FORM C

UOG Faculty/ Staff

UNIVERSITY OF GUAM
UNIBETSEDÅT GUAHAN

CHRS#:

For IRB Use Only

OFFICE OF RESEARCH & SPONSORED PROGRAMS

Application for Approval of Studies Involving Human Subjects

Section 1: P.I. Information

Project Title:

Principle Investigator(s):
Email: **Phone:**
Sponsoring College/ School:
☐College of Liberal Arts and Social Sciences ☐College of Natural and Applied Sciences
☐School of Business and Public Administration ☐School of Education
☐School of Engineering ☐School of Health
☐Other:
Project Period (Anticipated):
Start Date: End Date:
Research Design:
☐Experimental ☐Quasi-Experimental ☐Non- Experimental
☐Qualitative
☐ Secondary Data/ Collection/ Analysis ☐Program Evaluation or Quality Assurance
Dissemination of Results:
Will the results of the research be published? ☐ Yes ☐No
If yes, please specify where research will be published:
External IRB Review:
Will your IRB application be reviewed by another institution? ☐ Yes ☐No
If Yes, what institution will be reviewing your IRB application?
If you have prior approval from your external institution, please provide a copy of your approval letter and supporting documents.
Funding of Research:
Is your research being funded by a grant or contract ☐Yes ☐No

If Yes, please attach copy or grant application or contract. *Submit approval letter only.*

Human Subject Research Training

CITI Training Reference #: Date Completed:

Section 2: Category of Review

Please use the following checklist to determine your level of review. The IRB, upon review will make the final determination for the appropriate review. Check all categories that apply.

Exempt Review

Exempt Review means the study must still be reviewed, but not by the full IRB review process. The applicant must request exemption of the research, including the research protocol, from full Board review by submitting the appropriate application and noting at least one or more of the categories of exemption as described below.

A study may qualify for Exempt review if it into one of the categories outlined below. Check all those that apply:

☐ **Category 1: 45CFR 46.101(b)(1)**

Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(a) research on regular & special education instructional strategies, or

(b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2: 45 CFR 46.101(b)(2)**

FOR ADULTS: Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior UNLESS

(a) data obtained are recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects;

(b) any disclosure of the human subjects' responses would place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; and/or

(c) the research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

☐ **Category 3: 45 CFR 46.101(b)(3)**
FOR SUBJECTS WHO ARE ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE: Research involving the use of educational tests (e.g. cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior.

☐ **Category 4: 45 CFR 46.101(b)(4)**
Research involving the collection or study of existing data, documents, records, or specimens if:
(a) the sources are publicly available; or

(b) the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers or codes linked to the subjects. **Note 1**: "Existing" means the data have already been collected for some other purpose at the time the research is proposed. "Publicly available" means available to the general public, with or without charge. Under condition (b) above, investigators with legitimate access may view identified information, but may not record identities, identifiers, or codes that link private information to individual subjects. Even a brief recording of identifiers or codes disqualifies the exemption. This category excludes studies of publicly authored documentation such as newspaper articles, novels, works of art, or a literature review.

☐ **Category 5: 45 CFR 46.101(b)(5)**
Research and demonstration projects that are conducted by or subject to the approval of supporting agencies, and which are designed to study, evaluate, or otherwise examine:
(a) public benefit or service programs;
(b) procedures for obtaining benefits or services under those programs;
(c) possible changes in or alternatives to those programs or procedures; or
(d) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6: 45 CFR 46.101(b)(6)**
Taste and food quality evaluation and consumer acceptance studies,
(a) if wholesome foods without additives are consumed or
(b) 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 and approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: Exempt Categories do not apply to research involving deception of subjects, sensitive behavioral research, or children, pregnant women, military service veterans, prisoners, fetuses, individuals who are decisionally impaired (including psychiatric patients), and other subject populations determined to be vulnerable.

NOTE: Even if your initial determination is Exempt, complete the following checklists for Expedited and Full Reviews. If any of those categories apply, your study is not Exempt.

EXPEDITED REVIEW
Review by the IRB is provided for research which involves no more than minimal risk, no vulnerable populations, or review of minor changes in previously approved research or research protocols. For the review covered by the Regulations 45 CFR 46.110, the IRB will determine that all of the requirements are satisfied. Minimal risk as defined by 45CFR 46.102(I)
http://www.hhs.gov/ohrp/ means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. A study may qualify for an expedited IRB review if it fits into one of the categories outlined below.

A study may qualify for Expedited Review if it fits into one of the categories outlined below**.** Check <u>all</u> those that apply:
☐ **Category 1**. Studies involving the recording of information so that participants are identifiable (audio or video recordings) require at least an expedited review.
☐ **Category 2**. Studies using instruments, questionnaires, or surveys that have been generated or modified by the researchers require an informed consent and at least an expedited review.

