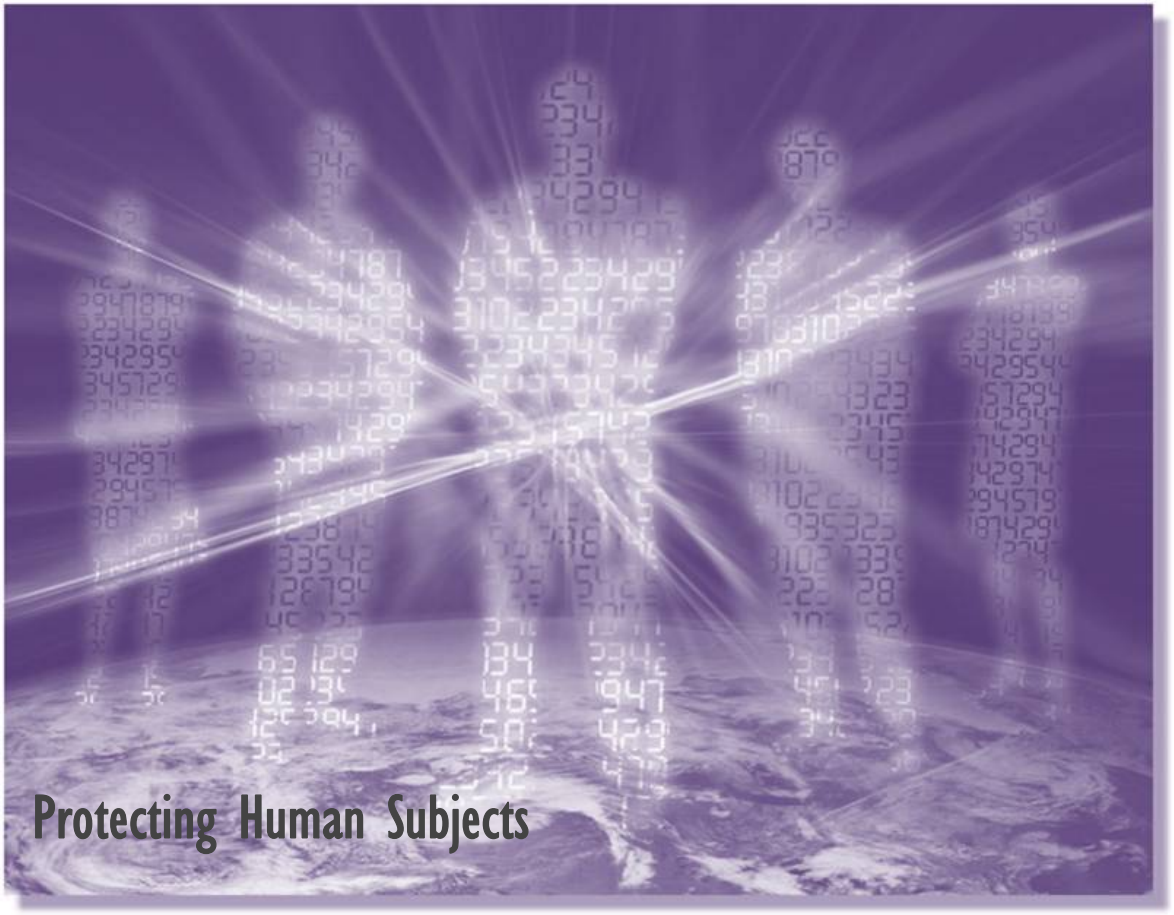
Grand Canyon University

Institutional Review Board
2014 Handbook

Version 7.0



College of Doctoral Studies
3300 West Camelback Rd.
Phoenix, AZ 85017

Phone: 602-639-7804
Email: irb@gcu.edu

Note: This handbook is intended to provide guidelines to researchers affiliated with Grand Canyon University who conduct research involving the use of human subjects. The Code of Federal Regulations, Title 45, Part 46, also referred to as the "Federal Policy" or the "Common Rule," takes precedence over the contents of this handbook.

Code of Federal Regulations

- U.S. Department of Health and Human Services (DHHS)
- National Institutes of Health (NIH)
- Office of Human Research Protections (OHRP)

Title 45 – Public Welfare

Part 46 – Protection of Human Subjects

- Subpart A – Federal policy for the protection of human subjects
- Subpart B – Additional DHHS protections for pregnant women, human fetuses, and neonates involved in research
- Subpart C – Additional DHHS protections pertaining to biomedical and behavioral research involving prisoners as subjects
- Subpart D – Additional DHHS protections for children involved as subjects in research (United States Department, 2005)

