BAKKE GRADUATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES

2018-2019

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

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Some sections of this manual were adapted with permission from the IRB Handbook of Azusa Pacific University in Azusa, California

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I. INTRODUCTION

Bakke Graduate University (BGU) encourages the conduct of ethical practices in relation to all research related to human subjects. BGU has adopted the guidelines outlined in the Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). This document is available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html and referred to in this manual as § 45 CFR 46.

Before collecting any research data related to human subjects, all students, faculty, project supervisors, and other staff members must obtain approval from the BGU Institutional Review Board (IRB) when required by criteria established in federal regulations defined in § 45 CFR 46 and described in this policy manual. Engaging in research with human subjects without IRB approval when required has serious ethical implications and violates university and federal policies. Questions regarding when BGU IRB approval is required may be directed to the IRB Coordinator at IRBCoordinator@bgu.edu

The National Research Act was passed in 1974 and established the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission published the *Belmont Report* in 1979 which established the ethical basis for the regulations outlined in § 45 CFR 46. The *Belmont Report* describes the following internationally recognized ethical principles.

> ***Respect for persons*** "incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection" [thus, the need to obtain informed consent].
>
> ***Beneficence*** entails treating persons "in an ethical manner not only by respecting their decisions, but also by making efforts to secure their well-being. Two general rules: (1) do no harm; and (2) protect from harm by maximizing anticipated results and minimizing possible risks of harm."
>
> ***Justice*** requires that the "benefits and burdens of research be distributed fairly" [thus, the principle of justice is applied in the selection of research subjects].

For more information on these ethical principles, please refer *to Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

A. DEFINITIONS

Federal regulations define *research* as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (§ 45 CFR. 46.102 [d]). These regulations define h*uman subjects* as "living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information" (§ 45 CFR 46.101[f]).

A project or study is "research" in this context if it: 1) is conducted with the intention of drawing conclusions that have some general applicability to populations or situations other than the one being studied ("generalizable knowledge"), and 2) uses a commonly accepted qualitative or

quantitative method. More specifically, generalizable knowledge is information based on results or findings that are expected 1) to be reproducible, and 2) to apply broadly with the expectation of predictable outcomes.

B. LEVELS OF REVIEW

All final projects for degree programs at BGU will generally meet the criteria of both "research" and with "human subjects" as noted above. All final projects proposals will require review and approval by the BGU Academic Cabinet. Based on the criteria stated in this manual, some final project proposals and some research for courses will require review and approval by the IRB. . In addition, the need for IRB review is not determined by whether the researcher intends to present or publish the study outcomes, since publishing the results of a project does not by itself classify the study as one that is generalizable. However, in some cases, the intent to publish can be used as one criterion for determining whether the project meets the above definition of "research."

Opportunity samples, pilot studies, and preliminary studies designed to help the researcher refine data collection procedures, instruments, or research design, require the same scrutiny as full-scale research projects. They are therefore subject to IRB review.

Research involving the secondary analysis of existing data (e.g., public de-identified data) does not require review when it does not meet the definition of research with human subjects noted above. However, the secondary use of data may qualify for Exempt Status under the federal regulations if the initial dataset is identifiable and if it would not be possible for the researcher to identify the subjects. In some cases, secondary use of data may warrant expedited or full board review (e.g., research involving prisoners, research using data collected for a previous study where additional informed consent may be warranted).

Studies initiated with the primary intent of improving institutional practice (sometimes labeled outcome studies or program assessment) are considered "quality improvement" activities and are typically not classified as research. However, some program evaluation projects may fall into the definition of research based on design and intent to generalize outside of the local area.

Studies conducted by faculty with their own students would not typically lead to generalizable outcomes and would not normally fall under the category of research to be reviewed by the IRB. Professors that choose to do research with their own university students should be aware that they will need to mitigate the inherent potential for bias built into that methodology.

If human subjects are involved in a study which does not meet the definition of "research," they must be protected using the same level of care as if IRB review had taken place. For example, the researcher must always obtain permission from participants and disclose any risks to them before collecting data. Please consult with a member of the IRB for additional guidance (also see the Decision Tree at: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, Chart 1. 5).

II. BGU INSTITUTIONAL REVIEW BOARD COMPOSITION AND FUNCTIONS

A. MEMBERSHIP AND MEETINGS

In regards to the membership of the BGU IRB, the following federal policies apply:

1. Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
2. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
3. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
4. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
5. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
6. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB (§ 45 CFR 46.107[d]).

Members are appointed to one-year terms by the Academic Dean. The IRB will meet at least bi-monthly for regularly convened meetings.

B. GENERAL FUNCTIONS OF THE IRB

All research requiring review according to federal policy § 45 CFR 46 will be subject to review by the BGU IRB, including but not limited to applicable coursework, dissertations, and other forms of final projects for academic programs. All dissertation/final project proposals will be reviewed and approved by the Academic Cabinet (AC). The AC will determine the research proposals that need IRB attention. When a full board review is required, the review of the proposed research will be conducted at regularly convened meetings of the IRB at which a majority of the members are present, including “at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it will receive approval of a majority of those members present at the meeting” (§ 45 CFR 46.108). IRB applications, meetings, documents, and minutes are confidential.

III. FACTORS CONSIDERED IN IRB REVIEWS

A. EVALUATION OF IRB REVIEW LEVEL

Several factors are considered in evaluating the level of IRB review to be required for research projects (see *The Belmont Report* for more details on these issues).