☐ **Category 3**. Obtaining data from subjects 19 years or older using routine noninvasive procedures2

☐ **Category 4**. Analysis of video or audio recordings

☐ **Category 5** Moderate exercise by healthy volunteers

☐ **Category 6** Studies involving collection of existing unidentifiable specimens by non-invasive means.

☐ **Category 7**. Studies of individual or group behavior, or characteristics of individuals, without manipulating subjects' behavior and in a manner that does not cause stress to subjects

NOTE: Even if your initial determination is Expedited Review, complete the checklist for Full Review. If any of those categories apply, your study is not Expedited.

FULL REVIEW
A Full-Board Review is indicated under the following conditions.

A study may qualify for Full-Board Review if it fits into one of the categories outlined below**.** Check <u>all</u> those that apply:

☐ **Category 1**. Surveys or interview questions whose answers, if known outside the research, would create legal liability or adverse financial or employment consequences for the participant.

☐ **Category 2**. Surveys of interviews involving questions dealing with very personal and sensitive behavior, such as sexual behavior, alcohol or drug use, or if subjects may be placed at risk for criminal or civil penalties or would otherwise suffer embarrassment or humiliation if the subjects' responses were to become known outside the research.

☐ **Category 3**. Studies that include members of a *protected population* in the pool of participants, including but not limited to children under age 19, veterans of military service, persons who are decisionally impaired, fetuses,

pregnant women, prisoners, and anyone else who cannot provide informed consent

☐ **Category 4**. Studies involving deception or if the subjects are not fully informed of the purpose and procedures of the study

☐ **Category 5**. Studies involving support from non-university sources requiring full IRB approval

☐ **Category 6**. Likelihood of risk or substantial stress or discomfort to the subject

☐ **Category 7**. Procedures that may potentially threaten or embarrass subjects

☐ **Category 8**. Personality tests, inventories or questionnaires of a personal and sensitive nature where subjects' identities will not be anonymous to the researcher

☐ **Category 9**. Healthcare procedures not conducted for the primary benefit of the subject

☐ **Category 10**. Diagnostic or therapeutic assessments, interventions, or measures that are not standard, generally acceptable, or common practice

☐ **Category 11**. Exposure to surgery, drugs, or chemical agents

☐ **Category 12**. Exposure to electromagnetic radiation (X-rays, microwaves), lasers, high frequency sound waves

☐ **Category 13**. Collection of blood samples or other body fluids in any amount.

NOTE: Minimal risk as defined by 45CFR 46.102(I) http://www.hhs.gov/ohrp/ means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Studies involving more than minimal risk to participants will not be approve

Section 3: Abstract of Research Proposal

1.) Summarize the Proposed Research, Outline Objectives and Methods:

2.a) Describe the participant group to be studied. (Gender, Age range, ethnicity, how many)

Check if any subjects of this research project will be selected from the following categories:

☐Minors	☐Mentally Disabled	☐Mentally Retarded
☐Abortuses	☐Fetuses	☐Other:
☐Prisoners	☐Pregnant Women	

2b.) Describe how you will recruit participants. Describe all sites where research will be conducted.

3.) Research involving Human Subjects often exposes subjects to risks.
Check All Risks to Humans to be involved in this project:

☐Physical Trauma	☐Deception*
☐Side effects of medications	☐Loss or Privacy
☐Contraction of Disease	☐Loss of Legal rights
☐Worsening of Illness	☐Other (Explain):
☐Psychological Pain	☐Other (Explain):

* If deception is used, explain why it is necessary and how participants will be debriefed about the deception after the completion of their study.

4a.) Describe mechanisms for safety monitoring. How will greater than anticipated harm to subjects be detected? What will be done if such risk is detected?

4b.) What steps will be taken to ensure participation will be confidential. How, where, and how long will data be kept to ensure that information will remain confidential and secure. Who will have access to the data.

5.) Briefly describe how the results of the research will benefit society or the participant(s). What, if any, benefits will the participants received from participating.

6.) Describe how voluntary consent will be obtained. *Attach informed consent to application. Sample informed consent may be found on the UOG IRB website at: www.uog.edu/research/institutional-review-board*

Section 4: Certification of Review

As Principle Investigator (PI), I certify that all required components are present. I also agree to the following:

1.) The research design conforms to discipline standards.
2.) The type of review requested is appropriate.
3.) The application is complete, accurate, and coherent.
4.) No substantial misspelling of other APA-style errors mar the application.
5.) I have thoroughly reviewed this research project.

_____ _____

Name of Principle Investigator **Date**

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Signature of Principle Investigator