Revision History

Date	Version	Change
October 2014	7.0	Cover updated Revised IRB Chair from Dean, College of Doctoral Studies to the Director of Academic Research Inserted https:// https://cirt.gcu.edu/ in appropriate sections to reference web-based electronic protocol management for request to obtain GCU site authorization. Added information for request to obtain GCU site authorization Modified Appendices list to reflect updated forms Corrected level headings and typos
November 2011	6.0	Cover updated Inserted https://www.IRBNet.org in appropriate sections to reference web-based electronic protocol management for application materials and procedures Modified Appendices list to reflect updated procedures Clarified exempt, expedited, and full review language Clarified language for curriculum based research
April 2010	5.0	Cover updated Identified Dean, College of Doctoral Studies as IRB Chair Corrected typos
April 2009	4.0	Cover updated; No change to Handbook contents
March 2007 January 2007	3.0 2.0	Clarified language for IRB membership to reflect closer alignment with federal requirements Identified Director, Center for Graduate Studies as IRB Chair Deleted requirement for researcher's social security number on Form 3, "IRB Application for Research Approval" Moved listing of "Informed Consent Resources" from IRB Informed Consent Checklist to Section 5.0, "Informed Consent" Corrected typos
January 2006	1.0	Language provisions for referencing GCU in publication of data Statement pertaining to GCU access to data

		IRB filing requirements for course-based research IRB filing requirements for marketing and institutional-based research Revision of Appendix enumeration and form enumeration Simplification of forms Creation of Form-2: IRB Notification for Marketing or Institutional-based Research
August 2005	1.0	Minor revision to IRB membership requirements Clarification regarding reference to GCU in publication of data Change in reference from “on-ground” to “campus”
April 2005		Origination of IRB Handbook.

Table of Contents

1.0 Introduction

The National Research Act, passed by Congress in 1974, established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (herein, the Commission). The purpose of the Commission is to ensure that the rights and well-being of human subjects involved in research are protected. Therefore, any institution that engages in or supports research must establish an Institutional Review Board (IRB) for the purpose of approving and monitoring research according to Federal Policy such that human subjects are protected during all phases of the research process.

The Department of Health and Human Services (DHHS), through its Office of Human Research Protections (OHRP), is tasked with providing guidelines, education, and registration of an IRB (United States Department, 2006). The IRB at Grand Canyon University (herein, GCU) is registered with the OHRP and has gained the status of Federal-wide Assurance, which assures that the GCU community of researchers abides by the Code of Federal Regulations, Title 45, Part 46 (herein, Federal Policy) and is therefore eligible to apply for and potentially conduct federally funded research on human subjects.

2.0 The Belmont Report

The Belmont Report, published by the Commission in 1974, is a statement of fundamental ethical principles and/or guidelines for investigators who conduct research using human participants or subjects (National Commission, 1979). The Belmont Report distinguishes between practice and research, defines basic ethical principles (the Belmont Principles) as they apply to research involving human subjects, and provides guidelines in the application of those ethical principles. There are many instances in which practice and research overlap. External and objective review of protocols is required only when human subjects are used in some aspect of research. The IRB at GCU bases all decisions on approval of research protocols according to the Belmont Principles.

2.1 The Belmont Principles

1. *Respect for Persons* – The ability of an individual to make personal decisions must be acknowledged, and additional protection is required for those who have diminished ability to make personal decisions or are vulnerable to coercion or manipulation when making a decision.

2. *Beneficence* – Research should not harm an individual, and any risk of harm should be minimized while any benefit to the human subject is maximized.

3. *Justice* – Provision of benefit to which an individual is entitled cannot be denied without good reason, and undue burden cannot be imposed on a human subject. Equals should be treated as such with regard to share, individual need, individual effort, individual societal contribution, or individual merit.

2.2 Application of the Belmont Principles

1. *Informed Consent* - Providing opportunity for individuals to choose what shall or shall not happen to them; upholds the principle of respect for persons

2. *Risk/Benefit Analysis* – A balance between the risk to a human subject and the benefit gained from the research; establishes the beneficence of research on human subjects

3. *Selection of Subjects* – Researchers must exhibit fairness by avoiding preference among individuals or social biases in support of justice in human subject-based research

3.0 The Institutional Review Board at GCU

The IRB at GCU bases its goals on the Belmont Report: 1) to protect human subjects, 2) to develop and maintain an ethical research environment at GCU, 3) to assure that researchers are qualified to conduct research, and 4) to assure that the research has the potential to add value to the academic community and society.

3.1 Composition, length of term, and membership requirements.

The IRB of GCU is composed of one appointed full-time faculty member from each college, an appointed member who is not otherwise affiliated with GCU, and the Director of Academic Research and IRB who serves as the Chair and is responsible for impartial management of the IRB. An appointed non-voting member represents the legal department of the University and provides legal review as needed. The Provost of the University is a non-voting member who enforces institutional responsibility for the IRB. The Board is represented by faculty members who have graduate research experience. At least one member of the IRB must have scientific academic interests and at least one member must have non-scientific academic interests. Board members serve for repeatable two-year appointed terms, and rotating membership stabilizes the board's composition. In the first year, several IRB members will serve for one year to initiate board member rotation. All IRB members will complete the CITI training for IRB members. The IRB Chair is responsible for reporting IRB membership information to the Office of Human Research Protections.

3.2 Responsibilities and jurisdiction

The IRB has three primary responsibilities: 1) to recommend IRB policies to the Provost for review and approval and to develop supporting procedures, 2) to review and approve research proposals that involve human subjects, and 3) to monitor ongoing research that involves human subjects. The IRB is responsible for continuous quality improvement via self-evaluation. The results of this evaluation as well as a summary of the activities of the year are submitted in an annual report to the Provost in June of each year.

The research proposal review and approval process is detailed elsewhere in this handbook. All determinations are based on the Belmont Principles, Federal Policy, and the

institution's policies. The IRB determinations are based on whether proposed research is indeed research, as defined by the Belmont Report, and whether the human subjects involved in the research are adequately protected.

The IRB members may not vote on and/or oversee research in which they are personally or professionally involved. For example, a board member must abstain from making any decisions on a research proposal submitted by a relative or if the research in any way provides any benefit or detriment to the board member.

3.3 Meetings.

The purpose of IRB meetings is to review projects based on a review schedule (defined by project/research type), verify project requirements/protocols if received from someone other than the researcher, act on (approve/disapprove) proposed research changes, act on problem research/researchers who are in serious and/or continued noncompliance, and issue suspension or termination of IRB approval.

The Board will have face-to-face meetings at least two times each year for the purpose of policy and procedure review to assure that the Board's policies and procedures are compliant with federal regulations. In addition, these face-to-face meetings will include an educational component for the members and/or the institution. Research proposals will be reviewed as received electronically or through face-to-face meetings. If a particular proposal does not qualify as exempt from review nor qualify for expedited review, the Board may choose to call a face-to-face meeting as necessary.

Board meetings are documented and the minutes will be distributed to the members electronically. The meeting minutes must reflect the member attendance (present/absent), the agenda, and Board decisions. The IRB is responsible for providing a written summary of discussion of controvertible issues and their resolution.

3.4 Records retention

All IRB activities are documented and all records relating to the normal activity of the IRB are maintained for a minimum of three years. Documentation relating to specific research is maintained for a minimum of three years after the research concludes. Researchers must reapply for IRB approval if their application has expired as indicated by the timeline delineated elsewhere in this handbook. The required IRB documentation includes but is not limited to the following:

1. Meeting minutes
2. Policy recommendations, policy adoptions, and related procedural changes
3. All research proposals and supporting or sample documents
4. Action regarding all research proposals
5. Progress reports submitted by investigators
6. Copies of all correspondence with investigators and others
7. Copies of researcher's correspondence with subjects

8. Statements of significant findings provided to subjects
9. CITI Training records

3.5 Internal auditing

The IRB at GCU is responsible for reporting annually to the Provost all research activities using human subjects that are affiliated with GCU. The annual report identifies all academic programs in which curriculum-based research assignments using human subjects are used and confirms whether the activities are on file with the IRB. The report identifies all ongoing research and includes approval dates, review cycles, and any updates and outcomes of the research projects. In the event unauthorized research is identified, an official letter to cease and desist all research will be sent to the primary researcher and to the Dean of the appropriate college until an application has been submitted to, reviewed by, and approved by the IRB. The annual report provides attendance records and activities of IRB members and conveys to the appropriate dean of each college these data on each IRB member.

3.6 Federal wide assurance

The IRB has submitted and maintains written Assurance to the OHRP stating that GCU and all affiliated researchers will comply with all requirements of the Federal Policy. The written assurance must include the following:

1. Principles and/or guidelines that govern how the institution and researchers affiliated with the institution protect human subjects involved or participating in research;
2. Procedures by which the IRB conducts initial and continuing review of research and communicates findings or actions to the researcher and the institution's administration;
3. Procedures by which any unanticipated problems involving risks to subjects and/or researchers, any serious or continuing non-compliance with the Federal Policy or IRB requirements, or any suspension or termination of IRB approval is reported to the IRB and/or institution officials;
4. Descriptions of training opportunities made available to researchers to develop high quality proposals and for IRB members to understand the Federal Policy; and
5. Evidence of an internal auditing system and procedures that are implemented should unauthorized research on human subjects be identified.

4.0 Privacy Issues in Research

Two privacy issues must be considered in research. The first consideration is confidentiality - protecting the identity of the subject who voluntarily provided private information for the research. This issue is handled in the research design of a project. The second issue is that of invasion of privacy - accessing personal information about the individual without expressed permission or consent. Acquisition of private information must follow all legal standards and procedures. Invasion of privacy, per se, for purposes of research is acceptable either in a public, non-manipulated situation such that there is no

reasonable expectation of privacy and/or when the research question is of sufficient importance that such an intrusion may be justified.

4.1 Reference to GCU in publications

In order to protect the confidentiality and maintain anonymity of persons participating in research at or in affiliation with GCU, particularly when data are sensitive in nature, the IRB at GCU maintains that publications or public presentations of data collected from studies that involve human subjects shall not refer to GCU by name in any description of methodology. Researchers may cite the location at which data was collected using the following language: "Data was collected at (a campus/an online) institution of higher learning in the western region of the United States."

The language allows researchers to be complete in their descriptions of methodology by revealing a physical and perhaps cultural locality of data collection while maintaining sufficient ambiguity to enforce confidentiality.

