to contact the investigator if interested).

a. How will investigators identify potential subjects (how will they know whom to recruit)?

b. Where and how will potential subjects be informed of the opportunity to participate? *Include copies of recruitment letters, flyers, or advertisements, and/or a copy of the oral and written statements to be used at the time of recruitment of subjects.*

c. How will subjects be able to let the investigator know they wish to participate?

d. Recruitment Materials: Include a copy of any **participant recruitment materials** (e.g. posters, fliers, social media posts, website/intranet posts, etc.) and **any written statements or verbal scripts** to be used in describing the study to potential participants (e.g., by letter, phone call, email, presentation to a group).

Recruitment materials should include:

(1) Information on the purpose of the study; (2) What subjects will be asked to do if they participate; (3) Where the study will be carried out; (4) How much of the subjects' time participation may take; (5)What type of information they might be asked to provide; (6) clearly state that participation is voluntary and that subjects may withdraw from the study at any time.

Statements to children should state that written parental permission is required for participation and be in language appropriate to the subjects' age.

IV. HARMS AND BENEFITS TO SUBJECTS

Describe any potential harm/risk and benefit to the subjects. If there is no more than minimal risk to subjects (e.g., no greater than that of everyday life), then state that "there is no risk from participation beyond that of everyday life." If there is the possibility of greater than minimal risk, include a discussion of why the additional risk is justifiable.

For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risks. If appropriate, include information on how risk might be managed. For example, an investigator could provide a list of community or University counseling services when there is potential for emotional distress. Detail any direct benefits to subjects. If there are none, so state. Take care not to exaggerate potential benefits; research studies rarely provide direct benefits to subjects and that the results of research are often tenuous.

Note: Gifts or payment of any kind to participants are incentives or reimbursements, not benefits. If any gifts or incentives will be offered to subjects, provide details in the section on procedures.

V. PROCEDURES TO BE FOLLOWED

Describe the procedures to be followed in carrying out the project, the questions below provide guidance on information needed.

Please attach copies of full research instrument including: any survey, questionnaire, interview questions, testing protocols, experimental tasks/manipulations/games, etc.

a. Where will the study be conducted (if online, please identify the platform)?;

b. What will participants be expected to do at each stage of the project? (please provide details);

c. How much time does each activity require and what is the total time for participation?;

d. Who will supervise the participation or conduct interviews?

e. How will materials such as surveys, questionnaires, etc. be distributed to participants and returned upon completion?;

f. Will any incentives or subsistence allowances be provided? (describe and explain what participants receive if they withdraw before the study is completed). **Note:** Investigators cannot provide incentives, payments, reimbursements or remunerations to participants involved in Abu Dhabi based research, however they can provide a transport and/or subsistence allowance or student credit.

VI. INFORMED CONSENT AND PERMISSION

Enter description of proposed consent procedure. Attach copies of all forms, scripts, etc. to be used to obtain informed consent from adult subject(s) in non-protected populations and, if subjects are under 18 years of age or unable to provide consent, from their parents or legally authorized representatives.

Explain how participants will be given the consent form, parental or other permission forms and/or assent script (where and when), and how signed forms will be returned to the investigator.

Note:
In all cases in which subjects will be minors (under 18 years of age), a parental permission form is required. In addition:

- For minors over age 7: a written consent form appropriate to the age of the subject is required, and
- For children between 4 -7: an oral assent procedure and script appropriate to the age of the subject are required.

If video- or audiotapes are involved, the consent/permission form should indicate that the subject has the right to review all or any portion of the tape and request that it be destroyed. Parents may not review audio/videotapes of children.

If it is possible that the investigator might wish to quote or otherwise identify a subject in any publication, an attribution statement must be included and a justification for requesting attribution.

If the study involves focus group participation or other group activities, the consent form must include a statement of the limits of confidentiality in group settings, that is, while the investigator may hold all individual information confidential, he/she cannot guarantee that other members of the group will do so.

Subjects must be given a copy of the unsigned consent form before subjects' participation begins. Any proposed changes to the standard written informed consent process must be clearly detailed and justified as part of the application.
If adult participation will be completing surveys of questionnaires anonymously, a Project Summary Statement containing all the information included in a Consent Form without a signature may be used in place of a signed Consent Form.

Please refer to the Informed Consent Guideline on the website under *Forms and Guidance* for further details.

