



Grand Canyon University  
Institutional Review Board  
Handbook

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January 2007 Version 2.0

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
January 2007	2.0	<p>Clarified language for IRB membership to reflect closer alignment with federal requirements</p> <p>Identified Dean of Graduate School as IRB Chair</p> <p>Deleted requirement for researcher's social security number on Form 3, "IRB Application for Research Approval"</p> <p>Moved listing of "Informed Consent Resources" from IRB Informed Consent Checklist to Section 5.0, "Informed Consent"</p> <p>Corrected typos</p>
January 2006	1.0	<p>Language provisions for referencing GCU in publication of data</p> <p>Statement pertaining to GCU access to data</p> <p>IRB filing requirements for course-based research</p> <p>IRB filing requirements for marketing and institutional-based research</p> <p>Revision of Appendix enumeration and form enumeration</p> <p>Simplification of forms</p> <p>Creation of Form-2: IRB Notification for Marketing or Institutional-based Research</p>
August 2005	1.0	<p>Minor revision to IRB membership requirements</p> <p>Clarification regarding reference to GCU in publication of data</p> <p>Change in reference from "on-ground" to "campus"</p>
April 2005	1.5	<p>Origination of IRB Handbook.</p>

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## 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

*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.

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

*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

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

*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

*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 Dean of the Graduate School 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. 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 in October and March of each year for the purpose of policy review to assure that the Board's policies are compliant with federal regulations. In addition, these face-to-face meetings will include an educational component for the members and/or the institution. In the remaining months, board members will meet electronically via Blackboard© in order to review and approve research proposals. 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 are available to the members in Blackboard®. 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

### 3.5 Internal Auditing

The IRB at GCU is responsible for reporting to the Provost each June 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. Instructors who have not filed these activities with the IRB will be directed to do so immediately, and the Dean of the appropriate college will be notified. 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 were collected using the following language: “Data were collected at (a campus/an online) institution of higher learning in the southwestern 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. The following resources provide further information about Informed Consent:

Informed Consent Checklist

<http://hhs.gov/ohrp/humansubjects/assurance/consentckls.htm>

Informed Consent, Legally Effective and Prospectively Obtained

<http://hhs.gov/ohrp/humansubjects/guidance/hsdc93-03.htm>

Informed Consent, Non-English Speakers

<http://hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>

Certificates of Confidentiality

<http://hhs.gov/ohrp/humansubjects/guidance/certconf.pdf>

The Informed Consent Checklist (Appendix D) details all elements for consideration in the development of the Informed Consent document.

## 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 (Appendix D). 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 D) 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:

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

Other considerations for informed consent waiver include the following:

- 1) Review of records of deceased individuals;
- 2) Preliminary review of records in which information is not considered sensitive (e.g., sexual orientation, criminal history, socially stigmatized diseases);
- 3) 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).

### 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. See the IRB Review Decision Matrix (Appendix A).

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 IRB and final approval from the Provost of GCU. 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 of the IRB will determine whether protocols submitted to the IRB qualify to be exempt from review. The following categories of research involving human subjects are generally exempt from review.

- 1) Research activities or exercises conducted as part of the curriculum for coursework in which
  - a) There is minimal risk, *and*
  - b) Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to subjects, *and*
  - c) The information will not be made public in the form of presentation or publication outside of the classroom or educational setting.
- 2) 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.
- 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior in which
  - c) The human subjects are elected or appointed public officials or candidates for public office, or

- d) 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 use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior in which
    - e) Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects, and
    - f) 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.
  - 5) 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.
  - 6) 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
    - g) Public benefit or service programs,
    - h) Procedures for obtaining benefits or services under those programs,
    - i) Possible changes in or alternatives to those programs or procedures, or
    - j) Possible changes in methods or levels of payment for benefits or services under those programs.
  - 7) Taste and food quality evaluation and consumer acceptance studies
    - k) If wholesome foods without additives are consumed or
    - l) 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. The following types of research may be considered for expedited review:

- 1) Clinical data collected from human subjects (18 years or older) using noninvasive procedures and/or low risk procedures. For example, research in which subjects are

weighed may be expedited; research involving x-ray examinations may not be expedited.