Benefit - Federal regulations charge the IRB with determining that research benefits outweigh research risks. Benefit can be defined as value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge.

Risk - Risk can be defined as the magnitude of the potential harm or discomfort and the probability of the harm or discomfort occurring. For purposes of protecting human subjects in research projects, risk includes:

1. Violation of privacy
2. Violation of confidentiality
3. Questions that the participant may consider sensitive
4. Possible emotional distress or physical injury
5. Invasive procedures

Minimal Risk - 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.

Benefit vs. Risk - The “Common Rule” developed and agreed upon by various federal agencies instructs Institutional Review Boards to ensure that “risks to subjects are minimized” and “risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be reasonably expected to result”.

Vulnerable populations - Vulnerable populations are individuals or groups who, by reason of disability, illness, age, or other status exhibit diminished personal autonomy. Vulnerable categories include but are not limited to children, prisoners, handicapped or mentally disabled persons, socially or economically disadvantaged persons, pregnant women, and human fetuses.

Sensitive topics - Any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential is considered sensitive topic research. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive. Sensitive topics include but are not limited to marriage and family personal practices, financial status, political opinions, religious beliefs, criminal activity, sexual orientation/attitudes/preferences/practices, and/or incest/rape/date rape/sexual molestation.

Privacy - Privacy is defined as having control over extent, timing and circumstances of sharing oneself with others. Please be attentive to threats to participants’ privacy. An acceptable practice is to distribute invitations to a broad population and ask for persons to self-identify as

meeting more narrow criteria. An option for some sensitive interview research is to offer the participant the opportunity to review publication drafts for unintended markers of identity.

Confidentiality - Confidentiality pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes.

B. GENERAL CRITERIA FOR IRB APPROVALS

In order to approve research, the IRB must ensure that the following requirements are satisfied (see Appendix C for Initial Review Form):

1. Risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from those participants would receive even if not participating.
3. Selection of participants is equitable. The IRB should consider the purposes of the research and the setting in which the research will be conducted and be particularly mindful of the special problems of research involving vulnerable populations. Participants should share equally in foreseeable benefits and risks.
4. Informed consent is sought, and will be obtained, from each prospective participant or the participant's legally authorized representative in accordance with, and to the extent required by § 45 CFR 46.116.
5. Informed consent is appropriately documented in accordance with, and to the extent required by § 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. Additionally, when some or all of the participants are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, or mentally disabled, economically disadvantaged, or educationally disadvantaged persons) additional safeguards are included in the study to protect the rights and welfare of these participants.

The IRB has the authority to approve, require modifications (in order to secure approval), or not approve all research activities. The IRB will notify the researcher in writing of its decision to approve or not approve the proposed research or of modifications required to secure IRB approval. If the proposed research is not approved, the IRB will include in its written notification a statement of the reasons for its decision and give the researcher an opportunity to reapply. When the convened IRB requests substantive clarifications or modifications of protocol or informed consent documents from the researcher, IRB approval of the proposed research must be deferred, pending subsequent review by the convened IRB.

C. IRB CRITERIA FOR RESEARCH WITH CHILDREN

The IRB will often approve research involving children if the board determines:

1. there is no greater than minimal risk,
2. adequate provisions have been made for soliciting the assent of the children, and
3. permission has been obtained from their parents or guardians (See § 45 CFR 46.404).

If the IRB determines research involving children may involve greater than minimal risk, they may approve the project if the board considers:

1. the risk is justified by the anticipated benefit to the subjects,
2. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by any other available alternatives, and
3. the requirements for assent and permission have been met. (See § 45 CFR 46.405)

If the children are not likely to directly benefit from the study, the IRB may still approve the research if the board considers:

1. the risk represents a minor increase over minimal risk,
2. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual psychological, social or educational situations,
3. the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or treatment of the subject's disorder or condition, and
4. the requirements for assent and permission have been met. (see § 45 CFR 46.406)

Any other research with children that does not meet the above requirements may be approved under special circumstances defined in § 45 CFR 46.407.

D. SUSPENSION OR TERMINATION OF IRB APPROVAL

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported within two business days to the investigator, faculty supervisor (if a student is involved), Department Chair and Dean, Provost, and any pertinent governing institution (such as a funding agency or the Office of Human Research Protection). As a response to complaints, pressing concerns, or evidence of harm to subjects, the RIO or IRB Chair may suspend a study. If necessary, the RIO may, with one or more IRB members, initiate an investigation. Every investigator will be given the opportunity to respond to the concerns. The convened IRB must vote on any action of suspension or termination upon completion of an investigation.

E. REQUEST FOR REVISION OR ADDITION TO APPROVED RESEARCH

Researchers who will in any way modify their research protocol or personnel which has been previously submitted to and approved by the IRB must submit a report to the IRB requesting revisions of additions review. Deviations from this approved protocol may result in termination of approval by the IRB.

F. RENEWALS FOR CONTINUING RESEARCH

After the initial approval, all studies must undergo continuing review by the IRB to ensure that the risk-benefit relationship of the research remains acceptable, the informed consent process and documents are still appropriate, and the enrollment of subjects has been equitable. By federal regulation, the maximum period between these IRB reviews is one year. The researcher is responsible for applying for continuing review in a timely manner to ensure IRB approval is continuous.

