IRB Policy Manual

Southern Adventist University IRB Members

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2009-2010: Robert S. Coombs, Ph.D., IRB Chair; Linda Crumley, Ph.D.; Michael Hasel, Ph.D.; Carlos Martin, Ph.D.; Jillian Willis, M.S.N.; Joe Rudd, Ph.D.; Joyce Azevedo, Ph.D.; Ron Johnson, Ph.D., Bob Gadd, Ph.D., ARC Chair

2008-2009: Ann Foster, Ph.D., IRB Chair; Joyce Azevedo, Ph.D.; Linda Crumley, Ph.D.; Ron Johnson, Ph.D.; Mitch Menzmer, Ph.D.; Jillian Wills, M.S.N.; Bob Gadd, Ph.D., ARC Chair

If you have any information prior to 2008-2009 please share it with the IRB Chair by emailing it to irb@southern.edu

The Instructional Review Board of Southern Adventist University would like to thank University of Tennessee at Chattanooga, University of North Carolina at Charlotte and the University of Iowa for sharing their IRB manuals and assisting us as we created a new one for Southern Adventist University.

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HISTORICAL BACKGROUND OF HUMAN RESEARCH EXPERIMENTATION

For many years, state and federal laws were silent on the issue of human research and experimentation. The situation changed, however, in 1971 with the first of a series of federal regulations. The then US Department of Health, Education and Welfare (DHEW) issued The Institutional Guide to DHEW Policy on Protection of Human Subjects. These guidelines set the initial review criteria into motion. Three years later, on July 12, 1974, Public Law 93-348 (known as the "National Research Act of 1974") was signed into law, creating the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, and set the definitive standards of the Institutional Review Board. Section 212 of the law specified, in part, that:

"The Secretary of DHEW shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application assurances satisfactory to the Secretary that it has established a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects...in order to protect the rights of the human subjects of such research."

The Belmont Report was published on April 18, 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report was an outgrowth of intensive discussions held in February 1976 at the Smithsonian Institution's Belmont Conference Center that were supplemented by the monthly deliberations of the Commission that were held over a period of three years. The Belmont Report is a statement of basic ethical principles and guidelines meant to assist individuals in resolving ethical problems that surround the conduct of research with human subjects.

Two years later, on January 27, 1981, the Food and Drug Administration (FDA) and the National Institutes of Health set the regulatory standards in place for the Protection of Human Subjects and for the Operating Standards of the Institutional Review Boards.

On March 8, 1983, the US Department of Health and Human Services (DHHS), in response to the Belmont Report and the FDA's standards, extensively revised its 1974 basic policy and added new regulations governing additional protection for special classes of human subjects -- fetuses, pregnant women, in vitro fertilization, prisoners, children, mental and physical disabled or institutionalized individuals, and the elderly.

In April 1989, the White House Office of Science and Technology ordered all governmental agencies to adopt the DHHS policy as their own, with the Office for Human Research Protections (OHRP) of the National Institutes of Health as the coordinating agency. On June 18, 1991, OHRP issued its revised policies for the Protection of Human Subjects and two months later, on August 19, 1991, the regulations became effective, with OHRP becoming the coordinating agency for 19 US governmental agencies to ensure that institutions comply with the federal regulations, which protect human subjects in research. The regulations are known as the Model Federal Policy of 1991 or simply by its legal citation, 45 CFR 46.

PART 1: THE ACADEMIC RESEARCH COMMITTEE (ARC) and INSTITUTIONAL REVIEW BOARD (IRB)

The ARC is a standing University Senate Committee directly accountable to the University Senate and subject to Senate Review and is accountable to the University Board. IRB is a subcommittee of ARC developed to handle all research applications. The minutes of the committee and subcommittee are available to any employee upon request. Such requests may be directed to the respective committee chair that is responsible for protecting privacy issues.

The IRB is a subcommittee of the Academic Research Committee and acts to facilitate the conduct of ethical academic research campus wide.

ACADEMIC RESEARCH COMMITTEE (ARC) Reports through VP Academic Administration

MANDATE

The Academic Research Committee (ARC) operates as a University Senate committee and the Institutional Review Board (IRB) of Southern Adventist University (Southern) operates as a subcommittee of ARC. ARC 's mandate is to assess and award ARC Grant Applications for both ARC $500 initial research proposals and ARC full research grant requests. These grants are available for each school year and are awarded with the expectation the funds will be utilized prior to May 31 of the current school year. If a full research project will cross fiscal years, continuation of funding is dependent on filling out and submitting an extension of funds form.

MISSION

The mission of the Academic Research Committee (ARC) and its subcommittee, the Institutional Review Board (IRB) is to ensure that vital, university research can be funded and conducted in full compliance with both the letter and the spirit of regulations designed to protect the rights and welfare of human subjects. Both ARC and IRB are charged to monitor research to ensure all human subjects involved with research are protected from undue risk and from deprivation of personal rights and dignity. This protection is assured by consideration of three principles that are the basis of ethical research:

1. That **voluntary participation** by the subjects, indicated by **free and informed consent**, is assured by the investigators;
2. That an appropriate balance exists between **potential benefits** of the research to the subject or to society **and the risks** assumed by the subject; and
3. That there are **fair procedures** and outcomes in the **selection of** research **subjects**.

JURISDICTION

All faculty and staff (both full-time and part-time) as Southern Researchers may apply for ARC grants and must apply to the IRB when conducting research other than for institutional reports. They must fill out the appropriate forms when using human subjects and vertebrates, or identifiable, private information about human subjects to conduct research within the course and scope of their duties, are required to have prior approval from the IRB *before research is initiated*. Please see this manual for complete details as to which forms are required.

All projects must be approved. This policy also applies to students whose research is conducted under the advisement of a faculty member. ***All research proposals must be reviewed by the IRB and no individual other than the IRB Chair may exempt a proposal from further review.***

Research is defined as: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities" (Code of Federal Regulations, 45 CFR 46.102d).

A Human Subject means: "A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (Code of Federal Regulations, 45 CFR 46.102f)

MEMBERSHIP

Thirteen members consisting of a total of nine faculty members appointed by the University Senate. Faculty positions are staggered, three-year, non-renewable terms (eligible for another term after a one-year hiatus). Three faculty are to be selected from each of the following areas: **Science/ Math** (Biology, Chemistry, Computer Science, Math, and Physics & Engineering). **Life Sciences** (Center for Teaching Excellence, Online Campus, Business & Management, Education & Psychology, Journalism & Communication, Nursing, Physical Education Health & Wellness, Social Work, and Technology). **Liberal Arts** (English, History, Library, Modern Languages, Music, Religion, and Visual Art & Design). Student Association shall appoint one student for a one-year, non-renewable term (recommended that this student be selected from the pool of Southern Scholars), the vice president for Academic Administration, ex officio, Associate Vice President for Budget and Finance, ex officio and the IRB Chair ex officio.

The ARC will elect a chair and secretary from among its membership. The secretary position is for two years, beginning at the time of election. The secretary is the chair-elect. The chair position is for two years, beginning at the time of appointment as chair, and is non-renewable.

The ARC will elect three IRB Committee members from among its membership, one member each from Science/Math, Life Sciences and Liberal Arts. IRB Committee positions are for one-year terms renewable as long as they are still members of the ARC.

AUTHORITY AND RESPONSIBILITY

Authority to Act

The Academic Research Committee facilitates academic research for faculty and students through four functions: support, quality assurance/review, funding and reporting. The Committee has authority to act in each of these areas as follows:

Support -The ARC

1. Encourages and supports research initiatives and activities, including evaluating needs for in-service training and mentorship.
2. Recommends, through established administrative policy-making channels and the University Senate, actions and/or changes to policies applicable to research under its jurisdiction.
3. Makes available to faculty and staff, ARC grant applications and IRB applications.

Quality Assurance/Review - The ARC and the IRB

1. Coordinates with SOUTHERN legal counsel, SOUTHERN Institutional Research, SOUTHERN Risk Management, and SOUTHERN Administration to ensure:
    a. Compliance with legal, regulatory, and ethical laws, regulations, mandates, and provisions, and
    b. Containment of University risk exposure related to academic research.
2. Receives notification of the development of unexpected risks in the course of conducting research, and, where appropriate, recommends actions relating to that risk.
3. Supports the integrity of University research activities, including quality, feasibility, and value.

Funding - The ARC

1. Reviews, approves or denies funding requests from SOUTHERN faculty for academic research.
2. Cooperates with the SOUTHERN Associate Vice President for Budget and Finance to establish the annual grant budget used by the Academic Research Committee to facilitate campus-wide academic research.
3. Coordinates with the SOUTHERN Accounting Department Office in distributing approved research grant funds.

Recording and Reporting - The ARC, through the IRB subcommittee

1. Receives, reviews and maintains records of all on-going campus wide academic research conducted by faculty and students which meet the following criteria:
    a. Research is seeking either internal or external funding.
    b. Research involves human subjects.
    c. Research involves animals or plants.
2. Reports annually, and as requested, to the University Senate the activities of the Academic Research Committee and the Institutional Review Board subcommittee.
3. Makes available to Academic Administration and Dean of Graduate Studies, through the ARC and IRB SharePoint sites, the current status of on-going campus wide academic research.

INSTITUTIONAL REVIEW BOARD (IRB) Reports through VP Academic Administration

MANDATE

The Institutional Review Board (IRB) of Southern Adventist University (Southern) operates as a subcommittee of the Southern Academic Research Committee (ARC) under the US Department of Health and Human Services regulations for the Protection of Human Research Subjects: Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46). The IRB also is guided by the ethical principles regarding all research involving humans as subjects as set forth in the April 18, 1979, report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," commonly referred to as The Belmont Report. For more information on these documents and the historical evolution of these principles, please consult the prior page.

MISSION

The mission of the Academic Research Committee (ARC) and its subcommittee, the Institutional Review Board (IRB) is to ensure that vital, university research can be conducted in full compliance with both the letter and the spirit of regulations designed to protect the rights and welfare of human subjects. Both ARC and IRB are charged to monitor research to ensure all human subjects involved with research are protected from undue risk and from deprivation of personal rights and dignity. This protection is assured by consideration of three principles that are the basis of ethical research:

1. That **voluntary participation** by the subjects, indicated by **free and informed consent**, is assured by the investigators;
2. That an appropriate balance exists between **potential benefits** of the research to the subject or to society **and the risks** assumed by the subject; and
3. That there are **fair procedures** and outcomes in the **selection of** research **subjects**.

The IRB Chair and Committee share authority over all IRB policy and procedures.

JURISDICTION

All faculty and staff (both full-time and part-time) using human subjects or identifiable, private information about human subjects to conduct research within the course and scope of their duties are required to have prior approval from the IRB. Projects must be approved regardless of whether or not the research is funded and regardless of the source of funds. Southern Researchers must apply to the IRB when conducting research other than for institutional reports. They must fill out the appropriate forms when using human subjects and vertebrates, or identifiable, private information about human subjects to conduct research within the course and scope of their duties, are required to have prior approval from the IRB *before research is initiated*. Please see this manual for complete details as to which forms are required.

All projects must be approved. This policy also applies to students whose research is conducted under the advisement of a faculty member. ***All research proposals must be reviewed by the IRB and no individual other than the IRB Chair may exempt a proposal from further review.***

Research is defined as: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities" (Code of Federal Regulations, 45 CFR 46.102d).

A Human Subject means: "A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" (Code of Federal Regulations, 45 CFR 46.102f)

AUTHORITY TO ACT

To provide a 'central repository' for all research on campus, specifically focused on that which meets the following criteria:

a. Research that is seeking either internal or external funding
b. Research involving human subjects, animals or plants
c. Research performed by faculty, graduate and undergraduate students

MEMBERSHIP

Seven members appointed by the Academic Research Committee are chosen to serve on the IRB sub-committee. The Director of the Center for Teaching Excellence and Biblical Foundations of Faith and Learning is Chair. Three Academic Research Committee members are appointed a one year renewable term, one appointee each selected from the following areas: **Science/ Math** (Biology, Chemistry, Computer Science, Math, and Physics & Engineering). **Life Sciences** (Center for Teaching Excellence, Online Campus, Business & Management, Education & Psychology, Journalism & Communication, Nursing, Physical Education Health & Wellness, Social Work, and Technology). **Liberal Arts** (English, History, Library, Modern Languages, Music, Religion, and Visual Art & Design). The Academic Research Committee Chair, ex officio, a veterinarian (not affiliated with Southern), and a physician (not affiliated with Southern).

Functions

1. To recommend to the Academic Research Committee (ARC) policies and procedures for the conduct of academic research involving human subjects, animals and plants campus-wide.
2. To review all academic research proposals to determine whether they are Exempt, Expedited or require Full Review approval from IRB:
    - Exempt studies are those with no risk to subjects.
    - Expedited studies are those with minimal risk to subjects.
    - Full Review studies are those which involve more than minimal risk to the subjects and require review by the full IRB committee membership.
3. To consider whether:
    - Risks to subjects are minimized
    - Risks are reasonable in relation to anticipated benefits
    - Selection of subjects is equitable
    - Informed consent is sought from each subject
    - Informed consent is appropriately documented

4. Review for approval, all non-exempt academic research proposals involving human subjects, animals and plants.
5. To ensure compliance with legal, regulatory, and ethical mandates and provisions relating to research involving human subjects, animals and plants.
6. To coordinate with the ARC, with Academic Administration and with the Dean of Graduate Studies in maintaining records of on-going academic research.
7. To coordinate with the ARC, with Academic Administration and with the Dean of Graduate Studies in maintaining records of ethics training of faculty and students.

Responsibilities

1. Complies with approved policies and procedures that ensure the integrity of campus-wide exempt, non-exempt, and full review academic research.
2. Provides certified research compliance training for faculty and students involved in academic research involving human subjects, animals or plants, and other as described.
3. Makes available to faculty and students the necessary IRB applications needed for IRB approval.
4. Provides assistance needed by faculty and students in completing the necessary IRB applications. An explanation of application forms is available in the IRB Policy Manual.
5. Reviews to approve, exempt, request modifications to secure approval, or disapprove all research activity proposals covered by this policy.
6. Conducts review of on-going research at intervals appropriate to the degree of risk, but not less than once per year.
7. Reviews proposed changes in research activities as requested on Form B to ensure that changes in approved research continues to comply with IRB protocols during the period for which IRB approval has been given.
8. Requires that information given to subjects as part of informed consent is in accordance with policy.
9. Requires or waives documentation of informed consent.
10. Notifies, in writing, investigators and the institution of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval for the research activity. If the IRB disapproves a research application, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person or in writing.
11. Monitors and provides additional safeguards when vulnerable subjects (minors, mentally incompetent, prisoners, economically disadvantaged, pregnant females) are involved in the research in order to protect against coercion or undue influence.
12. Conducts its review of potentially sensitive research (except when an approved exempt or expedited review procedure is used) at convened meetings where a majority of the members of the IRB are present.

13. Approves potentially sensitive research only with the concurrence of a majority of those members in attendance or with an e-vote.
14. Reports to Academic Administration and Dean of Graduate Studies any continuing or serious matters of non-compliance by investigators with the requirements and determination by the IRB.
15. Suspends or terminates approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected serious harm to subjects.
16. Archives records of all IRB actions related to research conducted at the institution.

Records

1. Retains copies of all research proposals reviewed, scientific evaluations, if any, that accompany proposals, approved sample consent documents, approved advertising or other solicitations for subjects, progress reports and injuries to subjects. The IRB through the ARC SharePoint.
2. Maintains minutes of all IRB meetings which shall be in sufficient detail to show meeting attendance, actions taken by the IRB, the vote on these actions, including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution.
3. Maintains records of completion of the Collaborative Institutional Training Initiative (CITI) modules which have been identified by ARC for faculty and student completion. These CITI modules are accessed through the IRB webpage site. Modules have been identified as most appropriate and necessary for completion prior to conducting research in the areas of: Science/Math, Life Sciences and Liberal Arts.
4. Maintains records of continuing review activities.
5. Retains copies of all correspondence between the IRB and investigators.
6. Maintains listings of all IRB members identified by name, earned degrees and their professional representative capacity.
7. Maintains a manual and website outlining IRB procedures and provides all IRB applications and forms.