REQUESTS FOR WAIVERS: In certain circumstances, the IRB may grant certain waivers for consent. Please check the relevant box below and follow the instructions. *If you <u>are not</u> requesting any waivers and your consent form meets all requirements, please skip this section*:

- ☐ I plan to obtain oral or online consent, i.e. not signed consent (CONTINUE TO 'A')
- ☐ I plan on obtaining consent but would like to exclude or alter some of the required elements (e.g. in cases of deception) (CONTINUE TO 'B')
- ☐ I do not plan on obtaining any consent due to the nature of the study (CONTINUE TO 'B')

A. Waiver of Documentation of Consent: To request a waiver of *signed* consent, and use oral or on-line consent instead, your answer must be 'Yes' to one or more of the following statements. **Please be specific in explaining why the following statement(s) are true for your research or the waiver will not be considered**.

Note: If the IRB accepts to waive signed consent, you will still be required to obtain oral/on-line consent, in which the investigator reads the consent text to participants and/or gives participants a chance to read the consent text and verbally consent (or 'click' to confirm participation

1) The only record linking the participant and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality (e.g. *domestic violence research where the principal risk is discovery by the abuser that the subject is talking to researchers*) ☐ Yes ☐ No

2) The research presents no more than minimal risk of harm to participants AND involves no procedures for which written consent is normally required outside the research context: ☐ Yes ☐ No

3) It is expected that the participant will not be able to sign their name due to illiteracy OR are wary of signing documents for cultural reasons. ☐ Yes ☐ No

B. Request for Alterations to consent or Full Waiver of Consent: The IRB may approve certain alterations to the required elements of consent (such as when the research requires deception). Under very rare circumstances, IRB may waive the requirement for informed consent all together. For waiver to apply, your answers must be 'Yes' to all the following statements.

Please be specific in explaining why the following statement(s) are true for your research or the waiver will not be considered:

1) The research could not be carried out without this waiver or alteration ☐ Yes ☐ No

2) The research presents no more than minimal risk of harm to participants ☐ Yes ☐ No

3) A waiver or alteration will not adversely affect the rights and welfare of the subjects ☐ Yes ☐ No

4) Whenever appropriate, the subjects must be provided with additional pertinent information after participation. ☐ Yes ☐ No

DEBRIEF AND RISK MANAGEMENT: If applicable, please provide the following:

- For research involving deception: a description of the debriefing procedures to be used
- For managing risk of harm: a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troublesome condition, emotional distress in reaction to sensitive questions, or other adverse effects. Such information should also be included in all Consent & Permission forms

VII. CONFIDENTIALITY

Providing **anonymity** of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, phone number, Email address, IP address, etc.), or the project cannot link individual responses with participants' identities. A study should not collect identifying information of research participants unless it is essential to the study protocol.

Maintaining **confidentiality** of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

If the study includes more than one session or instrument, investigators may want to assign code names that track participants' data from one session or document to another but are unrelated to participants' true names. If any on-line surveys or responses are included in the procedures, methods can be employed to ensure that identifying material will not be transmitted or recorded electronically (e.g., email address, IP numbers). Pay particular attention to the protection of subject data confidentiality in such settings as open or group situations. While investigators may promise to maintain confidentiality, they cannot guarantee that others in a group situation will do so.

a. Describe how you will obtain data anonymously *or*, if anonymity is not possible, the specific methods by which confidentiality will be protected (i.e., use of data coding systems or pseudonyms);

b. How and where will data and other identifiable materials (i.e. consent forms) be stored;

c. Who will have access to the data (faculty supervisors of student research always have access);

d. How long will the data be kept (regulations require that all data, including consent forms, be kept for at least 3 years after the completion of the project;

e. What will happen to data after the study is completed (if it will be retained, state how confidentiality will be maintained; if it will be destroyed, explain how).

VIII. COOPERATING INSTITUTIONS

Investigators may submit an Application for Review prior to obtaining approvals from all cooperating organizations; however, final approval to conduct research at a particular research site will not be granted until a copy of that institution's written approval has been submitted for the Committee's files. Institutional Review Board approval is required from all organizations which have an IRB. A letter from an appropriate senior official, on letterhead, should be obtained from organizations that do not have an IRB. List all institutions expected to provide access to potential subjects, to data necessary to identify subjects, to data previously collected, or facilities where the research is to be conducted, etc., including:

- hospitals (Institutional Review Board approval is required);
- Institutions of higher education (Institutional Review Board approval is required);
- Health care providers (e.g., clinics, physicians' offices); and
- Agencies, associations, or membership organizations.

Please indicate the status of cooperating institutions' approval (i.e., attached, in process, not yet requested). Attach originals of IRB approval or approval letters on the cooperating institutions' letterhead, from appropriate authorized officials at each institution listed or submit to the IRB as soon as available.

Investigators should be aware that approval processes at other organizations, particularly school boards and hospitals, may take considerable time. Please take this into account in planning the study.