INSTITUTIONAL REVIEW BOARD (IRB) REVIEW APPLICATION

Bakke Graduate University
strengthens leaders who steward resources
with and for vulnerable people and places,
by means of contextual, Christian-based education
innovatively delivered throughout the urban world.

Institutional Review Board
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IRBCoordinator@bgu.edu

For office use only:

Code number _____ Action _____

Date reviewed _____

Request for Approval of Research with Human Participants
In Social and Behavioral Research

Bakke Graduate University (BGU) and Federal policies require that each project involving studies of humans be reviewed to consider 1) the rights and welfare of the individuals involved; 2) the appropriateness of the methods used to secure informed consent; and 3) the risk and potential benefits of the investigation. All research proposals should be reviewed by the IRB Coordinator to determine if further review is required by the full IRB committee. The levels of review and their associated criteria are available in the current edition of the BGU IRB Policy and Procedures Manual, which is available on request to the IRB Coordinator. **Research involving human subjects may not be initiated prior to formal, written approval by the appropriate committee or person.**

The information on the following pages is necessary for review by the IRB. Please prepare a document that provides the information indicated. Answer each item thoroughly, and put N/A for those that do not apply. Label each piece of information by section letter (A – G), item number (1, 2, etc.), and the boldface headers for each item. **Proposals lacking information will be returned without review**. Attach this cover sheet to your document.

Submit the completed document to the BGU IRB Coordinator using the email address shown above. Please keep a copy of all material you submit because it will remain on file with the school and not be returned to you. You will be notified by letter or email of the committee's decision.

A. Identifying Information

1. **Date:**
2. **Principal Researcher:** name, address, phone number, and e-mail address.
3. **Co-researchers (if any):** name, address, phone number, and e-mail address.
4. **Project Title:**
5. **Key Words:** For classification purposes, give two or three key words that describe or categorize this research.
6. **Inclusive Dates of Project:** Indicate the beginning and ending dates for data collection and reporting of the results.
7. **Final Project Supervisor:** name (indicate if the supervisor is a BGU faculty member – if not, provide address, phone number, and email address).
8. **Funding Agency (if any):** organization name, contact person's name, address, phone number, agency-assigned grant number or other identifier
9. **Investigational Agents:** If the research involves the use of any drugs or experimental substances, give the IND or IDE number assigned by the FDA and the expiration date.

B. Participants in the Project

1. **Type of Participants** – Indicate if the project will involve only adults or other age categories of people. Adults are considered those 18 years of age and older who are of normal cognitive functioning. Any other groups (children, mentally disabled, emotionally disturbed, senile, special minorities, etc.) must be identified.
2. **Institutional Affiliation** – If participants are affiliated with some organization or institution through which they will be recruited (i.e., schools, prisons, hospitals, human services organizations, etc.), please identify.
3. **Approximate Number of Participants –** Indicate the approximate number of people from whom data will be collected in some manner.
4. **How Participants are Chosen** – Indicate specifically how participants will be selected for the project such as random selection, criteria-based selection, review of records, referrals, canvassing, etc. If records are used, indicate who gave approval for use of records.
5. **How Participants are Contacted** – Indicate specifically how you will contact and recruit participants such as by ads, emails, telephone calls, letters, etc.
6. **Inducements** – Describe what, if any, inducements will be offered before or after the study.
7. **Monetary Charges** – If participants will be charged for any research-related procedure, please describe.

C. Informed Consent

Submit an Informed Consent Form with this application (see sample in Appendix B of the IRB Policy and Procedures Manual or it is also available online at the BGU website). For research with minors, consent from parents or guardians is required in most cases.

D. Summary of the Project Focus and Research Design

1. **Project Focus –** Summarize the problem and purpose statements of the study.

2. **Research Design** – Indicated exactly how data will be collected from participants. Include when and where the data will be collected (attach copies of invitation letters if they will be used. what instructions will be given to the participants (attach a copy if the instructions are written out for the researcher and/or the participants to read), precisely how and when the informed consent will be requested, any tasks the participants will perform (attach a copy of all verbal and/or visual materials to be used), and how the participants will be debriefed regarding the purpose of the study.

E. Confidentiality

Specify steps that will be taken to ensure the confidentiality of the information collected. Please include information on who will have access to the data, where the data will be securely kept, and other steps you will take to protect the information. Also, please note that confidentiality also extends to the reporting of the data in written papers or presentations. Data should not be reported in a way that violates participants' confidentiality. If data will become part of a participant's permanent record or if some third party will be informed of anyone's participation in the study, explain exactly why this is necessary. If video or audiotaping is used, specify when and how the tapes will be destroyed.

F. Risks

Use the following chart to evaluate the level of risk to participants involved in your project. For items that apply to your project, indicate what precautions will be taken to minimize risk to the participants (use the Notes box or attach a separate sheet). If, in the course of review, the committee finds evidence of possible risk that is not addressed, the proposal will be rejected, and a re-submittal will be required.

Potential Risks	Yes	No	Notes
Will research involve any possible **invasion of privacy** of the participants or their families, including the review of personal information or records?			
Will research involve administration of any **physical stimulus** other than sensory stimuli associated with normal classroom situations and/or daily life?			
Will research involve any **deprivation** of physiological requirements such as nutrition or sleep, **manipulation** of psychological and/or social variables, e.g., sensory deprivation, social isolation, psychological stresses, etc.			
Will research involve any **deception** in which full informed consent cannot be obtained before the study begins? In these cases, the protocol must include a statement of why the deception is necessary and how participants will be debriefed upon completion of the study. Informed consent is *not* waived when deception			

is used; it must be obtained after the data are gathered but before analysis is performed.			
Will research involve asking participants anything regarding **sensitive information** that they may consider to be personal or sensitive in content?			
Will research involve the presentation of any materials which participants might find to be **offensive, threatening,** or **degrading**?			
Will research involve any **physical exertion** beyond normal classroom and daily life situations			
Will research involve any **vulnerable populations** including children under the age of 18, pregnant women, prisoners, wards, and other "vulnerable populations," such as mentally or physically disabled persons and economically or educationally disadvantaged persons (see Federal Code, 45 CFR 46 for definitions of vulnerable populations).			

G. Signatures

I certify that the information furnished concerning the procedures to be taken for the protection of human participants is correct. I will seek and obtain prior approval for any substantive modification in the proposal and will report promptly any unexpected or otherwise significant adverse effects in the course of this study.

Signature (typed electronic entry acceptable)

_____ Date _____