Acknowledgment of GCU in a publication or presentation is at the discretion of the researcher. To protect human subjects and avoid triangulation leading potentially to the identification of human subjects in research, researchers who choose to acknowledge GCU are asked to use the following language: "[salutations] to Grand Canyon University for support and advancement of this research."

The language allows researchers to recognize GCU as having some role in the research without the risk of revealing how GCU or GCU affiliated human subjects were involved in the research.

5.0 Informed Consent (Belmont Principle: Respect for Persons)

Informed consent is a critical component in preserving the rights of human subjects involved or participating in research and should be considered an ongoing process. Prospective human participants must be given sufficient information about the research procedure, its purpose, any risk or benefit of participating, any therapeutic procedural alternatives, and the opportunity to ask questions or withdraw from the study without bias or penalty. Investigators must ascertain whether the individual has sufficient comprehension of the information to make responsible decisions about their participation in the research. The conditions under which the decision to participate is made must be free of coercion and/or undue influence such that the decision to participate is strictly voluntary. Any information obtained during the course of the research that may influence a subject's decision to continue participating in the research must be provided to the subject immediately.

Signing the informed consent document or otherwise acknowledging informed consent does not waive the participant's legal rights. However, signing and/or acknowledgment of informed consent is verification that the participant was not coerced or was subject to undue influence by the researcher (institution/sponsor) to participate in the research. Informed consent guidelines, checklist and example templates can be found in the GCU IRBNet library

under Forms and Templates (https://www.irbnet.org). The Informed Consent Checklist details all elements for consideration in the development of the Informed Consent document. The following resources also provide further information about Informed Consent:

Informed Consent Checklist
http://www.hhs.gov/ohrp/policy/consentckls.html

Informed Consent, Legally Effective and Prospectively Obtained
http://www.hhs.gov/ohrp/policy/hsdc93-03.html

Informed Consent, Non-English Speakers
http://www.hhs.gov/ohrp/policy/ic-non-e.html

Certificates of Confidentiality
http://www.hhs.gov/ohrp/policy/certconf.html

5.1 Securing informed consent research

Particularly research, in which the participant is at more than minimal risk, requires that the participant provide informed consent to participate. The informed consent details all applicable issues listed on the Informed Consent Checklist. The participant must receive a copy of the signed document and the researcher must keep the original on file for a minimum of three years after the completion of the research. In cases in which the participant is at minimal risk, the IRB may approve an informed consent that is modified. Informed consent may be signified by the fact that the subject provides the requested data. For example, in the case of survey research, the researcher may state in the invitation to participate that by virtue of completing the survey, the subject was informed of the research and is providing informed consent to participate in the research. In cases where there is only oral communication with the subject, an IRB approved written script must be followed, and the subject or a witness representing the subject must sign the copy of the summary verifying that sufficient information was appropriately conveyed to the subject and that the subject adequately comprehended the information.

5.2 Exceptions to the standard informed consent

The IRB may waive and/or alter some of the requirements set forth in the Informed Consent Checklist (Appendix) if the following two conditions are met:

1. The study is conducted by or is subject to the approval of state or local government officials because the research is designed to study, evaluate, or otherwise examine these points:
    a) Public benefits 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 of services under those programs;

2. The study could not practicably be carried out without the waiver or alteration.

In order to grant a waiver of any of the conditions of informed consent or to modify any of the elements of the informed consent, the IRB must determine and document that all of the following conditions are met:

a) The research involves no more than minimal risk to the subjects, and subjects cannot be individually identified by the data;
b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
c) The research cannot be practicably carried out without the waiver or alteration;
d) Whenever appropriate, the subjects will be provided with additional pertinent information (debriefed) after participation.

Other considerations for informed consent waiver include the following:

a) Review of records of deceased individuals;
b) Preliminary review of records in which information is not considered sensitive (e.g., sexual orientation, criminal history, socially stigmatized diseases);
c) Review of records for which the investigator has devised procedures to protect the confidentiality of information such that the only link between the subject and the research is the informed consent.

Research may not be conducted if more than minimal risk is involved and if, prior to the start of the research, information is not provided to the subject that is material to a subject's decision to participate.

5.2.1 Informed consent for children: Assent.

In order for children to become subjects in a research study, they must assent or agree to participation. Children are defined as those who have not attained the legal age of consent under the applicable laws of the jurisdiction in which the research takes place. An assent is a form of informed consent that must be signed by a parent or guardian of a child prior to the start of the research. Assent by a child to participate in research is not necessarily granted by virtue of the fact that the child may not object to being a subject in the study. The IRB must consider all factors (e.g., age, maturity, psychological status, etc.) of children involved in the study to determine the ability of these subjects to grant assent on their own behalf (National Institutes, 2005). Sample written child assent forms can be found in the GCU IRBNet forms and templates library. (https://www.irbnet.org).

5.2.2 Informed consent for cognitively impaired individuals: Assent.

Individuals with cognitive or intellectual impairment require special protections. Assent by these individuals is necessary but not sufficient to include them in a study; assent must also be provided by a legal representative of the cognitively impaired individual. The IRB will take into consideration the potential risk to these individuals and assent by the

individual and legal representative. Guidelines for determining inclusion of cognitively impaired individuals and requirements for obtaining assent are described by the OHSR (National Institutes, 2005).

6.0 Risk/Benefit Analysis (Belmont Principle: Beneficence)

The IRB evaluates risk of harm only when there is a condition associated with research on human subjects that make a situation dangerous, per se, beyond those risks ordinarily encountered in daily life or during routine examinations or tests. The investigator is responsible for evaluating the research design and providing estimates of risk of harm and benefit based on previous research. Brutal or inhumane treatment is never justified in research, and minimal risk to personal or professional reputation or mental or physical health is justified only if it is necessary to achieve the research objective.

The justification for risk in research is weighed by the external reviewer(s), and the decision to participate in approved research involving any risk falls solely to the human subject. Significant risk must be extensively justified in terms of benefit to the subject and maintaining voluntary participation by the subject. The appropriateness of including vulnerable populations, those who may be more susceptible to mental, emotional, or physical manipulation because of condition or social status, must be determined. These risks and/or benefits must be included in the informed consent.

6.1 Periodic review of risk/benefit ratio.

Upon review of proposed research, the IRB must consider the following:

1. Identify risks to the subject associated with the research;
2. Determine that risks will be minimized;
3. Identify benefits to the subject and/or to society derived from the research;
4. Determine that the risks are reasonable in relation to benefits to the subject and/or society;
5. Assure that informed consent is accurate and complete;
6. Determine intervals of periodic review and any provisions for monitoring data collected based on risks to human subjects.

Period reviews must occur at least once per year and may be more frequent depending on the degree of risk to subjects. Periodic review has the purpose of determining any shift in the risk/benefit ratio and to determine whether any new information is to be provided to subjects that may influence their decision to continue participating in the research. The researcher is responsible for reporting any shift in the risk/benefit ratio or any significant findings to the IRB between periodic reviews.

7.0 Selection of Subjects (Belmont Principle: Justice)

Researchers must use objective and unbiased strategies for selecting individuals to participate as subjects in research. Selection must be equitable such that diversity on any level (e.g., race, sexual orientation, gender, economic status, etc.) is not a consideration for participation unless the research is designed expressly and appropriately to address questions about specific groups. Assignment to experimental and/or control groups must be random. Compensation for participation in the form of but not limited to payment or free services or treatments cannot be excessive such that it poses undue enticement or incentive for the prospective subject to participate in the research. No monetary or other inducements or compensations may be offered to pregnant women to terminate the pregnancy, whether an abortion is anticipated or not, for the purposes of research.

8.0 Review Categories for Research Proposals

All research proposals and projects involving human subjects, whether as a part of the established curriculum for a course or to be implemented by an individual researcher, must be submitted to the IRB. In some cases, the only action by the IRB will be to file the description of the proposed work. In other cases, full review and approval by the IRB are required. The course of action is determined by the category in which the research falls.

There are two broad review categories for research approval: nonexempt and exempt. Within the nonexempt category, review of research proposals may be expedited or require full review. Nonexempt research protocols may not be implemented without review and recommendation to approve by the full IRB or an appointed IRB reviewer in the case of expedited reviews. Research proposals falling under the exempt category are not reviewed but are filed by the IRB. Note that ad hoc IRB approval to conduct research will not be granted. The classification criteria shown below serve as guidelines for categorizing research proposals as exempt, expedited, or requiring full review. Guidelines for review categories follow those of the Federal Policy, the Department of Health and Human Services, National Institutes of Health, and Office for Protection from Research Risks.

8.1 Exempt from review

Research protocols that are exempt from review for approval must be on file with the IRB. The Chair/Director of the IRB will determine whether protocols submitted to the IRB qualify to be exempt from review. For a research project to be exempt from human subjects review, all items in Part A, AND at least one item in Part B, MUST apply.

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil

liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The research does not involve subjects under the age of 18 (**Exception**: Research with subjects under the age of 18 may still be considered exempt if the subjects are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B). Studies under Part B-2 that include minors should be submitted for expedited review.

5. The research does not involve deception.

6. The procedures of this research are generally free of foreseeable risk to the subject.

7. The research does not require a waiver from informed consent procedures.

Part B. (at least one item must apply)

1. Research conducted in established or commonly accepted educational settings that use normal educational practices, such as
   a) Research on regular and special education instructional strategies, or
   b) 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 in which
   a) Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects, and
   b) Any disclosure of the human subjects' responses outside the research could not 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 in which
   a) The human subjects are elected or appointed public officials or candidates for public office, or
   b) The confidentiality of the personally identifiable information will be maintained throughout the research and thereafter, without exception, according to federal statute(s) requirements.

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 public department heads or public agency heads 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.

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, an agricultural chemical, or environmental contaminant at or below the level determined 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 (National Institutes, 2005).

8.2 Expedited review

Expedited review is appropriate for research protocols involving no more than minimal risk or when minor changes occur in research protocols that were approved within the last year. The IRB Chair or an appointed IRB member reviews the research proposal. For a research project to be eligible for expedited review, all items in Part A, AND at least one item in Part B MUST apply.