- 2) Specimens collected from human subjects (18 years or older) in a noninvasive manner. For example, hair and nail clippings may be taken in expedited research; biopsies may not be taken in expedited research.
- 3) Data from existing sources such as public documents, records, or raw data from prior research. In all cases, privacy concerns must be addressed.
- 4) Examination of characteristics of individual or group behaviors where the research does not stress subjects or manipulate their behavior.
- 5) Other research in which the IRB determines there is minimal risk to subjects.

## 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 before the protocol is forwarded to the Provost of the University. 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.

### 8.3.1 Protected Classes

Because of their vulnerability, research involving the following classes of research subjects are never granted expedited review. These protected classes include the following:

- 1) Pregnant women, human fetuses, and neonates;
- 2) Prisoners;
- 3) Children;
- 4) Individuals with cognitive disabilities.

## 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

Research as part of the curriculum of a course does not require IRB approval but the protocols must be on file with the IRB. Instructors are responsible for submitting notification of exempt curriculum-based research assignments, the informed consent documentation, and the course syllabus to the IRB prior to the start of the course (Appendix B). For campus courses, instructors teaching the course are responsible for submitting the report; for online courses, the director of the curriculum development department is responsible for submitting the report. Course-based research does not include student teaching or internships.

If curriculum-based research exceeds exempt status, an application for research approval (Appendix C) 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.

### 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 (Appendix C). 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 application for research approval (Appendix D) 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 [irb@gcu.edu](mailto:irb@gcu.edu). 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.

## 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 researcher must complete and submit an IRB application, consisting of a completed application form (Appendix C) and appropriate supporting paperwork (e.g., survey or communication tools associated with implementing the research, informed consent documents, etc.). Researchers submit the IRB application to [irb@gcu.edu](mailto:irb@gcu.edu).

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. 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 report to the IRB (Appendix E) 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 Glossary

Many of the following definitions are taken directly from the Office of Human Research Protections web site at <http://ohsr.od.nih.gov/guidelines/45cfr46.html>.

- 1) Assent: A child's affirmative agreement to participate in research. Mere failure to object or absence of affirmative agreement should not be construed as assent.
- 2) Assurance: A statement of confidence that research on human subjects is in full compliance with appropriate regulating agencies.
- 3) Authorized Institutional Official: The organization, university, or institution representative who has the authority to halt procedures, enforce compliance, and uphold safety and other regulations.
- 4) Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted.
- 5) Cognitively Impaired Individual: A person who has limited faculties for making personal decisions.
- 6) Consent: The choice an individual makes to participate in or be subject to research without coercion, force, or anticipation of reward.
- 7) Guardian: An individual who is authorized under applicable state or local law to consent to general medical care of a child on behalf of the child.
- 8) Human Subjects: A living individual about whom an investigator (whether a professional or a student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.
- 9) Interaction: Communication or interpersonal contact between investigator and subject.
- 10) Intervention: Both the physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
- 11) IRB approval: The determination of the IRB that the research has been reviewed and may be conducted at the institution within the constraints set forth by the IRB and by other institutional, state, and/or Federal requirements.
- 12) Legal Representative: The individual who by virtue of power of attorney can make legal decisions on behalf of another defined individual.

- 13) 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.
- 14) Parent: The child's biological or adoptive legal guardian.
- 15) Permission: The agreement of parent(s) or guardian to the participation of their child or ward in research.
- 16) Practice: Treatments or interventions specifically designed with reasonable expectation of success for the well-being of an individual.
- 17) Private information: That which includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable for the purpose of obtaining the information to constitute research involving human subjects.
- 18) Protected Classes: Those individuals who by birth or circumstance are considered vulnerable to emotional or physical manipulation.
- 19) Protocol: The standardized procedure.
- 20) Public: That which is available to or useable by anyone.
- 21) Research: The process of testing an hypothesis from which conclusions may be drawn that contribute to a larger body of knowledge. Activities that meet this definition constitute research for purposes of the HHS regulations, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- 22) Risk: That which can be potentially harmful to one's mental or physical health, welfare, or reputation.