Therefore, researchers must submit an annual renewal request for their continuing research three weeks prior to the anniversary date of the original approval. Depending on the degree of risk involved, more frequent reporting may be requested by the IRB (see § 45 CFR 46.109.e). If a study is not re-approved before the study's expiration date, the research study is automatically suspended.

G. CLOSURE REPORT OF RESEARCH STUDY

A closure report must be submitted after all data collection and de-identification is complete, and PRIOR to the one-year anniversary date of your approval. IRB applications from researchers who are delinquent on closure reports from previous research will be delayed until closure reports are filed.

H. LEAVING BAKKE GRADUATE UNIVERSITY

Researchers must contact the IRB as soon as they are aware of an impending departure from BGU. They must file a closure report before their departure. The BGU IRB will no longer cover a researcher once he or she leaves the institution even if that person remains a member of the research team. In that situation, a study revision would be required indicating the researcher's new role and, if "engaged in research," the researcher must obtain IRB approval from his/her new institution.

III. REVIEW PROCESS CATEGORIES

A. EXEMPT STATUS

Some studies on human subjects may be exempt from the need for an extensive review by the IRB. Exempt research proposals are submitted to the IRB Coordinator and then reviewed for protection of human subjects by a member of the Institutional Review Board.

Qualifications for Exempt Status

The federal policy § 45 CFR 46 lists the following conditions for exempt status of research:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
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. (§ 45 CFR 46)

The IRB has the final authority in determining if a research project may be considered as qualifying for exempt status.

Research that Cannot Qualify for Exempt Status

Research that cannot qualify for exempt status includes:

1. Research involving interaction with children
2. Research involving prisoners
3. Research that involves deception or withholding of information from subjects
4. Research that involves intense physical exercise

5. Research that may cause emotional distress or discomfort greater that what would be expected in daily life

(See the Decision Trees at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, referring specifically to Charts 2-7.)

B. EXPEDITED REVIEW

Expedited review procedures refer to research that does not involve vulnerable populations, sensitive topics, and involves no more than minimal risk to human subjects.

IRB Criteria for Evaluating Expedited Research

Criteria for IRB approval of expedited review include:

1. Risks to subjects are minimized: a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
2. Risks to subjects are reasonable in relation to the anticipated benefits if any to subjects and the importance of the knowledge that may be reasonably expected to result.
3. Selection of the subjects is equitable.
4. Informed consent is received from each prospective subject.
5. Informed consent is appropriately documented.
6. The research plan makes adequate provision to ensure the safety of subjects.
7. Adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data. (Criteria is adapted from § 45 CFR 46.111)

All of the items above must apply for an application to be considered for Expedited Review. See Decision Trees at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, Charts 8 and 9.

Research that Generally Requires an IRB Expedited Review

The following categories generally require at least an IRB expedited review (for further explanation, see http://www.hhs.gov/ohrp under expedited review).

1. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
2. Information that could damage an individual's financial standing, employability, or reputation
3. Information (usually in medical records) that could lead to social stigmatization or discrimination
4. Psychological well-being or mental health, including physical or mental abuse
5. Sexual orientation, attitudes, preferences, or practices
6. Incest, rape, date rape, or sexual molestation
7. Genetic information

8. Religious orientation or views – Religion is just one example of a sensitive topic. As with all sensitive topics, the broader principle is whether or not there is a potential for harm if the data were revealed. Identifying religious orientation on a research project would not typically be considered a sensitive topic at Azusa Pacific University. However, it should be noted that there are many possible scenarios where religious research could be potentially harmful to the participant if confidential data were revealed.

9. Veteran or wartime experiences

10. Topics that may be perceived as sensitive or injurious by participants

11. Immigration status

For more information on issues related to an Expedited Review, see the Decision Trees at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, Charts 8 and 9.

C. FULL BOARD REVIEW

Research that involves (1) vulnerable populations, or (2) sensitive topics, or (3) involves more than minimal risk requires full board review. The criteria are discussed in the following sections.

Vulnerable Populations

Full IRB reviews are required for all research that involves fetuses, pregnant women, prisoners, some populations of children, and groups who may have diminished capacity to provide consent or who may be high risk must be provided full review. The § 45 CFR 46 regulations provide details on the following groups:

1. Pregnant women (§ 45 CFR 46.201 – 207);

2. Prisoners (§ 45 CFR 46.300 – 306)

3. Children and minors (§ 45 CFR 46.401-409) except as included under exempt and expedited categories discussed below in later sections of this manual

Sensitive Topics

Full IRB reviews are required for any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive. Examples of sensitive topics include, but are not limited to the following:

1. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products

2. Information that could damage an individual's financial standing, employability, or reputation

3. Information (usually in medical records) that could lead to social stigmatization or discrimination

4. Psychological well-being or mental health, including physical or mental abuse

5. Sexual orientation, attitudes, preferences, or practices

6. Incest, rape, date rape, or sexual molestation

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8. Religious orientation or views – Religion is just one example of a sensitive topic. As with all sensitive topics, the broader principle is whether or not there is a potential for harm if the data were revealed. Identifying religious orientation on a research project would not typically be considered a sensitive topic at Azusa Pacific University. However, it should be noted that there are many possible scenarios where religious research could be potentially harmful to the participant if confidential data were revealed.

9. Veteran or wartime experiences

10. Topics that may be perceived as sensitive or injurious by participants

11. Immigration status

More than Minimal Risk

Full IRB reviews are required when the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (§ 45 CFR 46). Invasive procedures, possible emotional distress, and the potential for lack of confidentiality, for example, are considered greater than minimal risk. In order to be approved by the Board, such risks must be addressed.