Quality Assurance/Review

1. Complies with approved policies and procedures that ensure the integrity of campus-wide exempt and non-exempt academic research.
2. Provides certified research compliance training for faculty and students involved in academic research.
3. Makes available to faculty and students the necessary IRB applications needed for submittal for IRB approval.
4. Provide assistance needed by faculty and students in completing the necessary IRB applications.
5. Reviews to approve, exempt, require modifications (to secure approval), or disapprove all research activities proposals covered by this policy.

6. Conducts review of on-going research at intervals appropriate to the degree of risk, but not less than once per year.
7. Reviews proposed changes in research activities to insure that changes in approved research, during the period for which IRB approval has been given continues to comply with IRB protocols.
8. Requires that information given to subjects as part of informed consent is in accordance with policy.
9. Requires or waives documentation of informed consent.
10. Notifies, in writing, investigators and the institution of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person or in writing.
11. Monitors additional safeguards when vulnerable subjects (minors, mentally incompetent, prisoners, economically disadvantaged, pregnant females) are involved in the research in order to protect against coercion or undue influence.
12. Conducts its review of potentially sensitive research (except when an approved exempt or expedited review procedure is used) at convened meetings where a majority of the members of the IRB are present.
13. Approves potentially sensitive research only with the concurrence of a majority of those members in attendance or with an e-vote.
14. Reports to the Graduate Dean and Academic VP any continuing or serious matters of non-compliance by investigators with the requirements and determination by the IRB.
15. Suspends or terminates approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected serious harm to subjects.
16. Maintains up to date records of all research conducted at SOUTHERN.

Recording and Reporting

The Institutional Review Board Chair and Graduate Assistant or Student Worker maintains:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany proposals, approved sample consent documents, approved advertising or other solicitations for subjects, progress reports and injuries to subjects.
2. Minutes of all ARC/IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
3. Records of IRB training programs including faculty and student completion of CITI training.
4. Records of continuing review activities.
5. Copies of all correspondence between the IRB and investigators.

6. A list of all IRB members identified by name; earned degrees and their professional representative capacity.
7. A manual and website outlining IRB procedures; and providing all IRB applications and forms. *https://teams.southern.edu/teams/irb* .

IRB APPROVAL INVOLVING EXTERNALLY FUNDED APPLICATIONS

Investigators are encouraged to submit IRB applications for approval prior to securing funding; however, if there is insufficient time to do so, proposals may be submitted with the assurance that IRB approval will be sought and received prior to pursing any research related activities. In these cases, the researcher must articulate the specific portion of the grant that will require IRB approval in the funding application and provide an anticipated start date for these activities. For example, a researcher might apply for a grant with a funding cycle that begins in January; however, there are no activities that require human subjects' approval until June. From January to June the investigators might be engaged in planning activities, drafting questionnaires, or offering direct services. In these types of cases, the investigator would use the following type of language in the grant application:

Any necessary IRB approvals will be secured prior to engaging in any research involving human subjects. If funded, the project will require IRB approval for the specific purpose of approval of questionnaires that will be used to evaluate the efficacy of the grant activities. It is anticipated that IRB approval would be secured no later than June 1, 20XX, of the university fiscal year and yearly a FORM B will be completed indicating the progress of the funded research grant. See FORM B details on page 32.

PART 2: CATEGORIES OF THE APPLICATION/APPROVAL and REVIEW PROCESS

Getting Started

Prior to initiating an IRB application, new researchers are required to complete the Collaborative Institutional Training Initiative (CITI) training, an introductory online course in human research ethics, as well as familiarize themselves with the IRB submission and review process. CITI Modules have been grouped for (1) Biomedical Research, (2) Social and Behavioral Research, and (3) Research Involving Data and Specimens Only. Select the group that best describes your area of research. CITI is accessed at: www.citiprogram.org. Create an account using a Southern email address and locate Southern Adventist University as the institution name, then continue the registration process.

Specific criteria for IRB approval of research are discussed in more detail in the following sections; however, the following elements are central to IRB decisions. The IRB will consider whether:

1. Risks to subjects are minimized;
2. Risks are reasonable in relation to anticipated benefits;
3. Selection of subjects is equitable;
4. Informed consent is sought from each subject; and
5. Informed consent is appropriately documented.

Below is a list of applications forms for research projects involving all subjects: human, animal or plant.

1. FORM A
    a. Exempt
    b. Expedited
    c. Full Review
    d. Animal/Plant

2. FORM B
    a. Modification
    b. Annual Review
    c. Project Termination
    d. Project Completion

3. FORM C – Certification of Readiness for Student Class Projects

4. FORM D – Certification of Completion of Student Class Projects

FORM A

FORM A - EXEMPT

Definition of Exempt Research

According to the Department of Health and Human Services regulation 45 CFR 46. 101, there are certain classifications of research that are exempt under federal jurisdiction. Exempt research conducted to benefit only SOUTHERN does not require submission of an IRB application (see specific classifications listed below**).** ***All other exempt research must submit an application to the IRB***. The application will be reviewed by the IRB Chair to determine that the research protocol does meet the criteria to qualify as exempt research. This procedure does not include honors projects, theses, or dissertations. These types of research require normal review according to the SOUTHERN IRB policy.

Exempt Research That *DOES NOT* Require an IRB FORM A - Exempt Application

There are several classifications of research that may involve human subjects but are exempt from the IRB's policies and jurisdiction. All of the types of research listed below are exempt and do not require IRB applications or approvals.

1. SOUTHERN teacher and student evaluations;
2. Program evaluation research to benefit SOUTHERN and carried out by SOUTHERN administrative officials and/or their designees;
3. Evaluation projects designed to enhance or increase curricula offerings;
4. SOUTHERN employee performance evaluations;
5. Marketing research (designed to market the institution as a product).

Exempt Research That *DOES* Require an IRB FORM A – Exempt Application

1. The research is conducted in established or commonly accepted educational settings, involving normal education practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. The research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or observation of public behavior, UNLESS,

    a. information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; OR,

   b. Any disclosure of this information outside the research could reasonably place the subject at risk of criminal liability or civil liability or be damaging to the subject's financial standing, employability or reputation.[1]

3. The research involves the use of educational tests, survey or interview procedures, or observations of public behavior when the human subjects are elected or appointed public officials or candidates for public office.

4. The research involves the use of educational tests, survey or interview procedures, or observations of public behavior and federal statutes require without exception that the confidentiality of the personally identifiable information will be managed throughout the research and thereafter.

5. The research involves 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.

Studies qualifying for an Exempt Review are those with no risk to the participants. These studies usually include research that is conducted in established or commonly accepted educational settings and involves normal education practices, such as the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Other studies that may fall under an Exempt Review are research that involves the use of educational tests, survey procedures, interview procedures, or observation of public behavior, as well as research that involve the collection or study of existing data, documents, records, pathological specimens, or diagnosis specimens. Confidentiality of all personally identifiable information must be managed throughout the research and thereafter. The information collected must be recorded in such a manner that the human subjects cannot be identified directly or indirectly. If any disclosure of information outside the research could reasonably place the subject at risk of criminal liability or civil liability or be damaging to the subject's financial standing, employability or reputation then it no longer qualifies for an Exempt Review.

Except for the examples above, all other research involving human subjects MUST complete a FORM A - Exempt application to be deemed exempt. Exempt categories of research do not require a full IRB hearing, but must be reviewed by the IRB. Funding agencies do not allow investigators to make this determination on their own, nor does SOUTHERN. Service projects involving human subjects are encouraged to contact the IRB and/or submit a proposal to ensure that they are exempt from IRB review.

The IRB must approve any exempt proposal before the proposed research may proceed and the investigator must receive a letter from the Chair of the IRB confirming this decision. There is no such thing as an "emergency" exemption and no university official other than the IRB Chair may designate research as exempt.

[1] "When children are involved in survey or interview procedures or observations of public behavior they are NOT exempt unless the research involves observation of public behavior by children when the investigator(s) do not participate in the activities being observed" [45 CFR 46.401(b)].

Application Process

Investigators who believe their study qualifies as exempt from IRB review should complete a FORM A - Exempt application. A FORM A – Exempt application requires the investigator to discuss the background and rational for the study; purpose/objectives of the research; methods and/or procedures; description of research sample; participant recruitment; content sensitivity; privacy and confidentiality; funding; participation compensation and costs; risk factors; how results will be disseminated; and justification for the exemption.

Upon submission of a FORM A – Exempt application the IRB will review and determine if the application qualifies for an Exempt classification. A FORM A – Exempt application and any special attachments including questionnaires or surveys if applicable must be submitted to the IRB via electronic submission to email: ***irb@southern.edu***. Application forms and contact information can be found on the IRB webpage.

FORM A - Exempt applications may be submitted at any time (i.e., there are no deadlines or specific time frames). Electronic submission is required. Please include all required materials or your application may be returned until all of the documents are attached in a single application.

Review Process

The review process typically takes about one to two weeks from the time the application is received by the IRB. If the IRB approves the proposal they will send an email notification of approval to the principal investigator noting that the research qualifies as exempt. If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for exempt status, invasion of the subjects' privacy, or confidentiality of research records) the applicant will receive an email which will outline the concerns that must be addressed in order to continue the review process. It also may indicate that the research does not qualify as exempt and ask the investigator to submit an application including the additional information needed for either Expedited or Full Board Review.

Conditions of Approval

Approval is valid for one year. At that time, investigators must file a **FORM B** noting the project is complete or request a renewal. Projects approved under the Exempt Review process require an annual review by the IRB.

Modifications to the Research Project

If **major changes** are planned, the investigator should submit a new IRB application **FORM A**, to irb@southern.edu. A new application will be treated in accordance with any other IRB application and the process outlined elsewhere in the policy will apply.

Minor changes (e.g., a change in principal investigator, minimal changes in wording of a survey instrument, or increasing the sample size from the same sample pool) may be approved by submission of **FORM B**. The investigator must fill out a **FORM B** outlining the modifications **prior to** making any changes that will affect the information given on a previously approved expedited application. The **FORM B** must be submitted to the IRB. Once the IRB Chair approves the changes, the investigator will receive notification of approval. The IRB will contact the investigator in writing if the changes outlined on the **FORM B** are not acceptable.

FORM A - EXPEDITED

This research procedure does not include honors projects, theses, or dissertations. These types of research require normal review according to the SOUTHERN IRB policy.

Definition of Expedited Research

Federal regulations and institutional policy allow for expedited review of certain types of research that have been determined to place a human subject at *minimal risk* in a research setting (45 CFR 46.110 and 21 CFR 56.110).

Studies qualifying for an Expedited are those with minimal risk to the participants. Minimal risk is defined by research that does not exceed the average probability and degree of psychological or physical harm normally encountered in the everyday life of a human being. It also must not exceed the risk or harm experienced during a routine clinical intervention.

Investigators may apply to the IRB for expedited review if their research falls into one of the nine categories discussed in the Research categories section which follows; although, the activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion merely means that the activity is eligible for review through the expedited review procedure when the proposed research involves minimal risk to human subjects. Both the Applicability and the Research Categories sections of the regulations need to be considered in order to qualify for expedited review; however*, if subjects will be randomized to treatment and control groups, then the study does not qualify for expedited review.*

Applicability

1. The categories in this list apply regardless of the age of subjects, except as noted.

2. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal.

3. The expedited review procedure may not be used for classified research involving human subjects.

4. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

   Categories one (1) through four (4) pertain to both initial and continuing IRB review. The IRB Committee must approve any expedited proposal BEFORE the proposed research may proceed and the investigator must receive a letter from the IRB Chair confirming this

decision. There is no such thing as an "emergency" exemption and no university official other than the IRB Committee may grant approval.

Research Categories

1. **Limited studies of approved drugs and devices:** Clinical studies of drugs and medical devices when condition (a) or (b) is met.

   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b. Research on medical devices for which (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Note: The drug or device must be approved and used exactly according to its labeling. All study procedures other than the use of drug or device must themselves be of minimal risk for the study to qualify for expedited review. Few studies fit this category.

2. **Blood sampling:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a. From healthy, non-pregnant adults who weigh at least 110 pounds (50 kg). For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Children are defined in the HHS regulations as "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" 45 CFR 46.402(a).

3. **Noninvasive specimen collection:** Prospective collection of biological specimens for research purposes by non-invasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (c) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more

invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. **Noninvasive clinical procedures**: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples:

   a. 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;

   b. Weighing or testing sensory acuity;

   c. Magnetic resonance imaging;

   d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

   e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Use of data or specimens collected for non-research purposes:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Note: (a) This category refers to materials collected for "non-research purposes," but can be used to cover research materials if the investigator's role is simply to analyze them. That is, if an investigator is receiving materials from colleagues who have separate approval to collect them, and the materials are handled with code numbers and other protections for confidentiality, he or she may apply for expedited review for the analysis; (b) This type or research is exempt from review only if the data collected has no link whatsoever to identifiers, not even a code number.

6. **Use of recordings:** Collection of data from voice, video, digital, or image recordings made for research purposes.

7. **Low risk behavioral research**: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.

Note: Only very specific types of behavioral research are exempt from review. Again, there usually must be no link whatsoever to identifiers [not even a code number.]

8. **Renewal of inactive research protocols or protocols that is essentially complete:** Continuing review of 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 no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. **Renewal of other minimal risk research protocols:** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Application Process

Investigators who believe their study qualifies for an expedited review from the IRB should complete a **FORM A – Expedited** application. A **FORM A – Expedited** application requires the investigator to discuss the background and rational for the study; purpose/objectives of the research; methods and/or procedures; description of research sample; participant recruitment; content sensitivity; privacy and confidentiality; funding; participation compensation and costs; risk factors; and how results will be disseminated.

Upon submission of a **FORM A – Expedited** application the IRB will review and determine if the application qualifies for an Expedited classification. A **FORM A – Expedited a**pplication and any special attachments including questionnaires or surveys if applicable must be submitted to the IRB via electronic submission **to email: *irb@southern.edu***. Application forms and contact information can be found on the IRB webpage.

FORM A - Expedited applications may be submitted at any time (i.e., there are no deadlines or specific time frames). Electronic submission is required. Please include all required materials or your application may be returned until all of the documents are attached in a single application.

Approvals from other IRBs - Cooperative research projects involve research that involves more than one institution. In these instances, federal law holds each institution responsible for safeguarding the rights and welfare of human subjects and for complying with federal policy; therefore, SOUTHERN IRB

applications must be made even if there is another institution conducting a review of the same research project. When a study is being carried out at a non-USA site, approval from the other institutional review boards at the foreign site must be sought. The IRB recommends that a copy of each IRB approval be submitted.

Questionnaires/Other Instruments - Any questionnaires, tests, survey instruments or data collections sheets which are not standard and well known must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.
Advertisements/Notices/Recruitment Flyers - The text of any advertisement, video display, notice, sign, brochure or flyer used to recruit subjects either should be included as an attachment.

Review Process

The review process for expedited review typically takes about two to three weeks from the time the application is received by the IRB (provided there are no modifications or clarifications needed to the application)**.** An expedited review will normally be processed by **two IRB committee members** who will be assigned by the Chair of the IRB. Expedited reviews will be rotated among IRB committee members based on expertise and workload. Under some circumstances such as summer break the IRB Chair alone may conduct the expedited review.

If both reviewers indicate approval at the expedited level, the IRB will approve the application send a letter of approval to the research Principle Investigator (PI) or the faculty advisor noting that the research has been approved. If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for expedited status, invasion of the subjects' privacy, or confidentiality of research records) on the part of either reviewer, the applicant will receive an email from the IRB which will outline the concerns that must be addressed in order to continue the review process. If the investigator does not agree with the comments of the reviewer or feels that any suggested changes conflict with the investigators vision of the research project, they may request a hearing by the Full IRB Board in an appeal. Likewise, the IRB or any reviewer may refer the application to the Full IRB for review. If the IRB have concerns about an application, they must refer it to the Full Board for a hearing***.***

Conditions of Approval

Approval is valid for one year. At that time, investigators must file a **FORM B** noting the project is complete or request a renewal. Projects approved under the Expedited Review process require an annual review by the IRB.

Modifications to the Research Project

If **major changes** are planned, the investigator should submit a new IRB application **FORM A** to irb@southern.edu. A new application will be treated in accordance with any other IRB application and the process outlined elsewhere in the policy will apply.

Minor changes (e.g., a change in principal investigator, minimal changes in wording of a survey instrument, or increasing the sample size from the same sample pool) may be approved by submission of **FORM B**. The investigator must fill out a **FORM B** outlining the modifications **prior to** making any

changes that will affect the information given on a previously approved expedited application. The **FORM B** must be submitted to the IRB. Once the IRB Chair approves the changes, the investigator will receive notification of approval. The IRB will contact the investigator in writing if the changes outlined on the **FORM B** are not acceptable.

FORM A - FULL REVIEW

Definition of Full Review

This type of application is used for studies that involve more than minimal risk to the subjects and require review by the full IRB committee membership. Studies that involve more than minimal risk to the subjects and require review of the full IRB committee membership. Contact the IRB chair before submitting a full review request.

The IRB must approve any Full Board application before the proposed research may proceed and the investigator must receive a letter confirming this decision. There is no such thing as an "emergency" exemption and no university official other than the IRB may grant approval**.**

Application Process

Investigators who believe their study qualifies for a Full Review from the IRB should complete a FORM A – Full Review application. A **FORM A – Full Review** application requires the investigator to discuss the background and rational for the study; purpose/objectives of the research; methods and/or procedures; description of research sample; participant recruitment; content sensitivity; privacy and confidentiality; funding; participation compensation and costs; risk factors; and how results will be disseminated.

Upon submission of a **FORM A – Full Review** application the IRB will review and determine if the application qualifies for a Full Board classification. A **FORM A – Full Review** application and any special attachments including questionnaires or surveys if applicable must be submitted to the IRB via electronic submission to email: ***irb@southern.edu***. Application forms and contact information can be found on the IRB webpage.

FORM A – Full Review applications may be submitted at any time (i.e., there are no deadlines or specific time frames). Electronic submission is required. Please include all required materials or your application may be returned until all of the documents are attached in a single application.

Review Process

The IRB Full Board meets on an ad hoc basis; therefore, investigators should consult the IRB Chair to ensure that they are scheduled for review. The Full IRB membership will review applications during their meetings. Every attempt will be made to schedule a meeting to hear these applications within 3-5 weeks from the time the application is received by the IRB Chair (provided there are no modifications or clarifications needed to the application).

Votes are taken and recorded at the meeting of the Full Board after a discussion of the proposal. A quorum is required to hear applications and a nonscientific committee member must be present. If the majority of the members vote to approve the proposal, it is considered approved at the meeting. The IRB will promptly notify the investigators in writing of the decision. If the IRB committee has unanswered questions or concerns about the proposal, a majority vote may result in a request for additional information, clarification, or changes to the application. The IRB will issue an email explaining the issues or problems as discussed in the meeting. (These comments also will be reflected in the IRB Committee minutes). The principal investigator must then address a response and/or revise the

application in order to obtain approval. The investigator also may request to meet, in person, with the Committee.

On very rare occasions, the IRB may encounter major difficulty in making a risk/benefit assessment, and an outside reviewer may be asked to consider the protocol and provide input based on their specific expertise; however, this reviewer will not be allowed to vote under any circumstances. The IRB Committee also may request the principal investigator to attend a Full Board meeting to discuss or clarify issues with the application.

Conditions of Approval

Approval is valid for one year. At that time, investigators must file a **FORM B** noting the project is complete or request a renewal. Projects approved under the Full Board Review process require an annual review by the Full Board committee membership.

Modifications to the Research Project

If **major changes** are planned, the investigator should submit a new IRB application **FORM A** to irb@southern.edu. A new application will be treated in accordance with any other IRB application and the process outlined elsewhere in the policy will apply.

Minor changes (e.g., a change in principal investigator, minimal changes in wording of a survey instrument, or increasing the sample size from the same sample pool) may be approved by submission of **FORM B**. The investigator must fill out a **FORM B** outlining the modifications **prior to** making any changes that will affect the information given on a previously approved expedited application. The **FORM B** must be submitted to the IRB. Once the changes are approved by the IRB Chair, the investigator will receive notification of approval. The IRB will contact the investigator in writing if the changes outlined on the **FORM B** are not acceptable.

FORM A – ANIMAL/PLANT

IRB policy and federal law require review and approval for proposed activities related to the humane treatment and safe use of vertebrate and invertebrate animals; and the use of plants for research purposes. The maximum period of approval is three years. (An annual review of your approved protocol is also required utilizing the Annual Review Form, which will be sent to you 60 days prior to the annual review date.

Definition of Animal/Plant Application Form

This type of application is used for studies that involves the utilization of vertebrate and invertebrate animals or plant species collected or observed within a described research protocol.

Animal/Plant Research that *DOES* require an IRB Application

Approval must be obtained before initiating any research testing or instructional project involving the use of live vertebrate or plants. Before a person can touch, work with or have access to animals or plants for the purpose of conducting research, he/she must first be listed on an approved animal/plant protocol.

FORM A - Animal/Plant is required for:

- Projects involving the use of vertebrate animals.
- Projects where animals are not directly purchased (i.e., wild trapping, in-house breeding, field observation).
- Projects where plants are not directly purchased (field observation, collection).
- Analysis of plants

The research involves 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.

Animal/Plant Research That *DOES NOT* Require an IRB Application

Approval is not required for:

- Tissues obtained from an abattoir or market.
- Pre-hatched chicken eggs.
- Tissues from another Investigator.*
- Plant collections as part of a class assignment.
- Use of plants in class presentations

*An Animal Protocol is required if an animal is purchased or euthanized for the sole purpose of obtaining tissues.

The IRB must approve any **FORM A - Animal/Plant** proposal before the proposed research may proceed and the investigator must receive a letter from the Chair of the IRB confirming this decision. There is no such thing as an "emergency" exemption and no university official other than the IRB Chair may designate research as exempt.

Application Process

Investigators who believe their study qualifies for an Animal/Plant Review from the IRB should complete a **FORM A – Animal/Plant** application. A **FORM A – Animal/Plant** application requires the investigator to discuss the background and rational for the study; purpose/objectives of the research; methods and/or procedures; description of research sample; funding; risk factors; and how results will be disseminated.

Upon submission of a **FORM A – Animal/Plant** application the IRB will review and determine if the application qualifies for a Animal/Plant classification. A **FORM A – Animal/Plant** application and any special attachments including questionnaires or surveys if applicable must be submitted to the IRB via electronic submission to email: ***irb@southern.edu***. Applications and contact information can be located at the IRB webpage.

A **FORM A – Animal/Plant** application may be submitted at any time (i.e., there are no deadlines or specific time frames). Electronic submission is required. Please include all required materials or your application may be returned until all of the documents are attached in a single application.

Review Process

The review process typically takes about one to two weeks from the time the application is received by the IRB. If the IRB approves the proposal they will send an email notification of approval to the principal investigator noting that the research is approved as submitted. If the information on the application seems incomplete or raises any concerns, the applicant will receive an email which will outline what must be addressed in order to continue the review process.

Conditions of Approval

Approval is valid for one year. At that time, investigators must file a **FORM B** noting the project is complete or request a renewal. Projects approved under the **FORM A - Animal/Plant** process require an annual review by the IRB.

Modifications to the Research Project

If **major changes** are planned, the investigator should submit a new IRB application **FORM A** to irb@southern.edu. A new application will be treated in accordance with any other IRB application and the process outlined elsewhere in the policy will apply.

Minor changes (e.g., a change in principal investigator, minimal changes in wording of a survey instrument, or increasing the sample size from the same sample pool) may be approved by submission of **FORM B**. The investigator must fill out a **FORM B** outlining the modifications ***prior* to** making any changes that will affect the information given on a previously approved expedited application. The

FORM B must be submitted to the IRB. Once the IRB Chair approves the changes, the investigator will receive notification of approval. The IRB will contact the investigator in writing if the changes outlined on the **FORM B** are not acceptable.

Principles for the Care and Use of Laboratory Animals

I. The transportation, care and use of animals must be in accordance with the **Animal Welfare Act** and other applicable federal and state laws, guidelines, and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Alternative methods such as mathematical models, computer simulation, and in vitro biological systems must be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless he contrary is established, investigators must consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures must not be performed on anaesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved must be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure. UI veterinarians have the authority to euthanize animals whose welfare is seriously threatened. The action will follow contact or several efforts to contact the responsible investigators.

VII. The living conditions of the animals should be appropriate or their species and contribute to their health and comfort. Normally the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studies. In any case, veterinary care shall be provided.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate group such as an institutional research committee. Such exception should not be made solely for the purpose of teaching or demonstration.

FORM B

This form should be used by the professor to make minor changes to a previously approved study, when the study needs to be extended, the study has been terminated, or the study is completed. Check the appropriate box on the FORM B.

FORM B – MODIFICATION

Definition of Modifications (Minor vs. Major Changes)

Minor project changes have no impact upon the original goals and protocols outlined in the original application. Minor changes include those that do not adversely alter the overall harm-benefit profile of the study or would not potentially affect the willingness of current subjects to remain or enroll in the study. Examples include: change of project title, minimal changes in wording of a survey instrument, minor grammatical changes to an informed consent and/or child's assent form, addition or deletion of collaborators and/or co- principal investigators, change in student advisor, additional sites for the performance of the research (include a letter from the authorized individual for a new location).

Major changes involve substantial changes to the research protocol including changes in the purpose or process of the research project. Examples might include changes in: sampling population, survey instruments, interview protocols, administration of a treatment of any kind, and/or the informed consent process. Any research, by definition, that increases the level of risk to the participant relative to the initial application MUST assume that the changes are major.

The initial evaluation as to whether an addendum/modification is major or minor starts with the principal investigator, who should assess the degree of change in procedures and risks. The IRB Chair or committee reviewers may change the status of that designation if they deem the designation inappropriate (see below).

The IRB must approve any proposed changes to the original application before any modifications may proceed and the investigator must receive an email confirming this decision. There is no such thing as an “emergency” exemption and no university official other than the IRB Chair may grant approval.

Application Process

If **major changes** are planned, the investigator should submit a new IRB application, **FORM A**, to irb@southern.edu. A new application will be treated in accordance with any other IRB application and the process outlined elsewhere in the policy will apply.

Minor changes (e.g., a change in principal investigator, minimal changes in wording of a survey instrument, or increasing the sample size from the same sample pool) may be approved by submission of **FORM B – Modification** application. The investigator must fill out a **FORM B – Modification** application outlining the modifications prior to making any changes within the research that will affect the information given on a previously approved application. The **FORM B – Modification** application must be submitted to the IRB. Once the IRB Chair approves the changes, the investigator will receive

notification of approval. The IRB will contact the investigator by email if the changes outlined on the **FORM B – Modification** application are not acceptable. **FORM B – Modification application** and any special attachments (including questionnaires or surveys if applicable) must be submitted to the IRB via electronic submission to ***irb@southern.edu*.** Application forms and contact information for the IRB can be found in the IRB webpage. Research applications may be submitted at any time. There are no deadlines or specific time frames. Electronic submission is required.

Review Process

The review process for minor changes and modifications typically takes about one week from the time the application is received by the IRB (provided there are no modifications or clarifications needed to the application). The review process for major changes where you submit a new FORM A typically takes about three to five weeks.

The IRB will review requests for minor changes, unless the proposed modification is deemed to be a major change. Committee members assigned by the IRB Chair, consistent with expedited review processes, will review major changes. Consistent with that procedure, any reviewer or the IRB Chair may request a Full Board hearing to review requests for changes. In addition, any major change proposed to an application that was initially approved by a Full Board hearing will require another Full Board hearing to approve any modifications. If a Full Board hearing is required to hear major changes, the Committee will follow the procedures that govern Full Board hearings.

Conditions of Approval

Approval for renewal status is valid for one year. After that year is complete, investigators must file an additional **FORM B** – **Annual Review** application. Unless major changes have been made and approved, necessitating a new **FORM A**, the anniversary date of the original approval will always remain the date of the original IRB formal email of approval.

Projects that are found to be continuing without IRB approval are in non-compliance with SOUTHERN policy and federal regulations. In these circumstances a non-compliance report will be sent to the Academic VP for further action.

FORM B - ANNUAL REVIEW

The Department of Health and Human Services (DHHS), The Food and Drug Administration (FDA) and SOUTHERN requires annual review of all projects involving human subjects. The annual review date is an anniversary date that is one calendar year later than the date on the original IRB formal email of approval.

Application Process

Investigators are required to complete a **FORM B – Annual** Review **application** to the IRB at least four weeks before the anniversary date. As a courtesy, the IRB sends out renewal reminders six to eight weeks before the study expires informing the investigator that if the project will continue into the next year. It is, however, ultimately the investigator's responsibility to initiate a renewal application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. If any project activity occurs or continues after the expiration date, the investigator is out of compliance with both federal and university policy.

The investigator must receive an email from the IRB stating that the research is renewed prior to the anniversary date or the research must be suspended pending an approved renewal notice. There is no such thing as an emergency approval and no university official other than the IRB may grant approval for the research to continue past the anniversary date.

Like the initial protocols, Annual Review Forms are classified as exempt, expedited, or Full Board reviews and requires different levels of review. The IRB will review all renewal reports and determine the appropriate level of review. If exempt or expedited review status is granted, the forms will be forwarded to the IRB for approval. The IRB may simply sign off on the **FORM B – Annual Review application** provided there have been no major changes to the project**.** All IRB applications that were originally approved as a result of a Full Board Hearing also require a hearing of the full committee for renewal. The IRB Chair will schedule these meetings.

Review Process

If the Chair determines if a full IRB review is warranted, because of the on-going nature of the research or because of major changes outlined in the update, she/he will notify the principal investigator by email and request that a new **FORM B – Annual Review application** be completed for review by the Full IRB Board.

Conditions of Approval

Approval for renewal status is valid for one year. At that time, investigators must file an additional **FORM B** noting the project is complete or request a renewal. Unless major changes have been made and approved (necessitating a new **FORM B**), the anniversary date of the project will always remain the date of the original IRB formal letter of approval.

Projects that are found to be continuing without IRB approval are in non-compliance with SOUTHERN policy and federal regulations. In these circumstances a non-compliance report will be sent to the Academic VP for further action.

FORM B - RESEARCH TERMINATION

Definition of Termination

Projects are considered terminated if they received IRB approval and are abandoned for any reason regardless of whether or not the project actually began the research process.

Process of Termination

The Principal Investigator must complete a **FORM B – Project Termination** within four weeks of termination of a project and submit it to the IRB. The Investigator should simply indicate the project will not be conducted at all by marking the appropriate box on the **FORM B – Project Termination**.

For thesis/dissertation research: IRB-approved projects should **NOT** be terminated until the thesis/dissertation committee has approved and signed off on the final submission.

FORM B – RESEARCH COMPLETION

Definition of Completion

Projects are considered completed when the study is officially closed to new participants and follow up, and all data collection is complete. If the investigators continue to actively follow research participants, the study is not considered closed and requires annual renewal. Normally, projects may be considered complete during the process of analyzing data, unless the data contains identifiable private information that can be linked to specific individuals. In these cases, the project is considered complete when data analyses are completed.

Process of Completion

The Principal Investigator must complete a **FORM B – Project Completion** within four weeks of completion of a project and submit it to the IRB. The Investigator should simply indicate the project is completed by marking the appropriate box on the **FORM B – Project Completion**. For thesis/dissertation research: IRB-approved projects should **NOT** be completed until the thesis/dissertation committee has approved and signed off on the final submission.

FORMS C and D – STUDENT RESEARCH AND CLASS PROJECTS

At the university, students participate in research projects in order to learn about the process of conducting research. These projects do not usually meet the definition of research as outlined in the IRB policy unless the research is intended to contribute to the generalized body of knowledge in the field, then a properly selected **FORM A** must be submitted to the IRB. There is a need to ensure that these assignments do not compromise any of the principles outlined in the SOUTHERN IRB policy. It also is essential that students be socialized to the ethical and procedural concerns associated with institutional review practices and the need to protect human subjects. These IRB application form files must be maintained for no less than three years by the faculty member of record and may be periodically audited by the IRB. Students are required to complete the online CITI training on the IRB process as part of the course work and given adequate academic credit for this assignment. All forms can be located on the IRB webpage.

Student projects may be exempt from IRB review if the assignment meets the criteria outlined below. This procedure does not include honors projects, theses, or dissertations. These types of research require normal IRB application and review according to the Southern IRB policy.

When to use these forms

Use these forms if you are a professor teaching research within a course or for the School or Department. The purpose of these forms is to assist the professor and the IRB with tracking student research from the IRB application process, approval phase, on to the completion phase. Y**ou must have completed the CITI training** and be qualified to approve student research.

Faculty members may elect to use the procedure outlined in this section of the policy if student projects meet all of the following criteria:

1. The purpose of the student research is for students to learn about the process of engaging in research or applying a pedagogical technique. Publications, formal reports, or presentations at professional conferences are planned, the student(s) must complete CITI training and submit their CITI training certification along with their IRB application forms directly to the IRB, listing the faculty member supervising the research project.

2. The assignment is part of a class, course credit is earned for completing the CITI training and the research project, and the student research is conducted under faculty supervision.

3. The project is eligible for an exempt or expedited review (i.e., no project requiring Full Board approval may be dealt with under this procedure).

4. All students must complete the CITI on-line training. Student CITI training certification of completion forms should be filed with the appropriate IRB application forms in the faculty members' office and kept for a period of three years following the end of the research project. Should a faculty member leave SOUTHERN employment, these files should be transferred to the IRB for storage.

Faculty members acting within the IRB policy who use this procedure must:

1. Submit a **FORM C** to the IRB once the research project has been identified. On this form you will indicate the name of the course, the assignment, and the name of researcher(s) along with the Title of the Research Project. This Form must be approved by the IRB prior to proceeding with the research project(s). All projects for this course may be submitted on the same FORM C.

2. Students are required to submit a completed **FORM A** and a copy of their certificate of CITI training completion to the professor for approval by the professor instead of the IRB.

3. The professor will review and approve the exempt and expedited review forms submitted by the student to them as instructor of record and keep these forms in a locked file in their office.

4. Submit a **FORM D** at the end of the semester which outlines the course, the assignment, and the name of each researcher(s) along with the Title of the Research Project to the IRB designating completion of the research project.

PART 3: INFORMED CONSENT

Purpose of the Consent Document

Informed consent is a process, not just a form. Information must be presented to enable people to voluntarily decide whether or not to participate as research subjects. It ensures respect for people by providing the opportunity for thoughtful consent to ensure that participation is voluntary. The procedures used to obtain informed consent should be designed to educate the subject population in terms that they can understand to ensure that research participants understand the consent they have provided. As a result, the IRB will seek to ensure that the following general requirements of informed consent are satisfied in all studies:

1. Informed consent must be prospectively obtained from the participants or their legally authorized representatives;

2. Information must be conveyed in understandable language;

3. Subjects must be given sufficient opportunity to consider whether they want to participate;

4. Consent must be given without coercion or undue influence; and

5. Subjects must not be made to give up legal rights or be given the impression that they are being asked to.

Elements of Consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. See Appendix A for sample Informed Consent Forms.

Basic Required Elements of Consent

Federal regulations on informed consent stipulate eight basic required elements of consent, and note six additional elements that may be added to a standard consent form when appropriate (see Title 45, Code of Federal Regulations, Part 46.116.) The following information shall be provided to each subject when seeking informed consent (except as provided in paragraph (c) or (d) of this section):

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional Elements of Informed Consent

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

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

Exceptions to Required Elements of Consent

Social Security Exception

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in methods or levels of payment for benefits or services under those programs; or (iv) possible changes in methods or levels of payment for benefits or services under those programs, and

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

Other Exceptions

An IRB also may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, except as descripted in paragraph (c) later in this section. A copy shall be given to the person signing the form.

The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent outlined previously in this policy. This form may be read to the subject or the subject's legally authorized

representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short form written consent document stating that the elements of informed consent required by this policy have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Exceptions/Waivers for Documentation of Informed Consent

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

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The IRB will usually waive the requirement of signed consent in the following situations:

1. When the identities of subjects will be completely anonymous if the consent form is not signed, and there is minimal risk involved in the study;

2. When obtaining a signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study;

3. When there is a possible legal, social, or economic risk to the subject entailed in signing the consent form, e.g., for HIV antibody-positive individuals who might be identified as such by signing the consent form.
4. Retrospective chart review or use of pathological specimens where the patients need not be contacted as part of the study, and appropriate precautions to protect the confidentiality of the data are described;

5. Use of extra blood which is taken at the time of a venipuncture being done for clinical reasons; or

6. Use of leftover biological material taken from another study for which consent was obtained.

If an investigator does request a waiver of signed consent, then the application should provide a written justification for doing so and cite one of the above categories.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The IRB is likely to require use of such a written statement, in the form of an information sheet, which includes most or all of the same elements as a consent form, but does not require the signature of the subject. The IRB will review the request for a waiver of consent and determine if approval of the waiver is justifiable.

General Information to be Considered When Constructing Informed Consent Forms

Consent forms should be simple and straightforward so that all subjects will have an easily understood form that outlines the proposed research. (*For a sample Consent Form, see Appendix A.)* As such, investigators should consider the following elements when constructing consent forms:

Reading level: For most studies, it is recommended that the consent forms be written at an eighth grade reading level

Lay Language: Unless the subjects are themselves medical professionals, scientific or technical terms should either be replaced with or defined in lay language.

Legal terms: Legalistic sounding language should not be used. These phrases interfere with a subject's comprehension of the consent form and lend the appearance of a legal document to the consent form. (Examples include: "You hereby agree," "You certify that," "You understand that," "You, the undersigned, do acknowledge that," "You realize that," "You have been told that," or "It has been explained to you that."

Proofreading: The entire form should be carefully proofread for correct spelling and grammar before it is submitted for IRB review.

Elements to Include in a Consent Form

When constructing consent form, the investigator should review the following items and include them when appropriate to ensure they are addressing the elements of consent as outlined by federal law and SOUTHERN Policy. Research participants must be told about the purpose, procedures, risks and benefits of a particular study, the subject's rights in participating in research, the freedom to decline to participate without any jeopardy. If applicable, the alternative treatments available will be explained. The individual will also be given the opportunity to obtain further information and answers to questions related to the study. Sample consent forms are included in Appendix A and are available on the SOUTHERN IRB web site.

Investigators who are requesting exempt status normally will not need to use a signed informed consent form when the identities of subjects will be completely anonymous if the consent form is not signed and there is minimal risk involved in the study. Investigators in these instances, however, should be conscious of the ethical principles guiding the process of informed consent and ensure that they have provided sufficient information to satisfy the basic elements of informed consent.) At a minimum, they should either provide a cover letter or introductory remarks (e.g., at the beginning of a survey) that provide: a reference to SOUTHERN and the title of the research project; the identity of the principal investigator(s) and their contact information; an introduction to the study; the aims of the study; a brief

summary of the background or reason for the project; a summary of why the individual has been asked to participate in the study; a description of the type of participation requested and any procedures; an outline of any risks; an overview of how confidentiality will be maintained; an discussion of any benefits; a description of any alternatives to participation; a discussion of any costs and/or benefits; and a method of securing additional information or asking questions.

A. Heading and Title: Reference to Southern Adventist University and notification that a research project is being discussed should be included in the heading of all consent forms. The study title also should be included in the heading of the form. (If the official title is technical and difficult to understand, a simplified non-technical title should be used in addition to the official title.) If a study has more than one consent form, each form should be labeled or titled appropriately, and the same references used within the application, in order to avoid confusion.

Example Heading:

SOUTHERN ADVENTIST UNIVERSITY INFORMED CONSENT FORM
Attitudes toward Cartoon Violence and its Real or Perceived Impact
Upon Children

B. Identify Principal Investigator(s): This section should indicate who is conducting the research. The first and last names of the principal investigator(s) should be used and the investigators identified with titles and department and other pertinent contact information at the beginning of the form, so that it is clear who is carrying out the study.

C. Purpose and Background: This section should introduce the study, state the aim of the study, give a brief summary of the background or reason for the project, discuss the number of subjects expected to participate in the study, and explain why the individual has been asked to participate. The reason a person has been asked to participate should be simply but specifically stated (e.g., "because you have tried to quit smoking in the past but have not been successful," "because you're undergoing surgery and will be given a general anesthetic," "because you are a healthy person") and should not include a discussion of the inclusion/exclusion criteria. If the study is sponsored research, the sponsor should be named.

If an investigational drug or device is being used in the study, this should be mentioned in this section and the drug or device should be named. The name the drug or device referred in this section should be used consistently throughout the form. This section should not begin with such phrases as "You agree to participate ..." since the prospective subject has not yet had a chance to read the form and, thus, could not yet make an informed decision about whether or not to participate.

D. Procedures: To emphasize the voluntary nature of participation in research, this section should begin with a phrase like, "If I agree to be in this study, the following will happen."

Each procedure should then be listed, preferably in the order in which it occurs, and discussed. If the study involves screening procedures, these should be mentioned first and identified as tests that will determine eligibility to continue in the study. The Procedures section should clearly state what would be done to the individual as a result of participation in the study, and, where appropriate, how this differs from standard treatment or what would happen to the individual if he/she did not participate in the study.

When a study involves randomization, it should be described as a study procedure, and the term "randomization" explained in lay language. Information about the probability of assignment to each treatment or condition should be given. Other terms, which might not be, familiar to the average layperson (e.g., "placebo") should be defined the first time they are mentioned in the form or use a lay term.

If a standard medical procedure is being done as part of the study, it should not be referred to as "standard" or "routine," since this could easily imply that the procedure would be done anyway for clinical reasons. Rather, what should be conveyed is that this procedure is an extra laboratory test that is commonly done for clinical purposes, but is being done here for research purposes.

If patient records will be reviewed for purposes of the study, this should be listed as a procedure. Amounts of blood or tissue to be taken for study purposes should be specified, using lay equivalents (e.g., teaspoons, ounces) for metric terms.

The number of times a procedure will be done, the time involved for each procedure, and the total amount of time for participation in the study should be specified. The location(s) where the procedures will be done should also be stated.

E. Risks and/or Discomforts: The risks and/or possible discomforts of all study procedures should be listed and explained in this section. It is usually best to describe the risks of each procedure in a separate point. Risks should be arranged and described according to their severity and the likelihood of their occurrence. Where appropriate, it should be indicated what precautions would be taken to avoid certain side effects or outcomes from occurring, and what will be done should they occur. A statement should be included that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

   To the extent possible, consent forms should characterize the likelihood of risks using words like "likely," "frequent," "occasional," and "rare." The first time these words are used in a form they should be defined using percentages, as follows:

   Likely events: Expected to happen to more than 50% of subjects
   Frequent events: Will probably happen to 10-50% of subjects
   Occasional events: Will happen to 1-10% of subjects
   Rare events: Will happen to less than 1% of subjects

   For studies involving investigational agents, or experimental doses or combinations of drugs and/or treatments, subjects should be warned that there may be as yet unknown risks associated with the drug/treatment but that they will be advised if any new information becomes available that may affect their desire to participate in the study.

F. Confidentiality: Since one of the risks of participating in research is a loss of privacy, a discussion of confidentiality issues should be included in the Risks section. It should describe briefly how the confidentiality will be protected, i.e., coding of records, limiting access to the study records, not using any individual identifiers in publications or reports resulting from the study.

   Food and Drug Administration regulations also require a statement about the extent of confidentiality of records be included in the consent form. For studies involving investigation of drugs or devices, both

officials from the sponsoring company and the FDA have at least some limited right to review individual records; subjects in such studies must be forewarned about this intrusion into their privacy.

For all statements regarding confidentiality of research records, it should be kept in mind that there is no legal privilege between investigator and subject as there is between physician and patient or counselor and client. Thus, a guarantee of complete confidentiality, or "strictest confidentiality," should not be given or implied. One should always state instead that confidentiality will be protected "as far as is possible" or "as far as is possible under the law."

NOTE: The one way to protect research records from subpoena is through a Federal Certificate of Confidentiality. More information about this Certificate may be obtained by contacting the federal funding agency (see web-link http://grants1.nih.gov/grants/policy/coc/index.htm) If such a certificate is obtained; it is recommended that the consent briefly discuss the added degree of protection that this certificate provides.

G. Benefits: Any potential direct benefits to the subject should be described first, followed by potential general benefits (e.g., the group of patients to which the individual belongs, to medical knowledge, etc.). It is usually recommended that the description of possible direct benefits be qualified with the phrase, "... but this cannot be guaranteed." If there is no direct benefit to the subject anticipated from the study, this should be stated at the beginning of the section.

The FDA recommends that possible benefits such as medical or societal benefits resulting from a research study be considered separately from payment for participation in the study. Thus, the discussion of payment or reimbursement should be separated from the benefits statement and placed in its own separately labeled section.

H. Alternatives: This section should discuss the various alternatives to participation in the study. This can be a short statement, but it should make clear the possible choices (e.g., no treatment, standard therapy, other experimental treatments, or some or all of the protocol treatment, but without participating in the study) that are available if the individual chooses not to participate in the study. When alternative therapies are available, brief objective descriptions of their important benefits and risks should be included.

When the only alternative is to decline participation in the study (e.g., if the study involves only normal, healthy volunteers), this need not be mentioned in a separate section, since the individual's right to choose not to participate will be made clear in the last section of the form.

I. Costs/Financial Considerations: When there are no costs at all to be charged to the subject, this should be clearly stated in the form. However, a simple statement that there are no costs is usually not sufficient and could be misleading. The more typical situations are that the subject will have to pay for the usual costs of his or her medical care but will not be charged any extra for participating in the study or the cost of the study medication will be covered by the study but the subject will have to pay all other charges.

When participation in the study may result in any costs whatsoever to subjects, clear information must be provided in the consent form regarding these costs. Special attention must be paid to this issue in studies in which the subjects are also patients. In such cases, where individuals may be undergoing various procedures, tests, or hospitalizations that are part of their clinical diagnosis and treatment, and

others that are part of the research study, the costs section of the consent form should clearly distinguish which costs will be charged to the patient or his third party carrier, and which costs will be covered by the study. In addition, when appropriate, a statement should be included, warning subjects that because the therapy is experimental, the insurance carriers may not cover the costs involved.

Whenever substantial costs to the subject are involved (e.g., for many oncology, cardiology, and MRI studies) you may wish to consider referring subjects to a financial counselor. The consent form, then, should state that such a counselor is available and ask that subjects take advantage of this service.

J. Reimbursement/Payment: When referring to money that subjects will receive in return for participation in a study, either "reimbursement" or "payment" may be used. However, the term "compensation" should not be used, since it is used on consent forms to designate compensation for injury. Investigators should avoid connotations of undue influence to participate or that the subject is being employed by the investigator. Rather, the sense should be that subjects will be reimbursed for their time, travel expenses, and the inconvenience of being a research subject. However, unless the subject has actual receipts (e.g., parking, taxi, babysitting), the person is not being reimbursed in the strictest sense of the word, for either accounting or tax purposes.

This section should state the total dollar amount that the subject will be paid for participation in the study, and should give any other relevant information such as pro-rating if a subject does not complete the study, or bonus payment at the end of the study. If appropriate, a payment schedule should be included in this section. Subjects should not be required to complete the entire study in order to be reimbursed and bonus payments for study completion should be modest.

Subjects should be informed how payment will be made (e.g., in cash, by check) and when they will be paid (e.g., immediately after the interview, approximately six weeks after individual completion of the study).

Payments for research participation in excess of $600 per calendar year are considered taxable income. If subjects will be paid more than $600, the Reimbursement section should explain that the University will report this income to the IRS.

If there will be no payment or reimbursement of subjects for the study participation, this information should be so stated in this section.

K. Questions: This section should provide contact information for the subject in case of questions about the study. At least one permanent name and telephone number of one investigator, usually the principal investigator, must be typed into this section as submitted. Blank lines to be filled in later may be included for additional contact persons. If the principal investigator is a student, the faculty advisor's name and phone number should be included in this section as subjects often wish to contact the person who is supervising the project.

If the person explaining the study and obtaining consent is not the principal investigator, a blank line in this section may be filled in with the person's name, and telephone number, if different, at the time consent is obtained

L. Tissue and/or blood banking or storage: Some studies include the option to have tissue specimens or blood stored (or banked) for studies that may come available in the future, future diagnostic testing, or

other purposes not yet determined. Subjects should have the option to participate in the study whether or not they agree to tissue banking.

M. Consent: This section should state that the subject has been given (not just "offered") a copy of the consent form.

This section should then state the information that participation in research is voluntary, and explain the individual's right to decline to participate, or withdraw from the study at any time. If the subjects are patients, students, or employees, a phrase may be added indicating that refusal or withdrawal will be without jeopardy to status or care.

The investigator may also wish to advise subjects that they may be withdrawn from the study if the investigator deems it in the best interests of the subject or for other reasons that should be specified (e.g., medical interests, failure to keep appointments).

The IRB discourages such wording as "You have read this form and understand it; based on this understanding, you hereby agree to participate," since this does not guarantee an individual's comprehension, legally or otherwise. Rather it is recommended that investigators simply state that if the person wishes to participate in the study, he or she should sign the form; signature will then indicate agreement to participate.

N. Signature Section: Unless waiver of signed consent is approved by the IRB, this section should include lines for the subject's signature and the date of signature. The consent form also should include a signature line for the specific individual that secured or was present to obtain consent so that subjects have a record of who explained the study to them.

If the study involves subjects who cannot give consent for themselves (e.g., minors, unconscious patients, individuals with Alzheimer's Disease), and the IRB accepts the justification for their inclusion in the study, a separate signature should be obtained for the purpose of third party consent. For studies involving minors, this signature lines will be for parent(s) or guardian(s). In other studies where a legally authorized representative will give consent for the subject, an appropriately labeled signature line should be used. Note, only parents, guardians, conservators or those who have power of attorney for health care are so authorized.

If the study involves minors, an assent line also should be included for minors to sign when appropriate.

HIPAA Rules and Regulation (also see PART 5: The Health Insurance Portability and Accountability Act)

Ensure the following information is included in your informed consent form:

Confidentiality

1. Provide a statement explaining how individual identifiers will be used in maintaining the research records (i.e., research record labeled with subject's name or research records labeled with a code number. A master key that links the name and code number will be maintained in a separate and secure location).

2. Insert HIPAA authorization portion in confidentiality section. (refer to HIPAA authorization language template) If the study involves the use of a federal Certificate of Confidentiality, provide the information about the certificate and how it protects subject information from re-disclosure. *(Example: To further help protect your privacy, the investigators have obtained a confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). With this federal Certificate, the investigators cannot be forced (i.e., court order) to disclose information that may identify you in any federal, state or local court. However, disclosure is necessary upon the request of the DHHS (i.e., for audit or program evaluation).*

3. If information about the subject's participation in the study or the results of procedures performed in the study will be placed in the subject's medical record (as contrasted with research record), then it should be specified.

4. Specify that the individual subjects will not be identified in any presentations or publications based on the results of the research study.

PART 4: ADVERSE EVENTS REPORT

All investigators conducting research on human subjects must ***report two types of incidents*** if there are:

1. Any injuries or adverse events associated with the study procedures and/or problems involving the conduct of individuals associated with the study which occur during the course of their research project; and

2. Any possible breach of human subject protections that an investigator becomes aware of associated with research activities at SOUTHERN conducted by other investigators.

As the standard approval letter for the IRB applications states, "All problems involving risks and adverse events must be reported to the IRB immediately." Specifically, the following must be reported, in writing:

1. All serious adverse events associated with the study procedures, and/or

2. Any incidents or problems involving the conduct of the study or participation by research subjects, including problems with the recruitment and/or consent process.

The information below is provided to clarify IRB policy regarding reporting of adverse events as well as problems involving the conduct of the study. The "Adverse Event Report Form" should be used for reporting such events. All reports should be signed by the Principal Investigator. See Appendix B for sample Adverse Report Forms.

Adverse Events That Require A Report

All serious adverse events associated with the study procedures must be reported. All deaths, whether or not they are directly related to study procedures, must be reported. However, common sense must play a large role in deciding what to report; not every bruise or rash needs to be reported. If there is a question, investigators are encouraged to err on the side of "over-reporting."

In general, any serious or recurring problem, any unanticipated side effect, any adverse event reported to a study sponsor and/or to the FDA, any adverse event requiring treatment, or any side effect about which a subject is concerned, should be reported to the Chair IRB.

Any problems involving the conduct of the study or patient participation, including problems with the recruitment and/or consent processes also require reporting. For example, if a person who is contacted, either in writing or in person, about participating in a study becomes upset about the recruitment process, this should be reported.

Any deviations from the approved protocol should be reported in writing. Examples of a more serious nature include incidents of a person being enrolled in a study before signed consent has been obtained, an investigational drug being given prior to signed consent, or a subject being given a higher or lower dose of the drug than stated in the approved protocol.

Definition Of An Adequate Adverse Event Report

The Adverse Event Report Form was created to help ensure that sufficient information concerning an adverse event is submitted. Adverse event reports submitted to study sponsors and/or to the FDA may not be sufficient in that they rarely include an assessment of whether changes in the protocol or consent form should be made as a result of the adverse event.

If a study sponsor sends updated drug or device brochures, safety reports or other summaries of adverse effects please forward to the Chair IRB. The principal investigator should include an appropriate analysis and assessment.

The Effect Of Reporting An Adverse Event Report

A report is not an admission of any liability. However, for adverse events, the investigator should make an initial determination as to whether any changes are needed in the discussion of the risks and/or benefits in the consent form. In response to incidents, the investigator may need to re-evaluate the recruitment or consent process and modify existing procedures appropriately.

The Review Process For Adverse Events And/Or Incidents Reports

Full IRB Committee will review all adverse event reports and/or incident reports in order to re-evaluate the risks/benefits of the study and/or the appropriateness of the recruitment/consent process to determine if any changes should be made in the protocol or consent form. If the investigator has already modified the protocol or consent form in response to these events, the appropriateness of these changes are also reviewed.

The IRB is responsible for continuing review of all human subject research. This is done through the annual renewal process required for any ongoing study. Thus, all reported adverse events should also be included when a renewal application is submitted for the study, so that the IRB may consider renewal of the protocol in light of such information.

Serious adverse events or incident reports are forwarded to the Academic VP and Chair of the IRB who must be informed in case of inquiries, institutional liability, publicity, or to apply for University compensation policies. If the FDA or DHHS is involved, and if the problem is of sufficient magnitude, the appropriate agency officials will be informed. The IRB Chair will be responsible for notification in all of these instances.

The Effect Of Failing To Report Adverse Events

Failure to report is a breach of the conditions under which IRB approval is given, and could result in suspension or revocation of approval. Suspension or revocation of approval could result in loss of support by funding agencies and loss of right to publish.

Incident Reports Related To Other Research Activities

The IRB Chair will conduct an inquiry following any report of possible misconduct related to human research activities that may come from subjects, study personnel, staff, students, or faculty. If, for instance, a research project is being conducted without IRB approval, or an improper method of recruiting subjects is being used, or undue influence is being placed upon prospective subjects to participate in a study, the IRB has no means of learning about such situations and rectifying them unless it is informed that they are taking place. Thus, in order to fulfill its obligation to protect human subjects in research, the institution depends upon concerned individuals, including investigators, to inform the IRB Chair of any possible misconduct related to research activities of which they become aware.

Such incidents are usually reported by telephone or in writing to the Academic VP and other appropriate administrative officials by the IRB Chair. An inquiry is made to the investigator conducting the research activity, maintaining requested anonymity of the individual submitting the report whenever possible. Depending upon the outcome of the initial inquiry, information about the incident may be forwarded to the Academic VP, or the President for appropriate resolution.

PART 5: THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Federal guidelines establish the conditions under which **Protected Health Information** (PHI) may be used or disclosed by covered entities for research purposes [45 CFR §§ 164.501, 164.508(f), 164.512(i)]. The Privacy Rule outlined in HIPAA defines the means by which individuals/human research subjects are informed of how medical information about them will be used or disclosed, and their rights with regard to gaining access to information about them when such information is held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct vital research.

A researcher is considered to be a covered entity if he or she provides health care services to an individual and transmits that health information in electronically to a health care clearinghouse or a health care provider as defined in the Transparency Rule (see 45 CFR 160.102 and 160.103).

In the course of conducting research, researchers may create, use, and/or disclose individually identifiable health information. Under the Privacy Rule, covered entities are permitted to use and disclose PHI for research with individual authorization, or without individual authorization under limited circumstances.

All research involving health information and/or records of the same should complete a FORM A and attach it to any relevant IRB proposal.

Disclosure With Authorization By The Research Subject

The Privacy Rule permits researchers to use and disclose PHI for research when participants authorize the use or disclosure of information about themselves. Typically, a research participant's authorization will be sought for clinical trials and some research involving records. In these instances, specific elements must be included in the informed consent form.

Informed Consent under HIPAA

Certain language is required to ensure HIPAA compliance with respect to informed consent and PHI. This language is reproduced in the Authorization Template attached in the Appendix. This template must be inserted into the confidentiality section of the informed consent form exactly as written in the Appendix.

A valid authorization for the release of PHI for research also must contain the following required elements in the informed consent form:

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful manner;

2. The name of the covered entity or person(s) authorized to make the requested use or disclosure;

3. The name or other specific identification of the person(s) or entities, which may include the covered entity itself, to whom the covered entity may make the request for use or disclosure;

4. An expiration date and a signature and date;

5. The authorization must be written in plain language;

6. If the authorization is executed by a legal representative authorized to act for the individual, a description of his/her authority to act for the individual must be specified as well as the relationship to the individual;

7. A statement that the individual acknowledges that he/she has the right to revoke the authorization except to the extent that information has already been disclosed under the authorization;

8. A statement that the individual acknowledges that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by the federal privacy law;

9. A description of the purpose(s) of the requested use or disclosure;

10. A statement that the individual may inspect or copy the protected health information to be used or disclosed; and

11. A statement that the individual may refuse to sign the authorization.

Consent forms for actual or potential subjects in a research study must be retained for at least six years from the date permission is granted.

Research Use: Disclosure Without Authorization By The Research Subject

There are four circumstances that allow researchers to use and disclose PHI for research purposes without authorization by research subjects. These are:

1. Waiver of authorization;

2. Review of PHI preparatory to research;

3. Research involving a decedent's information; and

4. Use involving limited data sets.

All of these situations require IRB approval.

Application Process for Disclosure of Protected Health Information without Authorization by Research Subjects

All applications for disclosure of PHI without authorization by research subjects will require a Full Board hearing. At such time the IRB will consider the type of PHI, which is being considered for waiver and whether the investigators have met the criteria for waiver outlined in the following sections. Normal procedures for Full Board hearings will be used in hearing waiver applications (see Section 2.3.3). Investigators should submit applications to ***irb@southern.edu***. Application forms and contact information for the IRB can be found at the IRB webpage.

The IRB full board meets on an ad hoc basis; therefore, investigators should consult the IRB Chair to ensure that they are scheduled for review. Every attempt will be made to schedule a meeting to hear these applications within 3-5 weeks from the time the application is received by the IRB (provided there are no modifications or clarifications needed to the application). The IRB Chair will notify the applicant in writing of all decisions. The IRB approval letter will include the following elements:

1. Identification of the IRB and the date on which the waiver of authorization was approved;

2. A statement that the IRB has determined that the waiver satisfies the pertinent criteria;

3. Provide a brief description of the PHI for which use or access has been determined to be necessary by the IRB; and

4. Note that the request was approved based on a hearing by the Full Board.

Securing a Waiver of Authorization

A waiver of authorization may be sought for three specific research uses of PHI:

1. To identify potential research subjects through review of their PHI;

2. To contact potential subjects in order to determine their interest in research participation; and

3. To receive or collect PHI during the conduct of research studies.

A covered entity is permitted to disclose PHI for research purposes without a written authorization from the research subject if approval is obtained from the IRB. A covered entity also may use or disclose PHI without individuals' authorizations for the creation of a research database, provided they have documentation that an IRB has determined that the specified waiver criteria were satisfied.

Criteria to Determine if a Waiver is Authorized

A waiver of authorization form is attached in the Appendix. The investigator must information about the research study that enables the IRB to determine that three requirements are satisfied:

1. There must be no more than minimal risk to the privacy of individual subjects based on the presence of the following elements:

a) An adequate plan to protect the identifiers from improper use and disclosure;

b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (unless there is a health or research justification for retaining identifiers or such retention is otherwise required by law);

c) An adequate written assurance that the PHI will not be reused or disclosed to any other person or entity (except as required by law or for authorized oversight of the research study, or for other research for which the use or disclosure is permitted without authorization).

2. It must not be practicable to conduct the research without the waiver or alteration of the authorization requirement; and

3. It must not be practicable to conduct the research without access to and use of the PHI.

Documentation Required to Secure a Waiver

1. An investigator may use or disclose PHI for research purposes pursuant to a waiver of authorization by the IRB with documentation of all of the following:

2. The use or disclosure of PHI involves no more than minimal risk to the individuals;

3. The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

4. The research could not practicably be conducted without the alteration or waiver;

5. The research could not practicably be conducted without access to and use of the PHI;

6. The privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

7. There is an adequate plan to protect the identifiers from improper use and disclosure;

8. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

9. There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except as required by law for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this subpart.

Investigators seeking a waiver of authorization for PHI disclosure without consent of subjects must complete a Form G and submit it to the IRB Chair who will schedule a Full Board review.

Reviews Preparatory to Research

Investigators may review PHI without authorization to prepare a research protocol (i.e., limited to designing a study and/or determining the feasibility of completing a study). Neither recruitment nor patient contact is considered preparatory activity. Under this provision of the regulations, the investigator must provide the following assurances to the covered entity:

1. The investigator shall not remove any protected health information from the covered entity;

2. The use/disclosure of PHI is sought solely for the purpose of preparing a research protocol; and

3. The PHI for which use or access is sought is necessary for research purposes.

In addition, reviews preparatory to research must not involve making copies of PHI or making notes that include PHI. However, medical records of interest to investigators in preparing a study may be flagged for future reference.

Investigators seeking to use PHI in preparation for research must complete a FORM A and submit it to the IRB Chair who will schedule a Full Board review. Investigators must certify that they have complied with the provisions outlined above.

Research on Decedent's Information

An investigator is not normally required to secure IRB approval for research involving deceased individuals, unless other living individuals (such as family members) could be affected (i.e., genetic markers of certain diseases). If the research has no impact upon other living individuals, the investigator may use PHI of deceased individuals without authorization from the decedent's estate. If the research has an impact upon other living individuals, IRB review is necessary. Investigators who are not sure about this determination should err on the side of caution and submit an application for IRB approval.

Qualifications under this provision require that the researcher provide the covered entity:

1. Assurance that the use or disclosure is being sought solely for research on the PHI of decedents;

2. Documentation, at the request of the covered entity, of the death of such individuals; and

3. Assurance that the PHI is necessary for research purposes.

Investigators may use PHI in research on decedent's information if the investigator certifies they have met the provisions outlined above. Investigators must submit a form to the IRB Chair who will schedule a Full Board review.

Research Involving the Use of Limited Data Sets

Regulations permit covered entities to use or disclosure PHI for research purposes without subject authorization if the use or disclosure only involves a "limited data set" and the covered entity enters

into a data use agreement with the investigator. A "limited data set" is PHI that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual subjects:

1. Names
2. Postal address information, other than town or city, state and zip code
3. Telephone numbers
4. Fax numbers
5. Email addresses
6. Social security numbers
7. Health plan beneficiary numbers
8. Account numbers
9. Certificate/license numbers
10. Vehicle identifiers and serial numbers
11. Device identifiers and serial numbers
12. Web universal resources locators (URLs)
13. Internet protocol (IP) address numbers
14. Biometric identifiers, including finger and voice prints
15. Full face photographic images and any comparable images

A limited data set may, however include other indirect identifiers, especially dates of birth, treatment, discharge, or death.

Investigators may use a limited data set for research without subject authorization if they have completed a Limited Data Use Agreement with the entity releasing the data. Investigators in this situation should complete a Limited Data Use Agreement to the IRB Chair. (Normally, the entity releasing the data should provide the Limited Data Use Agreement; however, if the entity does not have such a form the investigator should contact the IRB Chair for examples of acceptable forms.).

Use Of De-Identified Data In Clinical Research

Under HIPAA, PHI can be released freely if it does not contain "individually identifiable information" as defined in the section above. PHI is not individually identified if the subject is not identified, directly or indirectly, and if the subject has no reasonable basis to believe that the information can be used to identify them. Research using De-Identified Data is exempt from the requirements. To be exempt, none of the subject identifiers identified in the previous section can be reviewed or recorded by the research team. In order to de-identify PHI, investigators must comply with one of the two following procedures.

Procedures to De-identify Datasets

HIPAA regulations allow researchers to use two procedures to de-identify data sets so that they may conduct research without securing waivers. These procedures are:

Use of a Statistician

Researchers may obtain the services of a person with appropriate experience and knowledge who applies generally acceptable statistical and scientific principles and methods to determine that the information is not individually identifiable; there is a very small risk that the information could be used by itself or in combination with other available information by the anticipated recipient(s) to identify the subject with the information; and who will document the methods and results in making such a determination.

Removal of Identifiers

Investigators may ensure that all identifiers listed above have been removed and certify that they have no actual knowledge that the information remaining could be used alone or in combination with other information to identify the patient who is the subject of the information.
Investigators who choose to "de-identify" PHI data must complete and submit a form to the IRB Chair who will schedule a Full Board review. The IRB shall determine if the PHI has been adequately de-identified in accordance with the privacy laws. If so, the IRB will notify the researcher in writing that the research has been approved as a de-identified health information data set. The investigator may then use the IRB approval notice to access and create the de-identified database.

Investigators' Responsibilities In Maintaining Databases

If an investigator maintains a database containing PHI, then the investigator has an obligation to ensure that the use and disclosure of PHI is in compliance with policies. The investigator is responsible for:

1. Maintaining applicable security for the database, including physical security and access control;

2. Controlling and managing the access, use and disclosure of PHI, including verifying appropriate IRB approvals and patient authorizations; and

3. Ensuring that any PHI in the database used for treatment or payment purposes must be a duplicate and the original must be included in the patient's medical record.

In order to use a research database containing PHI, one must have authorization or a waiver from the IRB. Another pathway to using PHI in a research database is by utilizing a limited data set.

Studies And Databases Initiated Prior To HIPAA Regulations

Databases created prior to April 14, 2003 are grandfathered in and do not have to meet the Privacy Act policies. Studies involving subjects that have enrolled prior to April 14, 2003 will not be required to re-consent. Investigators may continue to collect and use data gathered from these subjects and no new documentation is required.

Research Participants' Right Of Access To Research Records

With few exceptions, the Privacy Rule gives patients the right to inspect and obtain a copy of health information about them that is maintained in a "designated record set." A designated record set is a group of records that a covered entity uses to make decisions about individuals, and includes a health care provider's medical records and billing records, and a health plan's enrollment, payment, claims adjudication, and case or medical management record systems. Research records or results maintained in a designated record set are accessible to research participants unless one of the Privacy Rule's permitted exceptions applies.

One of the permitted exceptions, however, applies to PHI created or obtained by a covered health care provider/researcher for a clinical trial. The Privacy Rule permits the individual's access rights in these cases to be suspended while the clinical trial is in progress, provided the research participant agreed to this denial of access when consenting to participate in the clinical trial. In addition, the health care provider/researcher must inform the research participant that the right to access PHI will be reinstated at the conclusion of the clinical trial.

APPENDIX A- Consent Forms

Institutional Review Board Office
Southern Adventist University
PO Box 370
Collegedale, TN 37315

RESEARCH CONSENT FORM

Oral Consent (to be used in conjunction with short form written consent)

STUDY TITLE:

PRINCIPAL INVESTIGATOR:

IRB TRACKING NUMBER: (Please enter the IRB Tracking Number provided to you once your research is approved – and remove this sentence from the final copy.)

BACKGROUND AND PURPOSE: You are being asked to take part in a research project, which is being organized by _____, a group of Southern Adventist University faculty and/or students. The purpose of this research project is to learn more about _____ _____. This research is contributing to a greater assessment of where, how, and with whom, _____. You are in a position to provide insight to this project, and it would be appreciated if you agree to an interview or you would complete this survey – whichever best fits your request for participation with this research project.

PROCEDURES: The format of the interview will be a discussion or perhaps a group discussion. Expect the interview to take no longer than 1 hour. With your permission, a recording will be made during the interview solely for the purposes of accurately transcribing the conversation. With your permission, photographs could also take photographs. The recordings and photographs, as well as the transcriptions will be stored securely at the_____. The photographs will be used to present our research at various conferences and scholarly presentations.

RISK AND/OR DISCOMFORT: There is some risk involved if, for example, you divulge confidential information. Therefore, if you wish pseudonyms to be used to protect your privacy and confidentiality, we will be happy to do so.

CONFIDENTIALITY: Alternately, if you wish to be quoted by name on anything in particular we are also happy to accommodate this request. Please know though that you do not have to answer any questions or discuss any topics that make you feel uncomfortable.

BENEFITS TO YOU: There are no direct costs involved with participation, although you may miss an hour of work and possibly pay for that time. There are also no direct benefits to you. However, your participation will contribute to a greater awareness of_____. The final report will be presented at various conferences and your participation will help to bring greater attention to _____.

WITHDRAWAL OF PARTICIPATION: Should you decide at any time during the interview or discussion that you no longer wish to participate, you may withdraw your consent without prejudice.

REQUEST FOR MORE INFORMATION: You may ask more questions about the study at any time. Please contact insert your name and contact information here _____. This study has been approved by the Institutional Review Board at Southern Adventist University, so you may contact the IRB Administrator, Cynthia Gettys at cgettys@southern.edu or by calling 423.236.2285.

SIGNATURE: I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as benefits have been explained to the participant. All questions have been answered. The participant has agreed to participate in the study.

_____ _____
Signature of Person Granting Consent Date

_____ _____
Witness Signature Date

_____
Witness Name Printed

SAMPLE ONLINE SURVEY INFORMED CONSENT

(researcher's name) is conducting this survey on behalf of Southern Adventist University to obtain your opinion on various aspects of _____. Your responses to this survey are completely optional, and there are no consequences if you choose not to respond and you may discontinue the survey at any time. (Researcher name) will process all personal data you provide and will use such information for statistical and research purposes only. Southern Adventist University will only be provided with group-level data according to federal policies protecting individual respondent confidentiality.

Having read and understood the statement above, I voluntarily agree to complete this survey. Completion of this survey constitutes my agreement to participate in this research project.

SAMPLE PARENTAL CONSENT LETTER

Dear Parent:

I am a professor [*or a graduate student under the direction of Professor* _____] in the Department/Division/College of _____ at Southern Adventist University. I am conducting a research study to [*explain purpose of study*].

Your child's participation will involve [*Explain procedures and include the expected duration of the child's participation*]. Your participation, as well as that of your child, in this study is voluntary. If you or your child choose not to participate or to withdraw from the study at any time, there will be no penalty, (it will not affect your child's grade, treatment, or care, whichever applies). The results of the research study may be published, but your child's name will not be used. This research has been approved the University Institutional Review Board.

Although there may be no direct benefit to your child, the possible benefit of your child's participation is [*discuss*].

If you have any questions concerning this research study or your child's participation in the study, please call me [*or Dr.* _____] at [*phone number*] or email me at [*address*].

Sincerely,

[*researcher's name*]
[*Address if not using letterhead*]

I give consent for my child _____ to participate in the above study.

Parent's Name (print): _____

Parent's Signature _____ (Date) _____

If you have any questions about your rights as a subject/participant in this research, or if you feel you or your child have been placed at risk, you can contact Cynthia Gettys, Chair of the Institutional Review Board, at 423-236-2285.

SAMPLE ASSENT FORM FOR CHILD

The assent may be a separate permission form or may be added to the bottom of the parental consent form.

Language must be simplified as appropriate for the age group. For example:

I have been told that my parents (mom or dad) have said it's okay (or, have given permission) for me to participate, if I want to, in a project about
_____.

I know that I can stop at any time I want to and it will be okay if I want to stop.

Signature and Date: _____

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact Cynthia Gettys, Chair of the Institutional Review Board, at 423-236-2285.

OR

I have been informed that my parent(s) have given permission for me to participate, if I want to, in a study concerning _____. My participation in this project is voluntary and I have been told that I may stop my participation in this study at any time. If I choose not to participate, [d*escribe – such as it will not affect my grade, treatment, care, select whichever applies*] in any way.

Signature and Date: _____

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact Cynthia Gettys, Chair of the Institutional Review Board, at 423-236-2285.

Informed Consent

(Insert Title of Research here)

[*Date*]

Dear _____ [*Student, Employee, Committee Member, etc.*]:

I am professor [*or a student under the direction of Professor* _____] in the Department/ Division/College of _____ at Southern Adventist University. I am conducting a research study to [*state purpose of study*].

I am requesting your participation, which will involve [*describe the procedures and include the expected duration of the subject's participation*]. Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, there will be no penalty [*or something like it will not affect your grade, treatment/care, or job performance evaluation -- whichever applies*]. The results of the research study may be published, but your name will not be used. [*If an anonymous questionnaire is used, state "The attached questionnaire is anonymous. The results of the study may be published but your name will not be known*].

If you have any questions concerning the research study, please call me [*or faculty advisor if appropriate*] at [*phone number]* or e-mail me at [*address*].

This research has been approved by the SOUTHERN's Institutional Review Board (IRB). If you have any questions concerning the SOUTHERN IRB policies or procedures or your rights as a human subject, please contact Cynthia Gettys, IRB Committee Chair, at (423) 236-2654 or email institutionalreviewboard@southern.edu

Return of the questionnaire will be considered your consent to participate. Thank you.

Sincerely,

[*Researcher's name*]
[*Address if not using letterhead*]

If Consent form was explained by someone other than the above. Please contact him/her with any additional questions.
Name: _____
Phone: _____

Principal Investigator	
E-mail	
Department	
Faculty Supervisor	

Consent and Signature

_____

Signature of Participant Date

_____

Third Party Consent Signature parent(s), guaradian(s) Date

_____

Minors Assent Signature (when appropriate) Date

_____

Individual Present to Obtain Consent Date

SAMPLE - INFORMED CONSENT – **MORE THAN MINIMAL RISK**

Southern Adventist University
Dr. John Doe

I HAVE BEEN INFORMED THAT:

Dr. [*name*], [*position*] has requested my participation in a research study at this institution.

The purpose of the research is to [*Describe the justification for the research. If appropriate, indicate the number of subjects involved and why the subject is included]*.

My participation will involve [*Describe the subject's participation and identify those aspects of participation which are experimental if any. Indicate the expected duration of the subject's participation. If the subjects are students, patients, clients or employees, advise that nonparticipation or withdrawal from the study will not affect grade, treatment, care, employment status, as appropriate.*]

There are foreseeable risks or discomforts to me if I agree to participate in the study. The possible risks are [*discuss*]. Possible discomforts include [*Any foreseeable risks or discomforts are to be explained/described in lay language*]

OR

There are no foreseeable risks or discomforts if I agree to participate in this study.

The possible benefits of my participation in this research study are [*Describe the benefits of participants, or lack of benefits, to the individual subjects as well as to society.*]

OR

Although there may be no direct benefits to me, the possible benefits of my participation in the research are [*describe*].

The results of this research study may be published but my name or identity will not be revealed. The researcher will do the following to maintain confidentiality of my records. Dr. [*name*] will [*Indicate specifically how you will keep the names of subjects confidential, how information will be secured, and who will have access to the confidential information. A statement such as "Confidentiality will be maintained" is not acceptable. Additionally, confidentiality can only be given to subjects if researcher destroys any master/coding lists used in the research. It is a good idea to explain to subjects that their confidentiality will be maintained because you will destroy any master list containing identifying information after you have assigned subject codes*].

In case of injury I expect to receive the following treatment or care which will be provided at my expense: [*If more than minimal risk of foreseeable injury is anticipated, describe the facilities, medical treatment or services which will be made available in the event of injury or illness to a subject. Description may include on and off-campus services.*]

I will be paid for my participation as follows: [*If payment is to be provided to subject, include amount of payment, method of payment, and schedule for payment including whether payment will be made in increments or in one lump sum.*]

OR

I will not be paid for my participation.

Any questions I have concerning the research study or my participation will be answered by [*name of principal investigator, address telephone number, and e-mail address. If the researcher is a student, the name of the faculty advisor also must be included.*]

This research has been reviewed and approved by the SOUTHERN Institutional Review Board. If I have questions about my rights as a subject/participant in this research, or if I feel I have been placed at risk, I can contact the Chair of the Institutional Review Board, Cynthia Gettys, at (423) 236-2654.

The nature, demands, benefits and any risk of the project have been explained to me. I knowingly assume any risks involved. [*If you have previously indicated that "no foreseeable risk or discomfort" is expected, then omit this paragraph.*]

I have read the above informed consent form. I understand that I may withdraw my consent and discontinue participation at any time without penalty or loss of benefits to which I may otherwise be entitled. In signing this consent form, I am not waiving any legal claims, rights or remedies. A copy of this consent form will be given (offered) to me.

Subject's Name: (Print) _____

Signature _____ (Date) _____

Witness (if appropriate): _____

SAMPLE SURVEY INFORMED CONSENT – **SENSITIVE SUBJECT**

Dear Student:

We are conducting a study on attitudes toward relationships and relationship violence. The research is being conducted in conjunction with The University of Portsmouth and Southern Adventist University, and has been approved by the University Institutional Review Board. We would appreciate your participation and are asking you to complete a survey that will be passed out shortly.

While this survey deals with fictional and hypothetical events, sometimes thinking about relationship violence can be disturbing for some people. If the topic makes you uncomfortable, please do not participate. In addition, if you feel that you need to talk to anyone about any issues raised by this survey please contact any of the resources listed at the bottom of this letter.

A survey will be passed out to the entire class in a minute. If you choose to participate, please complete the survey according to the directions provided. Participation is completely voluntary. All responses are anonymous and confidential. Please do not put your name or any other identifying information on the survey. It will be impossible to link any individual to their responses. If you elect to take the survey and become uncomfortable, you are free to stop taking the survey at any time during the process. There is no extra credit or other incentive for participating; therefore, you will not be adversely affected in any way if you choose not to participate.

The person administering the survey will collect all responses in about 15 minutes. Please do not hand in your survey until you are asked for it. If you do not wish to take the survey, please sit quietly at your desk. You may do other work if you wish. When called for, please turn in your survey whether or not you chose to participate. It should take about 15 minutes to administer this survey.

You may get a copy of the finalized results and any reports once the data is analyzed. If you wish this information, please contact me at [contact information for you and your faculty advisor goes here].

Thank you for your time and consideration in this matter.

Sincerely,

Dr. Jane Smith
Dr. Mary Jones

If you have any questions about your rights as a subject/participant in this research, or if you feel you or your child have been placed at risk, you can contact Cynthia Gettys, Chair of Southern's Institutional Review Board at 423-236-2285.

For assistance in dealing with relationship violence you may contact the following sources. In addition, university counseling services at both universities can assist you with a wide variety of issues.

Southern Adventist University
Chattanooga Domestic Violence Hotline: 423-755-2700
National Domestic Violence Hotline: 1-800-799-SAFE

SAMPLE INFORMED CONSENT FORM – LIST **FORMAT**

PROTOCOL TITLE: THE EFFECTS OF CRYOTHERAPY ON ANKLE STRENGTH
SOUTHERN ADVENTIST UNIVERSITY

Please read this consent document carefully before you decide to participate in this study. This research has been approved by the University Institutional Review Board.

Purpose of the research study:

The purpose of this study is to examine the effects of cold therapy on ankle strength.

What you will be asked to do in the study:

Following a brief 5 minute warm-up on a stationary bicycle, you will be asked to volunteer to perform several stretching exercises. You will then be asked to sit on a kinetic testing device with your dominant ankle and lower leg securely fastened to the footplate attachment. You will be given a series of warm-up repetitions to familiarize yourself with the appropriate ankle motion to be tested. Following the warm-up you will be asked to perform 3 tests with your dominant ankle only. A total of 4 ankle motions will be tested at two different test speeds (slow and fast). The speed is controlled by the computer in the kinetic testing device. Following the test you will be asked to place your dominant ankle in a whirlpool tub filled with ice and cold water for 10 minutes. At the conclusion of the procedure you will again be tested for ankle strength using the identical procedure described above. At the conclusion of the test session, you will be asked to perform a series of stretches.

Time required:

1 hour

Risks and Benefits:

You may experience some mild muscle soreness in your calf muscles at a period of 24-48 hours after the test. If you have any cold allergies, you will be excluded from the study. We do not anticipate that you will benefit directly by participating in this experiment.

Compensation:

You will be paid $5.00 to cover parking expenses.

Confidentiality:

Your identity will be kept confidential to the extent provided by law. Your information will be assigned a code number. The list connecting your name to this number will be kept in a locked file in my faculty

supervisor's office. When the study is completed and the data have been analyzed, the list will be destroyed. Your name will not be used in any report.

Voluntary participation:

Your participation in this study is completely voluntary. There is no penalty for not participating.

Right to withdraw from the study:

You have the right to withdraw from the study at anytime without consequence.

Whom to contact if you have questions about the study:

Dr. Jane Doe (address, telephone number, and email). If this is a student project, include contact information for the student researcher and faculty advisor.

Agreement:

I have read the procedure described above. I voluntarily agree to participate in the procedure and I have received a copy of this description.

Participant: _____ Date: _____

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact Cynthia Gettys, Chair of the Institutional Review Board, at 423-236-2285.

SAMPLE LANGUAGE FOR AUDIO/VIDEOTAPING

If audio or videotaping participants, the following information must be included on the Informed Consent Form:

* Purpose of taping and what tapes will be used for
* Where tapes will be stored
* How long tapes will be kept
* When tapes will be destroyed (i.e., Month/Date/Year)

Example of language to be inserted:

I understand that I will be [*tape recorded or videotaped*] by the researcher. These tapes will be kept by the researcher in a locked filing cabinet. I understand that only the researcher will have access to these tapes and that they will destroyed by [*provide date including month and year*].

APPENDIX B – Adverse Events Form

Institutional Review Board Office
PO Box 370
Collegedale, TN 37315
423.236.2285
irb@southern.edu

Adverse Events Form

For Reporting Adverse Consequences to Humans Participating in Research. All forms must be completed, signed, and submitted as single-sided hard copy.

When to Use this Form: The Principal Investigator (PI) should complete and sign this form and submit it with related attachments for any event that falls into either Category A or Category B, below:

Category A – Any *Serious* Adverse Event that Occurs within 48 Hours of Participation in the Research: Science adverse events are those resulting in death, a life-threatening experience, hospitalization or prolongation of existing hospitalization, a persistent or significant disability or capacity, or a congenital anomaly or birth defect. Every serious adverse event must be reported on this form, even if the event does not appear to be associated with the research protocol. If applicable, also file an FDA Adverse Event Report (at http://www.fda.gov/cder/aers/). In addition, the IRB Office 423.236.2285; irb@southern.edu should be notified within 24 hours of discovery of any serious adverse event.

Category B – Any Event for which *All Three* of the Following are True:

(1) Subject or Risks to Subject or Others Adversely Affected: An event or outcome has occurred that has resulted in harm to the subject, has affected the subject detrimentally, has worsened as a result of their participation, or that has resulted in increased risk to the subject or to others, whether or not the risk has actually resulted in harm (for example, misplacing a subject's research would constitute an increased risk event that should be reported).

(2) Unexpected Event: The event or outcome was not described as a risk of participation in the research, or, though described as a risk, the event or outcome has occurred with unexpected severity or frequency.

(3) Possibly, Probably, or Definitely Related Event: The event or outcome was definitely related to participation in the research or it's reasonable to conclude that the event or outcome was related to participation, or it's possible the event or outcome was related but not enough information is available at this time to assess the likelihood of this possibility.

1. PROJECT TITLE:

IRB TRACKING NUMBER:

PRINCIPAL INVESTIGATOR (PI) FOR SOUTHERN:

Last Name:	First Name:	Academic Degree(s):	
School/Department:	Office Address:		Mail Code:
Street Address:	City:	State:	Zip Code:
Phone:	Fax:	E-mail:	

2. **DATE OF EVENT:**

3. **DATE OF ITS DISCOVERY BY RESEARCH PERSONNEL:**

4. **REPORT TYPE:** ☐ Initial ☐ Follow-up on Previously Reported Event

5. **RESEARCH SITE:** Where was the research activity conducted and where did the incident (or consequent events) occur?

6. **RESEARCH PERSONNEL:** Who was present when the incident (or consequent events) was (were) discovered?

7. **EVENT TYPE** ☐ Category A – Serious Adverse Event
☐ Category B – Other Unanticipated Event Adversely Affecting Subject or Others

8. **SUBJECT INFORMATION** Age: ☐ Male ☐ Female Known pre-existing condition(s) if any:

9. **DESCRIBE THIS EVENT (CHECK ALL THAT APPLY).**

☐ Life threatening experience
☐ Required emergency treatment
☐ Required transport to hospital
☐ Required hospitalization
☐ Prolonged current hospitalization
☐ Persistent or significant disability/incapacity
☐ Congenital anomaly/birth defect
☐ New diseases or problem
☐ Death – underlying or progressive disease
☐ Death – research related
☐ Psychological harm or injury occurred
☐ Social harm or injury occurred
☐ Economic harm occurred
☐ Breach of confidentiality occurred
☐ Risk of psychological, social, or economic harm increased
☐ Risk of confidentiality breach increased
☐ Related to this Drug _____
☐ Related to this Device _____
☐ Related to this Biological _____
☐ Other _____

10. **PROVIDE A BRIEF NARRATIVE OF THE EVENT.**

11. DESCRIBE ANY AND ALL STEPS AND ACTIONS TAKEN IN RESPONSE TO THE INCIDENT OR TO RESOLVE THE ISSUE.

12. WHAT WAS SUBJECT'S PARTICIPATION LEVEL AFTER THE EVENT?

☐ Subject stopped research participation
☐ Subject continued research participation
☐ Subject continued participation with follow-up only
☐ Other:
☐ Subject had already completed research
☐ Subject withdrew from further participation
☐ Investigator withdrew subject from further participation

13. PROGNOSIS

14. HAS ANY PREVIOUS RESEARCH BEEN CONDUCTED WITH THIS TYPE OF EVENT OR OUTCOME? ☐ Yes ☐ No

If Yes, describe and reference previous report(s):

15. MARK ONE IN BOTH A AND B TO CATEGORIZE THIS EVEN ACCORDING TO THE RPI'S JUDGMENT:

15A. ☐ Expected ☐ Unexpected **15B.** ☐ Serious ☐ Not serious

16. RELATION TO RESEARCH: In the PI's judgment, was there a relationship between the event and the research?

☐ Definitely – clearly related to the research
☐ Probably – likely related to the research
☐ Possibly – may be related to the research but information not yet available to assess the likelihood of this
☐ Probably Not – doubtfully related to the research
☐ Definitely Not – clearly not related to the research

17. RELATION TO STATE RISKS: In the PI's judgment, are the probability, magnitude, and reversibility of this event consistent with the risk information in the research protocol, IRB application, and informed consent document(s) previously reviewed and approved by the IRB? ☐ Yes ☐ No

If Yes, attach copies of the protocol, application, and consent document(s) with relevant sections highlighted.
☐ Attached ☐ Will Follow

18. REVISIONS NEEDED? In the PI's judgment, should the research protocol, application, or consent form(s) be revised?
☐ Yes ☐ No

If Yes, complete and attach a **FORM B** and all revised materials, as applicable.
☐ Attached ☐ Will Follow

19. NOTIFICATION OF SUBJECTS AND OTHERS: In the PI's judgment, which of the following subject groups, legally authorized representatives, or parents or guardians should be notified? Check all that apply.

☐ New subjects
☐ Subjects that have completed the research
☐ Currently enrolled subjects
☐ None

If any but "None" are marked, complete and attach a **FORM B** and revised consent form(s)

☐ Attached ☐ Will Follow

20. RE-CONSENT/ASSENT: In the PI's judgment, it is necessary to obtain anew the consent or assent of subjects, legally authorized representatives, or parents or guardians who have already given their consent or assent to participation?

☐ Yes ☐ No

If Yes, complete and attach a **FORM B** and revised consent form

☐ Attached ☐ Will Follow

21. AFFECT ON RESEARCH: In the PI's judgment, should the research

☐ **continue as planned** with no changes to the research protocol or consent process?
☐ **continue with changes** to the research protocol or consent process, as previously noted on this form?
☐ **suspend new subject** enrollment until the event is further assessed?
☐ **be terminated** (stopped completely), with all subjects removed from research?

22. REPORTS FILED: To whom has the event been reported? Mark all that apply and attach report(s)

Report Filed With	Date Reported	Report(s)
☐ Research sponsor/coordinated site		☐ Attached ☐ Will Follow
☐ Data monitoring committee		☐ Attached ☐ Will Follow
☐ Food & Drug Administration (FDA)		☐ Attached ☐ Will Follow
☐ Office, Human Research Protections (OHRP)		☐ Attached ☐ Will Follow
☐ Other collaborators		☐ Attached ☐ Will Follow
☐ Other:		☐ Attached ☐ Will Follow

23. INVESTIGATOR ASSURANCE(S): I have reviewed the contents of this form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge.

_____ _____
Responsible Principal Investigator Date Investigator Date

_____ _____
Investigator Date Investigator Date

APPENDIX C – IRB Guidance for Student Research and Course Assignments

IRB Guidance for Student Research and Course Assignments

All research classes, undergraduate and graduate, must apply for IRB approval. Federal regulations and university policies require Institutional Review Board (IRB) approval for research with human subjects. This applies whether the research is conducted by faculty or students, by individuals or a group. *Failure to obtain proper approval in advance may jeopardize your data, prevent you from publishing the results, and place you and the university in violation of federal regulations.* Many class projects are conducted for educational purposes and not as research, and will not require IRB approval. This guidance will help you determine whether you need to get approval from the IRB before conducting a given activity. Please note that IRBs do not have the option of granting "retroactive" approval after research is done; you should err on the side of submitting or consulting with the IRB if there is any doubt. All forms and additional guidance are available by contacting irb@southern.edu or www.southern.edu under Academic Administration, Faculty Information, Forms for Faculty.

Student research activities include, but are not limited to, projects that result in undergraduate honors theses, master's level theses, or doctoral dissertations. *IRB approval is generally required if* ***human subjects are involved****, either directly or through use of identifiable data about them... AND...* ***the intent is to develop new or expanded knowledge****.* Student researchers have the same submission options as any investigator. They may submit as Principal Investigator (PI) with a faculty advisor also listed, which may be appropriate for new projects where the student has a leading role. Alternatively, it may be appropriate for the student researcher to be included on an existing project that already has IRB approval, if the student activity is (or will be, after modification) subsumed under that existing study. This latter option precludes the need for a separate IRB application from the student. Each research scenario has its own set of circumstances that will dictate handling. Below are some common scenarios, with likely processing requirements:

RESEARCH that involves direct interaction with individuals (e.g., in person, or via mail, email, web survey, or telephone), or data from human subjects for which the researchers will have access to identifiers.	→ IRB approval required → Submit IRB application form, either with student as PI or listed as study personnel on faculty application; or modify existing study if student project is directly related. Student researcher, co-investigators (if a group) and faculty advisor are required to have current CITI research ethics certification
RESEARCH that is limited to secondary analysis of data, records or specimens that are either publicly available, de-identified or otherwise impossible to be linked to personal identities.	→Submit form for "Determination Whether Research or Similar Activity Requires IRB Approval." A data use agreement between the researcher and the data custodian may still be required to verify that the researcher will not have access to identifying codes. It is this "de-linking" of data from personal identifiers that allows the IRB to make this determination. If the IRB determines that this project is not human subject research, research ethics certification of the student(s) is not required by IRB, but may be required by the faculty advisor.
RESEARCH-like activities using departmental subject pools (e.g., Psychology, Business, Political Science, Journalism and Mass Communication) even when the activity is conducted for educational purposes as a class requirement.	→ IRB approval required → submit an IRB form for each activity by individual or small group Student researcher, co-investigators (if a group) and faculty advisor should have current CITI research ethics certification.

Class Project scenarios are discussed on the next page...

CLASS PROJECTS

Class projects are generally conducted for educational purposes and not as research. While some require submission of an **IRB application** or a **determination that IRB approval is not required,** many class projects require neither. Instructors and departments are encouraged to contact the relevant IRB for guidance about ways to handle topics such as privacy, confidentiality, informed consent, and professional ethics when class projects are part of the course syllabus. IRB chairs and staff can share expertise related to managing risks of deductive disclosure, coercion-free recruiting, informed consent, and special considerations for projects that include potentially vulnerable individuals. These issues may still remain even when IRB approval is not required, in which case instructors, advisors, departments and schools play an even greater role in providing the appropriate guidance and oversight. Common scenarios:

CLASS PROJECTS involving **secondary data analyses** that are assigned and conducted as educational exercises, using data that are either publicly available data, de-identified or otherwise impossible to be linked to personal identities.	→ **No IRB action required (neither approval nor determination of human research status)**
CLASS PROJECTS involving **secondary data analyses** that are assigned and conducted as educational exercises, and that use datasets that include private information and codes that link to identifiers, but the students do not have access to the identifiers.	→ **No IRB action required (neither approval nor determination of human research status)**
CLASS PROJECTS that involve direct interaction (e.g., in person, via mail, email, web surveys, or telephone), but where the purpose is training, an educational exercise or professional development, and **not** research. The project or practicum is not "research" even if students ask people questions as part of learning how to conduct interviews or surveys, take histories, administer assessments, or perform "in-house" evaluations as requested by the practicum site. **Exception:** If a student decides *after* the completion of a practicum activity to pursue additional activities with the same information for a master's project or paper, then an IRB application describing research use of secondary data should be submitted for approval.	→ **No IRB action required (neither approval nor determination of human research status)** → but may be requested if instructor or students are unsure, or if documentation is required by gatekeepers (e.g., schools, businesses) for access to participants. Class instructor and department are responsible for providing the necessary training in respecting the confidentiality of the data. Instructor provides information about the assignment for the students to distribute to people who participate.
CLASS PROJECTS that **involve direct interaction** or **secondary analyses of private identifiable data** and are undertaken as **both an educational experience and as research** (e.g., results of these activities will be presented publicly or otherwise disseminated, or the data will be stored and used by the students or others as research data). **Submission Tip:** Such projects may be very similar to one another. For example, each student may interview one or more persons for a group of oral histories, or conduct telephone surveys as part of a yearly poll, but all in the class follow the same general script or guidelines. If class projects follow different protocols, a table or chart can describe these more individualized activities, under the umbrella of a single IRB application.	→ **IRB approval required** → When there are several students in a class doing similar projects, a **single IRB application FORM A may be submitted by the course instructor as PI,** listing all students who will be involved. If projects vary greatly, it is preferable to submit individual IRB applications with the student(s) as PI. The PI must have current CITI research ethics certification. Taking into account the sensitivity of the information to be collected, the instructor can require that students complete the CITI online course.

APPENDIX D – IRB Process and Forms

Southern Adventist University Institutional Review Board Process

Begin by identifying which IRB form(s) you need to submit.

IRB Approval is not required for a literature review or academic exercises which will not be published or presented off of the SOUTHERN campus.

FORM A – Exempt

Studies qualifying for an Exempt Review are those with no risk to the participants. These studies usually include research that is conducted in established or commonly accepted educational settings and involves normal education practices, such as the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Other studies that may fall under an Exempt Review are research that involves the use of educational tests, survey procedures, interview procedures, or observation of public behavior, as well as research that involve the collection or study of existing data, documents, records, pathological specimens, or diagnosis specimens. Confidentiality of all personally identifiable information must be managed throughout the research and thereafter. The information collected must be recorded in such a manner that the human subjects cannot be identified directly or indirectly. If any disclosure of information outside the research could reasonably place the subject at risk of criminal liability or civil liability or be damaging to the subject's financial standing, employability or reputation then it no longer qualifies for an Exemption.

FORM A – Expedited (non-exempt)

Studies qualifying for an Expedited are those with minimal risk to the participants. Minimal risk is defined by research that does not exceed the average probability and degree of psychological or physical harm normally encountered in the everyday life of a human being. It also must not exceed the risk or harm experienced during a routine clinical intervention.

FORM A – Full Review

Studies that involve more than minimal risk to the subjects require review of the full IRB committee membership. Please note that the types of research conducted at SOUTHERN rarely require the full Board hearings so investigators are encouraged to contact IRB Chair prior to submitting a Full Review application. In most cases, expedited review is possible.

FORM A – Animal/Plant

University policy and federal law require review and approval for proposed activities related to the humane care and use of animals and plants.

FORM B – Modification, Annual Review, Research Termination, Research Completion

Use this form if you need to make minimal changes, would like to extend your study, have terminated or have completed your study.

FORMS C & D – Student Research and Class Projects

Use these forms to indicate that you as a professor have completed the CITI training and are qualified to approve student research. Please complete both forms within the semester they are applicable. The purpose of these forms is for both the professor and the IRB to track student research from the application and approval phases to the completion phase. All IRB forms should be signed, scanned and emailed to IRB@southern.edu .

All sections of the application must be completed. The application itself will include specific details on what information needs to be included. Please read each section carefully to ensure that you have provided all of the required information.

Researchers – Please list the name of the Principal Investigator and Other Investigators on the project. Contact information for all researchers should be included in the application. If the project is a student research project, the student (s) will be listed as investigator(s) and a Faculty Advisor must be listed. Please note that if this is student research, the application will have to be submitted electronically by the Faculty Sponsor directly to the IRB on behalf of the student or the student can obtain the signature of the Faculty Advisor, scan the form, and then submit themselves to the IRB.

Research Start Date – The anticipated start date entered on the application must be a date in the future (not a calendar date that has already passed by the time the application is submitted).

Research Purpose – The purpose of the research must be adequately explained. Give precise details on why you are conducting the research including information on your hypotheses and/or research questions. Describe the objectives of your research. This should be written so that the reviewers will have a clear understanding of exactly what you plan to do.

Background/Rationale – Clearly define the reason why you are conducting the research and explain your rationale for doing so. You must also include citations/references from previous research that has been done on the same or similar research topic.

Methods – Clearly describe the research methodology that will be used including information on the data collection procedures and how the procedures will allow you to address the hypotheses/research questions for your project.

Sample Population - Describe the sample population and the number of participants that you anticipate recruiting for the study. Describe the recruitment methods that will be used. If the research involves those considered as vulnerable populations, please be sure to check the appropriate box on the application form.

Informed Consent – Full details about the consent process should be included in the application. You will need to disclose the type of consent that will be used. Informed consent can be in an oral or written format, and in rare circumstances a waiver to consent can be requested. A waiver of consent can be requested when the consent itself would be the only identifiable information about the participant. When oral consent will be used, the same elements that would be included in a written consent should be verbally communicated to the subject before he or she agrees to participate. If the research involves children it may require both a parental consent form and an assent form (which the child signs). As a general rule, children age 7 and up can understand the basic information of the study if it is provided to them at their level.

Risks/Benefits- Describe in detail any risks (if any) associated with participation in the research project. Risks can range from physical dangers/side effects to psychological dangers/side effects. Inconvenience, travel, or boredom may also be considered risks of participation. Include information in the application about what precautions will be taken to minimize risks and/or what resources will be available to assist participants should some unforeseen instance occur. Describe the anticipated benefits to the participants or benefits that could contribute to generalizable knowledge.

Privacy/Confidentiality – Research cannot be both anonymous and confidential. Anonymous research is research that does not contain any identifiable information about the participants. Confidential research is research that does include some identifiers but the research data will be maintained in a confidential manner (only the researchers will know the identity of the participants). Within the application please clearly define if the research is anonymous or confidential. If the research is confidential please define how the records will be coded, how the data will be stored, how long the data will be maintained, and what will be done with the data once the information will no longer be maintained. If video or video tapes will be used you will need to include about how these instruments will be secured/stored and how/when they will be disposed of. If video or videotapes are used please add a sentence in the consent form stating that the participant can request that the videoing be stopped at any time.

Questionnaires/Other Instruments

Any questionnaires, tests, survey instruments or data collections sheets which are not standard and well known must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.

Please Review Your Application before Submitting IRB Forms

IRB
Institutional Review Board

FORM A
Not required for a literature review.
RESEARCH APPROVAL

This box is for Southern's – IRB Office Use Only

IRB Tracking #_____
Date Received _____ _____Exempt _____Expedited _____Full Review _____Animal/Plant

1) IRB Board Approver _____ _____ _____
Name Title Date

2) IRB Board Approver _____ _____ _____
Name Title Date

Date Approval Sent_____

Title of Research Project:_____

Research Request: _____Exempt _____Expedited _____Full Review _____Animal/Plant

Starting Date:	Estimated Completion Date:
Principal Investigator:	E-mail Address:
	Phone #:
Co-Investigator:	E-mail Address:
	Phone #
Co-Investigator:	E-mail Address:
	Phone #:
Co-Investigator	E-mail Address:
	Phone #:
Department:	Faculty Supervisor:

Cooperating Institutions: Is this research being done with any institutions, individuals or organizations not affiliated with SOUTHERN? If yes, *please provide the names and contact information of authorized officials below*.	
Name of Institution	**Address:**
Contact Name:	**Phone #:**
Contact E-mail:	
External Funding Agency:	**Identification # (if applicable)**
Grant Submission Deadline (if any)	

Please attach all of the following items, making sure the entire application is completely filled out (where applicable) before submitting the application:

- Any research instruments (tests, surveys, questionnaires, protocols, or any form else used to collect data)
- All informed consent documents
- Permission from applicable authorities (principals of schools, teachers of classrooms, etc.) to conduct your research at their facilities on their School Letterhead.
- Students need signatures from their faculty advisor.

All student applications must be signed by the faculty advisor then scanned and submitted electronically, or submitted directly by the faculty advisor. All applications should be submitted by email to irb@southern.edu

You cannot begin your research until you have been notified IRB has approved your application.

Type of Research, Check all areas that apply

____ Dissertation/Thesis
____ Funded Faculty Research
____ General Faculty Research
____ Applying for ARC Funding
____ Student Research
____ Animal/Plant

Background and Rationale for the Study: This section should present the context of the work by explaining the relation of the proposed research to previous investigations in the field. Include citations for relevant research.

Purpose/Objectives of the Research: Briefly state, in non-technical language, the purpose of the research and the problem to be investigated. When possible, state specific hypotheses to be tested or specific research questions to be answered. For pilot or exploratory studies, discuss the way in which the information obtained will be used in future studies so that the long-term benefits can be assessed.

Methods and/or Procedures: Briefly discuss, in non-technical language, the research methods which directly involve use of human subjects. Discuss how the methods employed will allow the investigator to address his/her hypotheses and/or research question(s).

Description of Research Sample: If human subjects are involved, please check all that apply:

____ Minors (**if minors are involved please attach a Childs Consent Form**)
____ Prison Inmates
____ Mentally Impaired
____ Physically Disabled
____ Institutionalized Residents
____ Anyone unable to make informed decisions about participation
____ Vulnerable or at-risk groups, e.g. poverty, pregnant women, substance abuse population
____ Health Care Data Information - be **sure to attach any necessary HIPAA forms if this line is checked**
____ Animals or plants will be used
____ Other: please describe

Approximate Number of Subjects: _____

Participant Recruitment:
Describe how participant recruitment will be performed. Include how potential participants are introduced to the study (Please check all that apply)

SOUTHERN Directory:	Postings or Flyers	Radio or TV
Email solicitation	How were addresses obtained	
Web-based solicitation? Yes No	Indicate Site	
Participant pool		
Other, please specify		
Attach any recruiting materials you plan to use and the email or web-based solicitations you will use		

Content Sensitivity:
Does your research address culturally or morally sensitive issues? ____Yes ____ No
If yes, please describe.

Privacy and Confidentiality:
Efforts will be made to keep personal information confidential. We cannot guarantee absolute confidentiality. Personal information may be disclosed if required by law. Identities will be help in confidence in reports in which the study may be published and databases in which results may be stored.

Will personal identifiers be collected? ____Yes ____No

Will identifiers be translated to a code? ____Yes ____No

Will recordings be made (audio, video) ____Yes ____No If yes, please describe.

Is Funding being sought to support this research? _____

Circle to indicate if the funding is: Internal or External Funding? Is there a funding risk? _____

Who will keep the financial records? _____

Who will have access to data (survey, questionnaires, recordings, interview records, etc.)? Please list below.

Participant Compensation and Costs

Are participants to be compensated for the study? ____Yes ____No

If yes, what is the amount, type and source of funds: Amount: $_____ Type:_____ Source:_____

Will participants who are students be offered class credit? ____Yes ____No____ NA

Are other inducements planned to recruit participants? ____Yes ____No If yes, please describe

Are there any costs to participants? ____Yes ____No If yes, please explain

Animals/Plants

Are the animals/plants being studied on the endangered list? _____

Are Scientific Collection Permits required, i.e. Tennessee Wildlife Resources Agency? _____

Have the animal(s) utilized in this study already been used in a previous study (non-naïve animals)? _____

Will the animal(s) used in this study be used in a future study? _____

Where will the animals be housed? _____

Will the rodents (if applicable) be housed in wire bottom cages? _____

Will plants be used for instructional purposes as part of teaching a course? _____

Are there any risks involved with this study? _____Yes _____No

Are there any potential damage or adverse consequences to researcher, participants, or environment? These might include physical, psychological, social, or spiritual risks whether as part of the protocol or a remote possibility. Please indicate all that apply.

____ **Physical Risk:** May include pain injury, and impairment of a sense such as touch or sight. These risks may be brief or extended, temporary or permanent, occur during participation in the research or arise after.

____ **Psychological Risk:** Can include anxiety, sadness, regret and emotional distress, among others. Psychological risks exist in many different types of research in addition to behavioral studies.

____ **Social Risk:** Can exist whenever there is the possibility that participating in research or the revelation of data collected by investigators in the course of the research, if disclosed to individuals or entities outside of the research, could negatively impact others' perceptions of the participant. Social risks can range from jeopardizing the individual's reputation and social standing, to placing the individual at-risk of political or social reprisals.

____ **Legal Risk:** Include the exposure of activities of a research subject "that could reasonable place the subjects at risk of criminal or civil liability".

____ **Economic Risk:** May exist if knowledge of one's participation in research, for example, could make it difficult for a research participant to retain a job or find a job, or if insurance premiums increase or loss of insurance is a result of the disclosure of research data.

____ **Spiritual Risk:** May exist if knowledge of one's spiritual beliefs or lack of, could be exposed which in turn could invoke an economic, social and or psychological risk.

Risks: In your opinion, do benefits outweigh risks? ____ Yes ____ No

Results:
The results will be disseminated as:

_____Classwork only _____Student conference _____ Professional conference

_____Published article _____Other If other, please specify: _____

Signatures: If submitted by a faculty member, electronic (typed) signatures are acceptable. If submitted by a student, please print out completed form, obtain the faculty advisor's signature, scan completed form, and submit it via e-mail. Only Word documents or PDF files are acceptable submissions.

_____ _____

Principal Investigator (PI) or Student **Date**

_____ _____

Faculty Advisor (for student applications) **Date**

All student applications must be signed by the faculty advisor then scanned and submitted electronically, or submitted directly by the faculty advisor. All applications should be submitted by email to: irb@southern.edu

Additional Special Requirements or Attachments to the Application:

Approvals from other IRBs – attach a copy
Cooperative research projects involve research that involves more than one institution. In these instances, federal law holds each institution responsible for safeguarding the rights and welfare of human subjects and for complying with federal policy; therefore, SOUTHERN IRB applications must be made even if there is another institution conducting a review of the same research project. When a study is being carried out at a non-USA site, and approval from other institutional review boards at the foreign site must be sought. The IRB requests that a copy of each IRB approval from other institutions be submitted.

Surveys or Instruments – attach a copy
Any questionnaires, tests, survey instruments or data collections sheets which are not standard and well known must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.

Advertisements/Notices/Recruitment Flyers – attach a copy
The text of any advertisement, video display, notice, sign, brochure or flyer used to recruit subjects should be included as an attachment.

Informed Consent for Participants – attach a copy
Please attach the consent form prepared to use with research participants.

IRB
Institutional Review Board

FORM B

This box is for Southern's – IRB Office Use Only

IRB Tracking #_____ _____Modification _____Annual Review _____Research Termination _____ Research Completion

Date Received _____ _____Exempt _____Expedited _____Full Review _____Animal/Plant

1) IRB Board Approver _____ _____ _____
Name Title Date

2) IRB Board Approver _____ _____ _____
Name Title Date

Date Approval Sent_____

Request For
_____Modification _____ Annual Review _____Research Termination _____Research Completion

Please complete the information below for our tracking purposes.

Title of Research Project:
_____

IRB TRACKING # _____

Principal Investigator:
E-mail:
Phone #:

Faculty Advisor (if applicable):
E-mail:
Phone #:

Provide the required information in the space available. If additional space is needed, attach a separate sheet or expand that section of the form. Both scanned original signatures and typed electronic signatures are acceptable.
Incomplete submissions will be returned to the applicant with review. All forms and research instruments should be submitted by email to irb@southern.edu.

Project Status: Please select the status of the project below:

_____ Active – Project ongoing.
_____ No changes are planned and the project will continue as previously approved by the IRB.
_____ Changes are planned. Please complete the section on page 2.
_____ Project completed!

Notification of Changes: Please check the appropriate boxes below and provide additional information where appropriate (e.g. new title, new PI, description of changes, etc.) If no changes are planned or project is completed, please leave blank.

_____ Change to the project title, if different from your last approval letter, ***please provide new title:*** _____

_____ Change(s) of principal or co-principal investigators(s), other collaborators, or change in faculty advisor(s). ***Insert name changes here***:_____
_____

_____ Changes(s) to project which will affect participation of human subjects. Revise and Amend any relevant sections of Form A and submit these changes with a Form B. ***This requires a new Form A as well as this Form B***. Remember, there is no change too small to report to IRB.

_____ Change(s) to informed consent forms and/or assent forms(s). ***Submit new consent Forms with a Form B.***

_____ Additional locations for conducting project. Submit with this Form B a copy of the letter(s) from these organizations which have given permission for you to conduct your research in their institution. The letters should be on the institution's own letterhead. ***List the new locations where research is being completed here:***
_____

_____ Unexpected risks to subjects. If you have encountered unexpected risks to research Subjects (e.g., breaches of confidentiality) or to yourself (e.g., angry parents, threats of violence). ***Submit a copy of the Incident Report Form(s) with a Form B and describe how you have or will resolve the problem***:_____
_____

_____ Other changes: ***Please explain these changes here:*** _____
_____
_____

Signatures: If submitted by a faculty member, electronic (typed) signatures are acceptable. If submitted by a student, please print out completed form, obtain the faculty advisor's signature, scan completed form, and submit it via e-mail. Only Word documents or PDF files are acceptable submissions.

_____ _____
Principal Investigator or Student Date

_____ _____
Faculty Advisor (if applicable) Date

IRB
Institutional Review Board

FORM C
CERTIFICATION for STUDENT CLASS PROJECTS

For Southern's IRB Use Only:

Tracking Number _____

Date Submitted _____

Date Approved _____

Title of Class: _____

Instructor _____

Semester _____

Instructor's Assurance: By submitting this application, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I will ensure that all student projects adhere to these principles. I also certify that all students submitted a completed FORM A application for review and that all human subjects' protections were met. I also certify that I will maintain these forms for no less than three years and I understand that the Chair of the IRB may periodically audit my records. I also certify I have completed CITI training and have granted academic credit for these students to complete CITI training.

All forms should be submitted by email to irb@southern.edu.

Class Name/Number/Semester: _____

_____ _____

Instructor Signature: **Date**

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, submit Form A to the IRB		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, submit Form A to the IRB		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

Student Name(s)			
Title of Project			
Informed Consent Attached	Yes _____	Confidentiality Assured	Yes ____
Study is Minimal Risk	Yes _____ If no, contact IRB Chair for other application		
Permission was obtained from other sites to conduct research (if applicable) Yes ____			
Students will complete any CITI trainings related to their studies Yes ____			

IRB
Institutional Review Board

FORM D
CERTIFICATION OF COMPLETION OF STUDENT CLASS PROJECTS

For Southern's IRB Use Only:

Tracking Number _____

Date Submitted _____

Title of Class: _____

Instructor _____

Semester _____

Date Approved _____

Instructor's Assurance: By submitting this protocol, I attest that I am aware of the applicable principles, policies, regulations, and laws governing the protection of human subjects in research and that I have ensured that all student projects adhered to these principles. I also certify that I will maintain these forms for no less than three years and I understand that the Chair of the IRB may periodically audit my records.
All forms should be submitted by email to irb@southern.edu.

Class Name/Number/Semester: _____

_____ _____
Instructor Signature: **Date**

Student Name(s)	
Title of Project	
Date of Completion	

Student Name(s)	
Title of Project	
Date of Completion	

Student Name(s)	
Title of Project	
Date of Completion	

Student Name(s)	
Title of Project	
Date of Completion	

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Student Name(s)	
Title of Project	
Date of Completion	

Student Name(s)	
Title of Project	
Date of Completion	