## 12.0 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.htm>

National Institutes of Health. (2005, June 23). Regulations and Ethical Guidelines. Retrieved January 11, 2007, from

<http://ohsr.od.nih.gov/guidelines/45cfr46.html>

United States Department of Health and Human Services. (2005, June 23). Code of Federal Regulations. Retrieved January 11, 2007, from

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

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/>

## 13.0 Appendices

Appendix A: IRB Review Decision Matrix

Appendix B: IRB Notification for Curriculum-based Exempt Research Assignments (Form 1)

Appendix C: IRB Notification for Marketing or Institutional-based Exempt Research (Form 2)

Appendix D: IRB Application for Research Approval (Form 3)

Appendix E: IRB Informed Consent Checklist

Appendix F: IRB Report for Periodic Review (Form 4)

Appendix G: IRB Change in Research Protocol or Consent (Form 5)

## Appendix A: IRB Review Decision Matrix

This matrix identifies required levels of IRB review based on specific research design conditions. The level of review for the entire research proposal is determined by the most stringent review requirement.

Category	Criteria	Exempt from Review	Non-Exempt Expedited Review	Non-Exempt Full Review
Curriculum-based research	Research activities or exercises that are part of the curriculum of a course	x		
	Minimal risk to human subject	x		
	Information is recorded in a manner that human subjects cannot be identified, directly or through identifiers	x		
	Information will not be made public in the form of presentation or publication outside of the classroom or educational setting	x		
Educational setting-based research	Use of normal educational practices	x		
	Research on regular and/or special education instructional strategies	x		
	Research on effectiveness/comparison among instructional	x		

	techniques, curricula, or classroom management methods			
Survey, interview, behavioral observation, or educational test-based research	Subjects are elected or appointed public officials or candidates	x		
	Confidentiality of personally identifiable information will be maintained through the research and thereafter	x		
	Information is recorded such that human subjects cannot be identified, directly or through identifiers linked to subjects	x		
	Disclosure of human subject information or responses outside of the research cannot place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation	x		
Existing data, documents, records, or pathologic/diagnostic specimens-based research	Information is publicly available	x		
	Information is recorded such that human subjects cannot be identified, directly or through identifiers linked to subjects	x		
Public program-based research	With department/agency head approval to study/evaluate/examine benefit or service programs—procedures for obtaining benefits or services, changes, payment methods for benefits or services	x		
Consumer acceptance-based research	Consumables are wholesome without additives	x		
	Consumables contain food ingredients, agricultural chemical, or environmental contaminants at or below the level determined to be safe <sup>1</sup>	x		
Medical records-based research	Information is extracted from or research involves access to medical records		x	

Clinical-based research	Subjects are 18 years of age or older		X	
	Data collection procedures are noninvasive and/or low risk		X	
	Specimen collection procedures are noninvasive and/or low risk		X	
	Examination of characteristics of individual or group behaviors does not stress or manipulate the subjects		X	
More than minimal risk-based research	Any research that may impose more than minimal risk to the health, financial well-being, or reputation of the subject			X
	Any research that deviates from established or common practices			X
	Any research that utilizes consumables that contain ingredients, chemicals, or contaminants that exceed levels determined to be safe			X
Protected classes-based research	Subjects are any of the following: pregnant women, human fetuses, neonates, prisoners, children (<18 years of age), cognitively impaired persons			X

## Appendix B: Form 1- IRB Notification for Exempt Curriculum-Based Research Assignments

Intended only for research projects involving human subjects that are components of the curriculum requirements for a course and that qualify for exempt status. Curriculum-based research protocols do not require pre-approval by the IRB. Data collected may not be published or presented publicly outside of the educational setting. This form must be completed and submitted to the IRB along with any supporting materials prior to the course start. Refer to the IRB Review Decision Matrix (Appendix A of the IRB Handbook).

Date submitted to IRB:

College:  Business  Education  Liberal Arts & Sciences  Nursing

Course Prefix and Number:  Online  Campus

Course Title:

Instructor or Director of Curriculum Development:

Supporting Materials Checklist:

The course syllabus

A copy of the script or cover letter used to recruit participants. Minimally, the participant is to be notified of the following:

- 1) Researcher's name and title
- 2) Contact information for the researcher and course instructor
- 3) College and course
- 4) Purpose of the study
- 5) Role of the participant
- 6) Time commitment by the participant
- 7) Statement that the study is voluntary and the participant may withdraw at anytime without penalty (e.g., grade, treatment)
- 8) Assurance of confidentiality

A copy of the data collection tool(s), if applicable. If an audio-visual tool is used, attach a copy of the notice advising participants of disposition of the materials after the research project is completed.