Part A (all items must apply)

1. The research does not involve as subjects pregnant women, fetuses, prisoners, the seriously ill, or mentally or cognitively compromised adults.

2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The procedures of this research present no more than minimal risk to the subject. ("Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Part B (at least one item must apply)

1. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected or will be collected solely for non-research purposes. [**NOTE:** These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or-video-tapes, names will be recorded, even if they are not directly associated with the data).]

2. Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice excluding procedures involving x-rays or microwaves; b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

3. Collection of data from voice, video, digital or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

4. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or research employing surveys, interviews, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies).

5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. [**NOTE:** Although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or videotapes, names will be recorded, even if they are not directly associated with the data).]

6. Research that involves mild deception. [**NOTE:** Deception must be scientifically justified and de-briefing procedures must be outlined in detail. Based upon the judgment of the reviewers, some protocols involving deception may qualify for expedited review. In other cases, the deception will be of sufficient consequence to require full IRB review. See description of Full IRB Review in Part C, below]

7. Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an

investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.

8. Research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where the research remains active only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; or (d) where no new subjects have been enrolled and no additional risks have been identified.

8.3 Full review

All members of the IRB review research the proposals that require full review, and unanimous recommendation to approve the proposals is required prior to initiating the research protocol. Full review is required when the research involves more than a minimal risk to human subjects and/or involves members of protected classes.

Changes in the conditions or protocols of research that gained IRB approval by full review within the last year must be reviewed for approval by the IRB. Full IRB review is required if ANY of these apply to the proposed research:

1. The research involves prisoners, fetuses, pregnant women, the seriously ill or mentally or cognitively compromised adults as subjects.

2. The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subjects' financial standing, employability, insurability, or reputation.

3. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4. The procedures of the research involve more than minimal risk to the subject. The risk may be actual or perceived. “More than minimal risk" means that the probability and magnitude of physical or psychological harm or discomfort likely to be experienced in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

5. Any research which does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

6. The research involves deception, and the nature of the deception is considered of sufficient consequence to require consideration by the full IRB. Deception of lesser consequence may be eligible for expedited review (See Section 8.2). During each full IRB review, the committee members will consider whether the degree of risk to human subjects requires IRB review more frequently than once per year.

The IRB meeting dates/times are determined by the Office of Academic Research and IRB. Approximately one week prior to the meeting, research-related documents required by members to conduct a thorough review are made available to all members expected to attend the meeting. The IRB reserves the discretion to limit the number of protocol submissions scheduled for each meeting so that the IRB can give reasonable and due consideration to each protocol.

Primary, secondary, and regulatory reviewer systems may be used by an IRB, as determined by the IRB Chair and Director of the Office of Academic Research and IRB, but all IRB members will be provided access to the full information for each agenda item, either through distribution, having files available for review by IRB members in the IRB office as well as having copies of the full protocol record at the convened IRB meeting. The primary, secondary and administrative reviewers and IRB members should use the Full Review Checklist as a guide while reviewing a project.

8.3.1 Protected classes

For information on research with other protected groups, you may consult the Federal regulations or a member of the IRB. These protected classes include the following:

1. Pregnant women, human fetuses, and neonates;
2. Prisoners;
3. Children and minors (Children under 18 years);
4. Cognitively compromised individuals;
5. Students and employees.

Federal regulations provide higher standards of protection for individuals belonging to certain classes of research subjects, such as prisoners, the seriously ill, mentally or cognitively compromised adults, and minors (children under the age of 18). In the case of prisoners, there is concern that the coercive environment of a prison may compromise the inmate's voluntary participation. With other protected classes, the issue is the ability of the subjects to provide adequate, informed consent, either because of physical/cognitive limitations, school or work conditions, or because of age.

Excluding exempt research (e.g., naturalistic observation), all research with children requires signed consent forms from the parents or legal guardians. In addition, the child, if of sufficient age to be verbal, must give her/his own **assent**, or agreement to participate. Such assent must follow an explanation at a level appropriate to the individual's age, maturity, experience, and condition--of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. Children should be asked if they wish to participate in the research or not. Mere failure to object on the part of the child should not, in the absence of affirmative agreement, be construed as assent. In the proposal, the investigator should indicate: 1) how assent will be obtained (what the investigator will say to the child and whether or not the child's parent(s) or guardian(s) will be present); and 2) how assent will be documented. The child may either sign a very brief

assent form or verbally indicate a willingness to participate. Whether assent is to be obtained verbally or in writing, a copy of the assent form must be submitted to the IRB with the proposal.

If the research is to be conducted in an institutional setting, the IRB also requires permission from an appropriate institutional official. Within a school system, the permission of a school superintendent or principal will be sufficient for research conducted in a public assembly or similar venue; research in a classroom, however, requires the additional permission of the classroom teacher.

9.0 Types of Research

The origin of or the support for various research projects may dictate how a research proposal is reviewed and/or determine the approval procedures the IRB follows. Research may be conducted under a number of conditions requiring more or less extensive or critical evaluation.