IV. INFORMED CONSENT

Based on federal regulations regarding research (see definitions in Section I of this manual), people may not be involved as a human subjects in the research unless legally effective informed consent has been obtained from the subject(s) or the subject's legally authorized representative (see § 45 CFR 46.116).

A. SPECIFIC CONTENT OF INFORMED CONSENT FORM

The Informed Consent will contain the following information:

1. A statement that the study involves research;
2. An explanation of the purpose of the research, an invitation to participate and explanation of why the participant was selected, and the expected duration of the participant's participation;
3. A description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the participant in another setting. Use of research methods such as randomization and placebo controls should be explained;
4. A statement of any financial or other means of sponsorship for the research;

5. A description of any foreseeable risks or discomforts to the participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them; as well as acknowledgment of potentially unforeseeable risks;
6. A description of any benefits to the participant or to others that may reasonably be expected from the research, and an estimate of their likelihood;
7. A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant;
8. A statement describing to what extent records will be kept confidential, including examples of who may have access to research records such as hospital personnel, the FDA, and drug sponsors;
9. An explanation and description of any compensation and any medical treatments that are available if participants are injured through participation; where further information can be obtained, and whom to contact in the event of research-related injury;
10. An explanation of whom to contact for answers to questions about the research and the research participant's rights including the name and phone number of the Principal Investigator (PI);
11. A statement informing the subject that inquiries regarding the nature of the research, his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the Research Integrity Officer at Azusa Pacific University;
12. A statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled;
13. A statement that if a participant declines to continue, any data gathered to that point may be part of data analysis;
14. A statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information presented;
15. A statement outlining the nature of subject remuneration (if any). Remuneration should be described as a “token of appreciation” for participating subjects. Care should be taken to ensure that remuneration is appropriate to the scope and context of the project. Excessive remuneration may be viewed as potentially coercive;
16. California Experimental Subject’s Bill of Rights - if human subjects are involved in an experimental clinical procedure;
17. Authorization for Use of Private Health Information - if personal information considered “Protected Health Information” is used in the study;
18. The signature of the researcher after explaining the research to the participant and when they are satisfied the participant fully understands. It is not appropriate for the researcher to sign in advance or to use a stamped signature.

See Appendix B for a sample Informed Consent Form.

B. ADDITIONAL ELEMENTS OF INFORMED CONSENT

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus) if the subject is or may become pregnant which are currently unforeseeable
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. Statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study (§ § 45 CFR 46.116).

C. DOCUMENTATION OF INFORMED CONSENT

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

See Decision Trees at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, Charts 10 and 11.

Except as provided in in the waiver criteria shown above, informed consent shall be documented by the use of a written consent form approved by the IRB or by use of an electronic consent form for electronic surveys (see Appendix B for sample Informed Consent Form). The written consent forms must be signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Except as provided in the waiver criteria shown above, of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by §45 CFR 46.116 above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short, written consent document stating that the elements of informed consent required by §45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. See §45 CFR 46.117 for additional related regulations.

See Appendix B for a sample Informed Consent Form.

D. ASSENT FORM FOR RESEARCH WITH CHILDREN

The IRB shall determine that adequate provisions are made for soliciting the assent of children participating in research when, in the judgment of the IRB, the children are capable of providing assent. Children 12-17 years of age must give their written assent to participate in research. The IRB may determine that children younger than 12 years of age must give their assent for a particular research project.

E. DECEPTION AND INCOMPLETE DISCLOSURE

In certain circumstances, the use of deception or incomplete disclosure in research are acceptable and important techniques, though these approaches place special responsibilities both on the researcher and on the IRB. In these cases, the IRB requests additional information from researchers and will review those proposals carefully. Whereas deception occurs when research subjects are deliberately given false information about some aspect of the research, incomplete disclosure results when the true nature or purpose of the research is withheld. It is therefore the provision of erroneous information (deception) or the omission of information (incomplete disclosure) which creates a circumstance warranting special consideration for the protection of those human subjects.

Requirements when Incomplete Disclosure is Intentionally Used in Research

In all cases of deception or incomplete disclosure, the following guidelines apply:

1. The research must involve no more than minimal risk to participants
2. The waiver or alteration of the informed consent may not adversely affect the rights and welfare of the participants
3. The research could not practicably be carried out without the alteration or waiver
4. At the appropriate time, participants will be provided with additional pertinent information regarding participation
5. Participants must be given the right to withdraw their participation once they are made fully aware of the study's purpose

IRB Application Content for Use of Deception or Incomplete Disclosure

IRB applications proposing to use deception or incomplete disclosure should include the following information:

1. A clear explanation of why deception or incomplete disclosure is justified and whether alternative methods could achieve the same research goals
2. An indication of whether deception or incomplete disclosure may affect a participant's willingness to participate in research

3. Identify what elements of the Informed Consent the researcher is requesting to waive
4. An explanation of the process to debrief participants including who will debrief them and at what point in the study (include a copy of the debriefing statement and the debriefing script). The informed consent document must include the fact that the information provided to the subject is incomplete and that they will be debriefed after research procedures are completed.
5. An explanation of whether deception or incomplete disclosure is likely to cause the subject discomfort before or after debriefing and how that risk will be minimized

The debriefing of participants is required at an appropriate point in time. Such a debriefing must include a full explanation of the research question and hypothesis, the procedures used for the study, and why deception was necessary. In no case can the debriefing cause more harm than the deception or incomplete disclosure.

In its review, the IRB must consider factors in addition to the scientific value of the research and the efficacy of alternative procedures. They will also need to confirm that the deception does not extend to influence the participants' willingness to participate, and that any experimentally induced harm may be removed through debriefing. Further, the IRB will consider whether the researcher is equipped to manage emotional reactions that may occur during debriefing, and whether the proposed deception could facilitate unwanted and inappropriate invasions of privacy.

Deception or incomplete disclosure cannot be approved if non-deceptive alternatives are available, if human subjects would likely not participate if the true purpose of the study were known to them, and if it places participants at significant risk of any type.

V. OTHER REQUIREMENTS FOR RESEARCHERS

A. INTEGRITY OF RESEARCH

BGU values honesty and integrity of research and is dedicated to ensuring the credibility and trustworthiness of the research conducted by our research community, to protecting this community from unsubstantiated allegations of research misconduct, and to upholding the university's high standards for research activity. Misconduct in research represents a breach of the policies of BGU, the standards expected by our sponsors, and the expectations of scholarly communities for accuracy, validity, and integrity in research. It is therefore the policy of BGU to inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged research misconduct. Further, it is also the policy to comply in a timely manner with sponsor requirements for reporting cases of possible research misconduct when sponsored project funds are involved. Each allegation of research misconduct will be responded to in a thorough, competent, objective, and fair manner. An Annual Report on Possible Research Misconduct is filed with the Office of Research Integrity (in the U.S. Department of Health and Human Services) by the Academic Dean of Coordinator of the IRB.

B. PRIVACY AND CONFIDENTIALITY

Privacy is defined as having control over extent, timing and circumstances of sharing oneself with others. Please be attentive to threats to participants' privacy. An acceptable practice is to distribute invitations to a broad population and ask for persons to self-identify as meeting more

narrow criteria. An option for some sensitive interview research is to offer the participant the opportunity to review publication drafts for unintended markers of identity.

Confidentiality pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. In most research, ensuring confidentiality can occur by following these routine practices:

1. Substituting codes for identifiers or encrypting identifiable data
2. Informed consent documents and de-identified research data are stored in separate secure locations
3. Use random numbers to identify research records (Social Security and student ID numbers are not acceptable)
4. Removing face sheets (containing identifiers such as names and addresses) from survey instruments containing data
5. Properly disposing of computer sheets and other papers
6. Limiting access to identifiable data
7. Educating the research staff on the importance of confidentiality
8. Storing paper records in locked cabinets or assigning security codes to computerized records

C. CONFLICT OF INTEREST

BGU's policies regarding Conflicts of Interest are consistent with federal requirements for research and best practices in academia (see various BGU policy manuals). A statement regarding Conflict of Interest will be included on all applications submitted to the IRB.

Faculty, administrators, and all personnel associated with BGU commit themselves to the pursuit of research in accordance with the highest standards of integrity and in compliance with legal, professional, ethical and other requirements that promote objectivity and protect against financial conflicts of interest in research. BGU will identify possible conflicts of interest in research, whether apparent or real, and provide mechanisms for their management, reduction or elimination in compliance with federal and state law as well as any relevant policies of entities funding research at the university.

The success of BGU depends upon the integrity of the research and the researchers as well as the public's confidence in them. Conflicts of interest in research strike at the heart of BGU's integrity. In pursuit of its mission as a private institution of higher education, BGU seeks excellence in the quality of its research, in the teaching and education it provides to its students, and in the service it provides to the broader community. This knowledge transfer inevitably leads to increasingly close relationships between universities and those with financial capital in the private sector. The benefits that potentially accrue from this proximity are accompanied by real or apparent risks that economic interests might compromise academic research by influencing an investigator's judgment about the design, conduct, reporting, or management of research, and, in the case of research involving human subjects, imperil the safety of participants.

Faculty assuming the responsibility for the design, conduct or reporting of research have a special obligation to avoid bias or the appearance of bias in the conduct of these studies. Any possible conflict of interest must be formally disclosed to the institution. Questions about the Conflict of Interest policies may be directed to the Academic Dean.

D. RECORDING DATA

In recording data, the researcher must properly care for records in a systematic manner to avoid problems if someone asks about or questions the work. Hard-copy evidence should be entered into a bound notebook so that there is no question later about the date and content of data collected. Any changes to data must be noted, indicating date and reasons for the change.

Electronic data should be validated to in regards to date and circumstances in regards to when it was recorded. It is easy to change dates on computers and thereby alter the date a particular file seems to have been created. Electronically collected data must be validated in some manner to show it has not been changed.

Responsible handling of data must begin with proper storage and protection from accidental damage, loss or theft:

1. Lab notebooks should be stored in a safe place.
2. Computer files should be backed up and the backup data saved in a secure place that is physically removed from the original data.
3. Samples should be appropriately saved so that they will not degrade over time.

Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes. There is, however, no common definition of a reasonable period of time.

The National institute for Health (NIH) generally requires that data be retained for 3 years following the submission of the closure report. Some government programs require retention for up to 7 years. BGU requires that data be kept for 3 years after the closure report unless a longer retention is required by a specific agency.

E. INTERNATIONAL AND CROSS CULTURAL RESEARCH

All human subject research conducted internationally or across cultures must adequately protect the rights and welfare of the research subjects. Researchers must provide evidence that research projects and translated documents are sensitive to participants' local research context, particularly culture and language. These protocols should be categorized (i.e., expedited, full board) using the same risk/benefit considerations applied to any other research project. In addition to obtaining IRB approval, the researcher must provide evidence that research projects and translated documents are sensitive to participant context and inclusive of culture and language. The first choice for documenting sensitivity to participant context is IRB review in the participants' country of residence. As an alternative, researchers may seek written documentation of sensitivity to local research context from persons who meet three criteria, namely (1) indigenous to the participant culture, (2) a resident of the research area for two of the last ten years, and (3) presently serving as an official of a local government or local academic institution.

International and cross cultural research proposals requiring translated documents should include contact information/scripts and informed consent. The researcher can demonstrate accuracy and sensitivity of translated documents through back translation by persons indigenous to the participant culture and fluent in participant language. The researcher can translate documents, but cannot serve as back translator of documents employed in his/her research. Local consulates may have personnel that meet IRB criteria that can assist with verifying that the planned research is culturally sensitive and/or with translations.

The International Compilation of Human Research Standards provides a resource of laws, regulations, and guidelines that govern human subject research as well as the standards from a number of international and regional organizations. These are listed by country and can be found here: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/.

F. EXTERNAL RESEARCH REVIEW PROCESS

IRB Involvement in External Research

All requests from researchers outside of BGU to involve BGU faculty, staff, and students for their research with human subjects should be sent to the IRB Coordinator who will assist the researcher in understanding the BGU specific review process for such requests. If the proposal is deemed to be "non-engaged research," the researcher should submit a copy of his/her IRB application from his/her home institution, if one exists. If the proposal is deemed to be "engaged research," the researcher must submit a completed BGU IRB application. This step is necessary, even if the research was classified as "exempt" at another institution. The IRB application should, whenever possible, identify a sponsor at BGU -- someone at the department chair or director level. The external researcher's proposal and supporting materials are forwarded to the BGU IRB.

The Academic Dean will also review the proposal for external research to consider factors including the timing of the project related to other planned research projects, whether such information has recently been collected at BGU, and the purpose and potential benefit of the research project. Based on the review, the Academic Dean will determine whether the proposed research is approved. The Academic Dean will notify the researcher of the approval or denial, noting any conditions in the case of approval, and will direct the external researcher to contact person for the BGU IRB. In the case of "engaged" research with human subjects, the next step is IRB review and approval. The IRB Coordinator will then direct the researcher to the on-line application process.

Institutional Authorization Agreement

An institutional authorization agreement (IAA) is a formal, written document that provides a mechanism for BGU to accept authority to review and approve research conducted elsewhere, or for BGU to cede that authority to another entity. An IAA is a joint review arrangement that facilitates collaboration on research of human subjects, enabling collaborating institutions to rely on a single IRB (an "IRB of Record") for review and for some or all aspects of continuing oversight of the research, in order avoid a duplication of efforts. The IRB must approve the arrangement. .

If a researcher at BGU collaborates on a project with another institution and his/her involvement is limited to data analysis of research collected by collaborating investigators at the other institution, then the other institution may agree to serve as the IRB of record for the project and BGU can cede authority. Likewise, if the BGU researcher fully collaborates with another

institution on a project and the IRB at the other institution is better-prepared to review the research, then that institution may agree to serve as the IRB of record for the project and BGU, may cede authority.

Researchers may request an IAA, but generally the agreement is initiated by the IRB and require approval of the appropriate officials at each institution. Factors to be considered include:

1. ensuring quality and thoroughness of protocol review;
2. local context issues;
3. institutional liability;
4. complexity of shared control and accountability;
5. costs of delegating or accepting review; and
6. relationship to the outside organization.

The IRB will determine eligibility for an IAA and will recommend the terms of such an agreement. For becoming the IRB-of-Record, considerations include, for example, the time and resources required to accept the review, BGU's expertise for initial and continuing review, and the willingness of the other institution to monitor compliance, review adverse events and to handle complaints. For ceding authority to another institution, considerations include the impracticability of an BGU IRB review, the appropriateness of the other IRB to review the protocol, and the proposed arrangements for that institution to monitor and oversee the research.

As part of the IAA or in a separate document, the parties must establish and clearly document roles and responsibilities, the IRB of record for a protocol, communication channels, etc. Research may not commence until the IAA is fully executed. Because establishing an IAA requires thorough review, it should not be considered as a time-saving effort; indeed, some agreements take several weeks to negotiate, rendering a full board review more expedient.

G. GUIDELINES FOR PROJECTS AFTER IRB APPROVAL

Once a project has been approved by the IRB, researchers must adhere to the approved protocol and follow any additional IRB instructions. The continuing responsibilities include:

1. enrolling only those subjects that meet IRB approved inclusion and exclusion criteria;
2. properly obtaining and documenting informed consent;
3. obtaining prior approval for any deviation from the approved protocol;
4. keeping accurate records;
5. promptly reporting to the IRB any unanticipated problems involving risks to subjects or others, including adverse events, noncompliance, and protocol deviations;

Research approved by the IRB may be monitored for compliance.

H. REPORTING UNANTICIPATED PROBLEMS AND PROTOCOL DEVIATIONS

Researchers are required to report to the IRB all unanticipated problems and adverse events, as well as protocol changes and deviations. It is the expectation of the IRB that all approved

protocol procedures are being followed without alteration unless the IRB has been informed of a protocol change or deviation either by reporting an unanticipated problem or adverse event by seeking a protocol revision.

Unanticipated problems involving risks to subjects or others refers to a problem, event, or information that is not expected, given the nature of the research procedures and the subject population being studied, and which suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was anticipated at the time IRB approval was conferred. Specifically, "unanticipated problems" are those that meet all three of the following criteria:

1. *Unexpected* (in terms of nature, specificity, severity, or frequency) given the research procedures described in the protocol-related documents and the characteristics of the subject population being studied.
2. *Related or possibly related* to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
3. *Suggests that the research places subjects or others at a greater risk of harm* (including physical, psychological, economic, legal, or social harm) than was anticipated at the time IRB approval was conferred.

An adverse event is defined as an untoward or unfavorable occurrence in a human subject which may or may not be related to the subject's participation in the research.

A serious adverse event is one which results in death, is life-threatening, requires hospitalization, results in a significant disability/incapacity, or any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed.

The timeframe for reporting unanticipated events is as follows:

1. Serious adverse events must be reported to the IRB or to the RIO within 24 hours of the occurrence of the event.
2. Other unanticipated problems or protocol changes and deviations that meet the three criteria above must be reported to the IRB within 5 days of the occurrence of the event.
3. All other events or adverse events that do not meet these reporting criteria, including unanticipated protocol changes and deviations, must be submitted within one week of the investigator becoming aware of the problem.

If unanticipated problems occur during research, the Principal Investigator must report the following to the Chair of the APU Institutional Review Board:

1. Research number as assigned by the IRB, title of approved research project
2. A detailed description of the adverse event, incident, experience, or outcome
3. An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem, and

4. A description of any recommended changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem

The report must be submitted in writing to the IRB Chair, who will promptly present the report to the IRB. If the IRB Chair is the Principal Investigator making the report under this policy, the report shall be presented directly to the Research Integrity Officer who will present the report to the IRB.

The IRB, the Chair or designee will review the report to consider whether the event impacts the risk/benefit ratio and whether that warrants a reconsideration of the approval of the study, modifications to the study, revisions to the continuing review timetable, suspension of the study, or other action required due to safety concerns. The IRB has the authority to require, as a condition of continued approval by the IRB, submission of more detailed information by the researcher or sponsor about any adverse event or unanticipated problem occurring in a research protocol. The IRB Coordinator will brief the Academic Dean concerning all reports.

For serious adverse events, the IRB Coordinator or designee has the authority and responsibility to make immediate changes to the study, as noted above, and will refer the issue to the full IRB as soon as is feasible for additional consideration. Only a full IRB can make a determination to take no action on a serious adverse event.

All BGU faculty and staff must promptly report to a member of the BGU IRB any of the following occurrences when required by law:

1. Unanticipated problems involving risks to subjects and others
2. Serious or continuing noncompliance with requirements or determinations of the IRB
3. Suspension or termination of IRB approval of non-exempt human subject research.

For further guidance, the researcher is encouraged to review the Department of Health and Human Services Guidance on Reviewing and Reporting Unanticipated Problems Involving Risk to Subject or Others and Adverse Events at http://www.hhs.gov/ohrp/policy/advevntguid.html.

REFERENCES

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APPENDIX A

APPLICATION FOR IRB REVIEW

Request for Approval of Research with Human Participants

In Social and Behavioral Research

Institutional Review Board for Research with Humans
Bakke Graduate University
8515 Greenville Ave.
Dallas, TX 75243-7039

College and Federal policies require that each project involving studies on 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. BGU designates three-levels of review, and not all research proposals need to come to the IRB committee. The levels of review and their associated criteria may be viewed on BGU website. **Research 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. 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 your typewritten pages to this cover sheet.

Submit the completed form to the BGU IRB committee at the above address or by email. 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 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** – Give 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

1) **Type of Participants** – Adults are considered those 18 and older who are of normal cognitive functioning. Any other groups (mentally disabled, emotionally disturbed, senile, special minorities) 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 identity
3) **Approximate Number of Participants**
4) **How Participants are Chosen** – records, classes, referrals, canvassing, etc. Be specific in describing this. If records are used, indicate who gave approval for use of records.
5) **How Participants are Contacted** – ads, email, telephone, letters, etc. Be specific about how people are asked to participate.
6) **Inducements** – Describe what, if any, inducements before or rewards after the study will be offered.
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 available online at the BGU website). For research with minors or with vulnerable populations, consent from parents or guardians is required in most cases.

D. Abstract and Protocol

1) **Hypothesis and Research Design** – Clearly state the problem and purpose statements of the study, and describe the design that will be used to address it.
2) **Protocol** – Describe exactly what will be done to and for the participants. Include when and where the data will be collected (attach copies of permission letters if participants are being recruited and/or tested in a field location), 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, what 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. Risks

Evaluate the following items carefully to see which apply to your study. For those that do apply, state which one(s) and **what precautions will be taken to minimize risk to the participants.** If an item is not a risk for your study, please state "No known risk identified." If, in the course of review, the committee finds evidence of possible risk that is not addressed, **the proposal will be immediately rejected**.

1) **Privacy** – any possible invasion of privacy of the participants or their families, including the use of personal information or records
2) **Physical stimuli** – administration of any stimulus other than sensory stimuli associated with normal classroom situations and/or daily life
3) **Deprivation** – withholding of physiological requirements such as nutrition or sleep, manipulation of psychological and/or social variables, e.g., sensory deprivation, social isolation, psychological stresses, etc.
4) **Deception** – any situation 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.
5) **Sensitive information** – anything participants are being asked that they may consider to be personal or sensitive
6) **Offensive materials** – presentation of any materials which participants might find to be offensive, threatening, or degrading
7) **Physical exertion** – any exertion beyond normal classroom and daily life situations

F. Confidentiality

Specify steps that will be taken to insure 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 audio-taping is used, specify when and how the tapes will be destroyed.

G. Signatures

Type the following paragraph at the end of the proposal and have all investigators and the research advisor (if applicable) sign and date below it.

"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."

APPENDIX B

PARTICIPANT CONSENT FORM

Bakke Graduate University

Participant Consent Form

Institutional Review Board for Research with Humans
Bakke Graduate University
8515 Greenville Ave.
Dallas, TX 75243-7039
800-935-4723

You are being asked to take part in a research study related to Bakke Graduate University on the topic of _____. Please read this form carefully and ask any questions you may have before agreeing to take part in the study. You must be at least 18 years old and _____ (indicate any other requirements for participants in this study).

What we will ask you to do: If you agree to be in this study, we will conduct an interview with you. The interview will include questions about

_____

_____

The interview will take about _____(time) to complete. With your permission, we would also like to tape-record the interview.

Risks and benefits: There is the risk that you may find some of the questions to be sensitive in nature. [Note: For studies posing no specific risks, use the IRB standard minimal risk statement, "I do not anticipate any risks to you participating in this study other than those encountered in day-to-day life."] There are no benefits to you other than what you may learn from the study

Compensation: You will earn no compensation participating in this study.

Your answers will be confidential. The records of this study will be kept private. In any sort of report we make public we will not include any information that will make it possible to identify you. Research records will be kept in a restricted or 'locked' file, where only the researchers will have access to the records. If we tape-record the interview, we will destroy the tape after it has been transcribed, which we anticipate will be within two months of its taping.

Taking part is voluntary: Taking part in this study is completely voluntary. You may skip any questions that you do not want to answer. If you decide not to take part or to skip some of the questions, it will not affect your current or future relationship with BGU. If you decide to take part, you are free to withdraw at any time.

If you have questions: The researchers conducting this study are _____ and _____, and they can be contacted at _____.

Please ask the researcher(s) any questions you have before signing this form. If you have questions later, you may contact any of the researcher indicated above.

If you have questions or concerns regarding your rights as a subject of this study or other question that you would like to discuss with a representative from Bakke Graduate University, you may contact the Coordinator of BGU Institutional Review Board, who can be contacted at _____ or you can call the school at the toll-free phone number listed at the top of this form. You can also use this phone number if you would like to report your concerns or complaints anonymously. You may also see information on Bakke Graduate University at the school website at www.bgu.edu.

You will be given a copy of this form to keep for your records.

Statement of Consent: I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature _____ Date _____

Your Name (printed)

_____

In addition to agreeing to participate, I also consent to having the interview tape-recorded.

Your Signature _____ Date _____

Signature of person obtaining consent _____ Date _____

Printed name of person obtaining consent _____ Date _____

NOTE: The researcher will keep this consent form for at least three years beyond the end of the study. The title of the study should appear at the top of every page.

APPENDIX C

IRB INITIAL REVIEW FORM

Review Requirement	Applicable Questions to Consider	Yes	No
1. The proposed research design is sound and will not unnecessarily expose subjects to risk.	a. Is the hypothesis clearly stated?		
	b. Is the research design appropriate?		
	c. Will the research contribute to generalized knowledge and be worth the risk?		
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of knowledge that may reasonably be expected to results.	What does the IRB consider Level of risk to be? __High __Medium __Low __Other	N/A	N/A
	What does researcher considered level of risk to be? __High __Medium __Low __Other	N/A	N/A
	Does the IRB consider there to be prospect of direct research benefit to subjects, excluding any financial compensation?		
3. Subject selection is equitable	a. Are participants clearly identified (such as men, women, children, ill-heath individuals, etc.)?		
	b. Are the subjects appropriate for the defined research methodology?		
4. Safeguards required for subjects likely to be vulnerable to coercion or undue influence.	Are appropriate safeguards in place for vulnerable subjects such as pregnant women, socially or economically disadvantaged, those with impaired decision-making abilities, etc.?		
5. Informed consent is obtained from research subjects or their legally authorized representative.	a. Does the Informed Consent form include all information based on the sample BGU Consent form?		
	b. Is the Informed Consent form clear to subjects?		
	c. Is it clear as to who will be responsible to obtain the informed consent?		
	d. If appropriate, is there a procedure for assent of children and their parents/guardians?		
	e. Is there a request for the IRB to waive or alter any informed consent requirements?		
6. Subject privacy is maximized.	a. Does the methodology minimize risks to subjects?		
	b. Do the circumstances of the project warrant an observation team to ensure safety of participants?		
7. Subject privacy and confidentiality are maximized.	a. Will personally-identifiable research data be protected from inappropriate access or use to the highest degree possible?		
	b. Are all special privacy and confidentiality issues properly address such as medical records, financial records, etc.?		
8. Other	Are there other issues that need to be addressed? (Add attached sheets as necessary)		

__ Recommend Approval __Make Changes and Resubmit __Reject