A brief statement of the kind or nature of research on human subjects to be conducted as part of the curriculum of the course.

Source(s) for the participant pool. (Sources may not violate privacy laws and, thus, must come from publicly available information.)

## Appendix C: Form 2- IRB Notification for Marketing or Institutional-based Research

Intended only for GCU marketing or institutional research projects that meet the criteria for filing requirements and that qualify for exempt status. Marketing or Institutional-based research protocols in which there is no opportunity for identification of participants and participation is strictly voluntary do not require pre-approval by the IRB. This form must be completed and submitted to the IRB along with any supporting materials prior to implementing the research. Refer to the IRB Review Decision Matrix (Appendix A of the IRB Handbook).

Date submitted to IRB:

Department Name:

Director or Responsible Party:

Supporting Materials Checklist:

A copy of the script or cover letter used to recruit participants. Minimally, the participant is to be notified of the following:

- 1) Researcher name and title
- 2) Contact information of the researcher and course instructor
- 3) College and course
- 4) Purpose of the study
- 5) Role of the participant
- 6) Time commitment by the participant
- 7) Statement that the study is voluntary and the participant may withdraw at anytime without penalty (e.g., grade, treatment)
- 8) Assurance of confidentiality

A copy of the data collection tool(s), if applicable. If an audio-visual tool is used, attach a copy of the notice advising participants of disposition of the materials after the research project is completed.

A brief statement of the kind or nature of research on human subjects to be conducted as part of the curriculum of the course.

Source(s) for the participant pool. (Sources may not violate privacy laws and, thus, must come from publicly available information.)

## Appendix D: Form 3- IRB Application for Research Approval

Intended only for proposed research that involves the use or study of human subjects and the data from which are intended for publication or public use and view. Do not use this form for curriculum-based exempt research assignments.

Date submitted to IRB:

Title of Study:

Primary Researcher:

Protocol Review Request:

- Exempt (Researcher must provide evidence demonstrating protocol is exempt from review.)
- Non-exempt Expedited Review
- Non-exempt Full Review

### Biographical Information

Primary Researcher:

Highest conferred degree:

Year conferred:

Email Address:

Phone:

University affiliation:  Faculty – Campus

Faculty -- Online

Staff

Graduate Student

Undergraduate Student

Other (please specify):

Collaborative Researcher:

Highest conferred degree:

Year conferred:

Email Address:

Phone:

University affiliation:  Faculty

Staff

Graduate Student

Undergraduate Student

Other (please specify):

Other collaborative researchers (Please list additional collaborative researchers here and provide biographical information on a separate page):

Indicate how the data from this research will be used: (Check all that apply.)

Masters thesis

Graduate project

Undergraduate project

Conference/Presentation

Peer-reviewed publication

Inform participants

Other (please specify):

## Funding Information

The proposal for which funding is awarded must be included with this application.

Research is externally funded:  Yes  No

Agency, Institute, or Foundation:

Award period for grant or contract: from \_\_\_\_\_ to \_\_\_\_\_

Award amount:

Title of proposed research or granted project:

Principle researcher (if different from above):

If the research in this application is part of a cooperative effort with another institution, please provide the following:

Name of institution:

Address of institution:

Chair of institution's IRB:

Chair email address:

Chair phone:

The cooperative institution's IRB has reviewed the research proposal:  Yes  No  
If Yes, please state the IRB recommendation(s). (Please attach supporting documentation):

## Description of Proposed Research using Human Subjects

The research will be conducted outside of the United States:  Yes  No  
If Yes, please provide locality information: (Please include the equivalent of IRB regulations or restrictions for the foreign country and any documentation of approval to conduct the research with this application):

### Informed Consent:

Intended subjects (Please check all that apply): (\*Identified as protected classes of human subjects.)

- Adults ( $\geq 18$  years if age)
- Elected or appointed public officials or candidates
- \*Pregnant women
- \*Human fetuses
- \*Human neonates
- \*Children ( $< 18$  years of age)
- \*Prisoners
- \*Cognitively impaired persons
- Traumatized or comatose persons
- Elderly or aged persons
- Minorities
- Students, Faculty, or Staff of GCU
- Other (please specify):

Informed consent documentation is required:  Yes  No  
(If Yes, please include the document to be reviewed and signed by subjects)

### Selection of Subjects:

Number of subjects needed for the research (Please partition by subject category if necessary):

Time commitment per subject (Please include any details or specifications if necessary):

Compensation per subject, if any (Please include any details or specifications if necessary):

Recruitment of subjects (Please describe the population(s) from which the research subjects will be selected and the means by which they will be selected. Include any fliers or communications used to recruit human subjects for the research):

### Proposed Research:

Provide a statement for each of the following six categorical items.