9.1 Curriculum-based research

Classroom curriculum projects, workshop evaluations, and administrative projects do not need IRB approval if they are not research. If the results will not be distributed outside the classroom, institutional setting, or if they are used solely for program review or evaluation, IRB review is not required. However, if such projects lead to generalizable information, through publication or dissemination of results external to GCU, they must undergo review. Regardless of whether the project is subject to review, all GCU faculty, staff and learners must adhere to ethical guidelines when conducting class or institutional projects with human participants. Research activities or exercises conducted as part of curriculum for coursework are considered exempt from IRB review when the following criteria are met:

1. There is minimal risk, *and*
2. The planned classroom exercise does not involve members of vulnerable populations,
3. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to subjects, *and*
4. The information will not be made public in the form of presentation or publication outside of the classroom or educational setting.

If curriculum-based research exceeds exempt status, an application for research approval is located in the forms and templates tab (https://www.irbnet.org/) which must be submitted to the IRB, and approval must be obtained prior to the start of the course. Videotaping or photography, which identifies the participant, requires that the participant relinquish his or her anonymity and, thus, the research will not qualify for exempt status unless those individuals being videotaped or photographed are students enrolled in the course.

Some examples of assignments involving curriculum based research that must undergo IRB review:

1. Presentation at scientific meetings or conferences
2. Research exhibitions with audiences that extend beyond members of the GCU

academic community
3. Master's theses, capstone projects or case studies
4. Undergraduate honors' theses

Some examples of assignments involving curriculum based research that do not require IRB review:

1. Classroom assignments involving human subject data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods (as in a research methods course)
2. Classroom assignments that exist solely to fulfill course requirements to train students in the use of particular method.

Please refer to Grand Canyon University's Faculty Handbook pages 22-23.
http://portal.gcu.edu/policies/Documents/GCU%20Faculty%20Handbook%202013-2014.pdf

9.2 Marketing and institutional-based research

Research as part of GCU marketing or institutional research does not require IRB approval, but the protocols for research (e.g., surveys) on prospective and current GCU students in which there is any opportunity for identity to be revealed must be on file with the IRB. The survey (or other tool), an informed consent, and the means by which the tool is administered must be on file with the IRB prior to conducting the research (https://www.irbnet.org). Protocols do not need to be on file with the IRB as long as the research is absolutely anonymous and participation is entirely voluntary. Institutional research and marketing protocols do not need to be on file with the IRB if data are collected from existing databases or information banks in which the data are owned and managed by GCU.

Research protocols for marketing or institutional research purposes that exceed exempt status must be approved by the IRB. The responsible party must submit an expedited or full application for research approval to the IRB, and approval must be obtained prior to the start of the research.

9.3 Observational research

Most observational research is exempt from Federal Policy regulations. However, observational research on adults must abide by the Federal Policy if data are collected in a manner that allows subjects to be identified directly or through identifiers or the subject would be placed at risk (emotional, physical, reputation, etc.) if the information collected from the observation became public. Observational research is not exempt if it involves children or minors unless the observations occur in a public situation and the researchers do not participate in any activities or manipulate the situation in any way.

9.4 Medical records-based research

The privacy of information about an individual is encountered when the research project involves accessing the subject's medical or other confidential records. Research that involves a human subject's medical records must comply with the regulations of the Health Insurance Portability and Accountability Act (HIPAA) of 1966. Researchers should contact the IRB for further information if research might be affected by HIPAA regulation.

9.5 Research in foreign countries

Research conducted outside of the United States by researchers affiliated with GCU must abide by the foreign country's regulations, and these regulations must be equivalent to or more stringent than those used in the United States. The IRB will make a final determination based on an examination of the regulations of the country in question and the regulations in force in the United States.

9.6 Grant-based research

When a grant or contract to conduct research is awarded to GCU, a GCU researcher, or a GCU research team, the initial agreement may not specify how human subjects are involved. Though the grant or contract may be awarded on general terms, the IRB must approve the final research proposal before research commences.

9.7 DHHS-funded research

Research funded by the Department of Health and Human Services may not be conducted at an institution unless the institution has filed an assurance of compliance. GCU holds the Federal-wide Assurance (FWA), which is accepted and approved by the OHRP for research funded by DHHS (United States Department, 2005).

10.0 IRB Approval for Research

All research conducted at GCU or by researchers affiliated with GCU must meet the goals or objectives of the IRB listed elsewhere in this handbook, and GCU may use data in any appropriate manner once the data are published or made public by the researcher. Researchers must submit an application for approval to the IRB at https://www.irbnet.org/. This section of the handbook contains descriptions of the GCU criteria by which research proposals are evaluated and the procedures for processing an application for IRB review.

10.1 Criteria for evaluation of research proposals

The researcher is responsible for demonstrating to the IRB that the research project can be exempt from review by the IRB. Criteria for exempt review are described elsewhere in this handbook. The IRB performs a more exhaustive evaluation of the research proposal when a research requires expedited or full review. The criteria for non-exempt review are described elsewhere in this handbook. It is not the purpose of a review by the IRB to

comment on research protocol or design unless it has bearing on the risk to human subjects. Criteria used by the IRB to determine whether a research proposal is subject to expedited or full review and subsequent approval may include but are not limited to the following considerations:

1. Whether the subjects are adequately protected according to the guidelines of the Belmont Principles;

2. Whether the research protocols and informed consent are in compliance with Federal Policy;

3. Whether the researcher(s) are qualified to conduct or oversee the research;

4. Whether the research is intended for publication or public review and the proposal is of high quality such that the research has the potential to add to a general body of knowledge.

10.1.1 Quality of the research proposal

The IRB evaluates the quality of the researcher's proposal to determine if the research, as planned, addresses the researcher's stated objectives. This is not an attempt to assure that all research is successful; rather it is an assurance for GCU and for the human subjects involved in the research that the proposal is complete and sound. Items that the IRB may consider include but are not limited to privacy of information and research design as it affects protection of human subjects. Each research proposal submitted through the IRBNet electronic submission system must include the following:

1. The purpose of the project.
2. Clear and concise statement of the research hypothesis or hypotheses (if applicable), written in terms that are understandable to non-scientist members of the IRB.
3. A full description of all procedures.
4. A description of the subject population, including the gender and racial/ethnic composition, and criteria for the inclusion or exclusion of any sub-population.
5. A description of the means by which subjects will be recruited.
6. A discussion of any and all risks to subjects, and how any such risks will be minimized (include copies of all survey instruments, consent forms, assent forms, recruitment flyers, sample recruitment letters and advertisements).

10.2 Application and review process

All research involving human subjects conducted by students or faculty persons affiliated with GCU must be on file with the IRB and/or approved by the IRB before the research commences. The following materials must be included:

Application: The researcher must complete and submit an electronic IRB application in IRBNet (**https://www.irbnet.org**) consisting of a completed application form and

appropriate supporting paperwork (e.g., survey or communication tools associated with implementing the research, informed consent documents, etc.). Additional information on how to submit an IRB application is located on the DC Network (https://dc.gcu.edu) or Center for Innovation in Teaching and Learning (CIRT) at https://cirt.gcu.edu.

CITI Training: Researchers must also submit an electronic training record documenting their completion of the CITI training for social and behavioral science researchers. The CITI training site is accessible at: **http://www.citiprogram.org** First time users must register as a new user by following the specified directions. Appendix A provides step-by-step instructions for registration. Researchers will submit the completed IRB application to **https://www.irbnet.org**.

Site Authorization: If you are a student or faculty member and would like to conduct research at GCU with faculty, staff or students, then you must request site authorization. Please click on the link below to enter application on the CIRT (Center for Innovation in Research and Teaching) website https://cirt.gcu.edu/research/researchsupport/irb

Data Sources: All researchers must load copy(s) of the applicable survey, instrument(s), or questionnaire(s) that will be used for the research study. In addition, permission to use any validated instruments, surveys, or questionnaires is required.

Upon receipt and initial review of the submitted materials, the IRB will inform the researcher whether the application has achieved exempt status or requires non-exempt review per IRB Review. Applicants requesting exemption from review must include sufficient documentation that the research does not fall under any category or criterion requiring non-exempt expedited or full review.

Applications requiring non-exempt expedited review may be reviewed by the chairperson or one or more experienced reviewers on the IRB, but disapproval of the application can only result from a non-exempt full review of the application. Applications requiring non-exempt full review are reviewed by all members of the IRB. Applications that are approved will be assigned a periodic review cycle (minimum of one review per year) at which time the IRB approval expires for the research. Researchers are responsible for submitting a continuing review report to the IRB (https://www.irbnet.org) according to the periodic review cycle.

10.3 Notification of changes in study protocol or consent

It is the researcher's responsibility to notify the IRB of proposed changes in study protocol, informed consent, or other information modifications (Appendix F). These changes may not be implemented until IRB approval is obtained. If the proposed protocol changes are substantial, the IRB may request re-submission of an application for research approval.

11.0 References

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979, April 18). The Belmont Report. Retrieved January 11, 2007, from http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

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United States Department of Health and Human Services. (2006, October 18). Office for Human Research Protections. Retrieved January 11, 2007, from http://www.hhs.gov/ohrp/

12.0 Appendix

Appendix A: IRBNet Step by Steps

- IRBNet Training Energizers
- GCU IRBNet General Information
- IRBNet Step-by-Step Guide for Board Members
- IRBNet Step-by-Step Submission Guide for Faculty Researchers
- IRBNet Step-by-Step Guide for Dissertation Chairs
- Faculty CITI Training Instructions

Appendix B: IRB Review Checklists

- IRBNet Documents Checklist
- Exempt Review Procedure
- Expedited Review Procedure
- Exempt/Expedited Reviewer Checklist
- Procedure for Full Committee Review
- Full Application Reviewer Checklist
- IRB Evaluation Form

Appendix C: IRB Forms

- IRB Informed Consent Checklist
- Informed Consent Form (Social Behavior) min. risk (sample)
- Informed Consent Form (Sample for Adults more than min. risk) (sample)
- HIPAA Authorization Form (sample)
- Information Letter – Interviews (sample)
- Information Letter – Group Interviews for Focus Groups (sample)
- Parental Permission Consent Form (sample)
- Recruitment Script (sample)