- 1) Research objective
- 2) Research justification
- 3) Research protocol (Explicitly state research questions, hypotheses, and tests.)
- 4) Data collection and analysis methods (Describe how data will be collected and analyzed; list and include any tools or communications that will be used in the research.)
- 5) Research timelines (Anticipated research start date, key milestones, anticipated research completion date.)
- 6) Data storage and protection (Describe how data will be stored such that privacy and/or anonymity of subjects is maintained.)

### Risk-benefit analysis:

Provide a statement for each of the following three categorical items.

- 1) Identify any risk(s) to human subjects and state how risk(s) will be minimized
- 2) Identify any probable benefit(s) to human subjects
- 3) Assessment of risk vs. benefit for human subjects

## Signature

Entering the researcher's name in the signature box and electronic submission of this application by the primary researcher constitutes signature.

Protocol title of research:

Primary researcher:

I have read and understand the GCU IRB policies and procedures and certify that I will abide by the guidelines as described in these documents. I further certify that I will notify the IRB and request written approval if any of the research protocols change from those approved herein. If my research requires informed consent, I will secure these documents for a minimum of three years after the completion of my research and be able to produce them if needed during that time.

Signature:

Date:

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Initial Review Status Requested:  Exempt  
 Non-exempt expedited review  
 Non-exempt full review

Notification sent to researcher of review status; Date:

Research Approved:  Yes  No

Final Review Status:  Exempt  
 Non-exempt expedited review  
 Non-exempt full review

Review Cycle:

Reviewers

IRB Chair:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

## Appendix E: IRB Informed Consent Checklist

Prior to participation in a study in which there is any risk to a human subject, the human subject must sign or agree to an informed consent in one of the following forms:

- 1) A document of all information for informed consent that is signed by the subject.
- 2) An oral presentation witnessed by a third person who signs a written summary of the presentation.
- 3) A document of all information for informed consent that is not signed by the subject.

Documents regarding informed consent must comply with the following checklist. Some items may not be applicable to the proposed research protocol. This checklist serves as a guideline of items to consider in the development of an Informed Consent document. Additional resources for informed consent are provided.

- 1)  The informed consent is on GCU letterhead or the letterhead of the sponsoring institution and includes the following:
  - a)  Title of study
  - b)  Name of the primary researcher
  - c)  Contact information for the primary researcher
  - d)  Name of the human subject or participant
- 2)  A statement that the human subject or participant is not asked to relinquish the right to hold the researcher, institution, and/or funding agency liable for negligence
  - a)  Contact information for questions about the research
  - b)  Contact information for questions about a subject's rights
- 3)  A clear statement of the research
  - a)  An explanation of the purpose of the research
  - b)  A description of research procedures
  - c)  Identification of any procedures or treatments that are experimental
  - d)  The approximate number of study participants involved in the research
  - e)  The expected duration of the research
- 4)  A clear description of any reasonably foreseeable risks and/or discomforts to the subject, an embryo, or a fetus associated with routine or experimental procedures
  - a)  Whom to contact in the event a research-related injury occurs
  - b)  Compensation and/or medical treatment in the event of injury
  - c)  Description of the medical treatment
  - d)  Where to obtain further information

- 5)  A clear statement of confidentiality that under no circumstances will information be disclosed to another entity for any purpose without specific and expressed agreement from the subject and a description of methods for assuring confidentiality
- 6)  A statement that participation is voluntary and refusal to participate or withdrawing from the study at any time involves no penalty or loss of benefits to which the subject is otherwise entitled
  - a)  Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
  - b)  The consequences, if any, of a participant's decision to withdraw from the research
  - c)  Procedural instructions for how the participant withdraws from the research
- 7)  Disclosure of any alternative procedures or courses of treatment that might be advantageous to the subject
- 8)  Details regarding reasonable benefits of the research and/or participation in the research
- 9)  Any cost that may be incurred by the subject as a result of participation in the research
- 10)  A statement assuring that if significant findings are developed that may relate to the subject's willingness for continued participation, the information will be provided to the participant who may choose to withdraw from the study
- 11)  For research using medical records, the following are addressed:
  - a)  Time limit of review of the record (e.g., two months following consent)
  - b)  The data or information that will be extracted from the record
  - c)  A clear description of how the data or information will be used in the study
  - d)  Permission language for contacting the subject in the event that the subject meets the research criteria
- 12)  The paragraph immediately preceding the signature/date line includes the following verbiage:

*By signing this consent form, I verify that I understand this research protocol and the risks that I may be exposed to as a participant the study. I have had the opportunity to ask questions for clarification about all aspects of the study. I realize that I have the right to ask questions and/or withdraw from the study at any time without penalty. If the study protocol changes in a way that would significantly affect the participants, I will be notified and asked to sign a new Informed Consent. Signing this form does not imply that I give up any legal rights in relation to the study. I will receive a copy of the signed consent form.*

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness (if necessary)

\_\_\_\_\_  
Date

## INVESTIGATOR'S AFFIDAVIT

The subject has been provided with the research study information detailed in this Informed Consent and has been given the opportunity to ask questions and receive clarification regarding any component of the study. I attest that the subject appears to understand the ramifications and risks of participating in the study. To the best of my knowledge, a medical, language, or other communication barrier has not hindered the subject's understanding of the proposed involvement in the research.

---

Signature of Investigator

---

Date

### Additional Protections for Vulnerable Populations

Incompetent adults cannot give consent. This may include the developmentally disabled, the cognitively-impaired elderly, and unconscious or inebriated individuals. Only legally authorized representatives in accordance with state law can give consent for incompetent adults to participate in research.

Additionally, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards shall be included in the study to protect the rights and welfare of these subjects.

OHRP strongly discourages use of the "first person" statement, "I have been fully informed about....," in consent documents. Such statements unacceptably ask subjects to make statements that the subject is not in a position to verify (e.g., the subject has no way to verify that the investigator has provided full and complete information).

## Appendix F: Form 4- IRB Report for Periodic Review

The primary researcher is responsible for submitting this completed form to the IRB according to the periodic review prescribed upon approval of the research. Provide information on a separate document if necessary.

Date Submitted to IRB:

Assigned IRB Application Number:

Title of IRB Approved Study:

Primary Researcher:

Periodic Review Cycle:

Provide a statement for each of the following six categories:

- 1) Preliminary data Analysis - Please submit any results that demonstrate progress towards the proposed timeline for the research.
- 2) Research protocol adherence - Please describe data collection methods.
- 3) Subject enrollment - Please describe the number of subjects used in the study to date. Include information regarding the number of subjects who refused to participate and/or withdrew from the study.
- 4) Report of unanticipated events - Please describe any events, including injury or death of subjects, that were not anticipated in the originally proposed research.
- 5) Protocol amendments - Please describe any amendments or adjustments made in the research protocol. Please include the IRB Change in Research Protocol or Consent documentation showing approval for such modifications, if applicable.
- 6) Changes affecting the perception of risk or benefit - Please provide any information that may alter the initial perception of risk or benefit by the subject or the IRB.

---

For Official Use Only – to be completed by the IRB

Notification sent to researcher of review status; Date:

Status:  Satisfactory     Unsatisfactory

Reviewers

IRB Chair:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

## Appendix G: Form 5- IRB 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. 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 IRB Application for Research Approval for the modified protocol. Provide information on a separate document if necessary.

Date Submitted to IRB:

Assigned IRB Application Number:

Title of IRB Approved Study:

Primary Researcher:

Periodic Review Cycle:

Date of initial IRB approval of research:

Provide a statement for each of the following criteria:

- 1) A brief description of the currently approved protocol or consent
  - 2) Proposed changes to the currently approved protocol or consent
  - 3) Revisions in language or presentation of Informed Consent documents or materials (Please provide any Informed Consent documentation and/or recruiting materials)
  - 4) Risk/benefit analysis as it pertains to the proposed change(s) (Please refer to the IRB Application for Research Approval)
- 

For Official Use Only – to be completed by the IRB

Notification sent to researcher of approval status; Date:

Status:  Approved  Disapproved; resubmit research approval application

Reviewers

IRB Chair:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date:

IRB Board Member:

Signature:

Date: