SIMPSON
UNIVERSITY

Simpson University Institutional Review Board

TABLE OF CONTENTS

The policies and procedures described below were established to guide the conduct of research involving human subjects, to protect the rights, well being, and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of Simpson University.

CHAPTER 1: INTRODUCTION

I. PURPOSE

Simpson University has established an Institutional Review Board (IRB) to review and approve research on The IRB at Simpson University aims to insure the protection of the rights of all human participants in research: 1) carried out by Simpson University faculty, staff, or students; or 2) involving Simpson University institutional data, facilities, faculty, staff, or students in any capacity.

II. RESPONSIBILITIES

Review: The IRB reviews all research involving human subjects.

Policies/Procedures: Policies and procedures for review of research involving human subjects are developed in consultation with the Federal guidelines.

Education: The IRB provides information regarding IRB policies, procedures, and regulations.

Records and Files: The IRB maintains a record of review proceedings and decisions, in accordance with Federal guidelines, for at least three years following termination of the research projects.

III. BOARD MEMBERSHIP AND STRUCTURE

The IRB will consist of a board Chair and a minimum of four members with varying backgrounds and expertise to promote complete and adequate review of research activities commonly conducted by the institution. The following federal regulations for IRBs will be met:

1. At least three board members shall be faculty. Committee members will be nominated by the Nominating Committee at Simpson University and approved by the faculty.
2. One member shall not be affiliated with Simpson University and shall not be part of the immediate family of someone who is affiliated with the University.
3. Members shall include at least one person whose primary concerns are in scientific areas and at least one person whose primary concerns are in nonscientific areas.

4. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants.

5. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

CHAPTER 2: DEFINITIONS

I. DEFINITION OF RESEARCH

Research means 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 or not 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.

If the primary purpose of an activity is for instructional purposes, then it is not considered research and an application for research does not need to be submitted for IRB approval. However, if the data (e.g., tests, papers, portfolios, etc.) are to be publicly broadcast or shared beyond the scope of the classroom (e.g., conference presentations, publications, etc.) then the use of data is considered to be for the purposes of research and an application for research must be submitted to the IRB and approved prior to any data collection.

II. DEFINITION OF HUMAN SUBJECT

A human subject is 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.

a) Intervention: includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

b) Private information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

III. INFORMED CONSENT

The researcher conducting a project that might place any individual at risk is obligated to obtain and document legally effective informed consent. Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The following types of consent can be used for research studies.

1. WRITTEN INFORMED CONSENT.

Written informed consent is required for all research studies not given waivers for consent or permission for verbal consent by the IRB [45. CFR 46.117a]. In the consent form, information about the study is to be conveyed in a manner that is clearly understandable to the potential study participant. After the potential participant (or in the case of minors or incompetent subjects, a parent, guardian, or other interested agent of the subject) clearly understands all aspects of the information and has had any questions answered to the mutual satisfaction of all concerned, the participant or his or her legally authorized representative must sign the consent form before the research may proceed. Each signatory shall receive a signed copy. Investigators must also retain signed copies.

Written consent may be obtained by using: 1) a full consent form approved by the IRB that includes all required elements for informed consent (see the Informed Consent Template); or 2) a short version of the consent form, after a summary statement of the full consent information has been presented to the potential participant.

If a short version of the consent form is used, the IRB must approve both the consent form and the summary statement, and there must be a witness to the oral presentation. The informed participant (or authorized representative) and the witness sign the short consent form. The summary statement is signed by: a) the person doing the presentation of the summary statement, and b) the witness. Copies of the signed consent form and the summary statement are given to the participant and/or his/her representative [45 CFR 16.117 b(2)].

2. SPOKEN INFORMED CONSENT (VERBAL CONSENT)

Verbal consent is acceptable for research when: a) the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; or b) the only record linking the participant and the research is the consent form, and the principal risk in the study is the potential harm resulting from a breach of confidentiality [45 CFR 46.117c].

In cases of verbal consent, the investigator must provide potential participants with a written statement, (e.g., invitational letter), describing the research. In this statement, all of the applicable informational elements listed in the Informed Consent Template below must be transmitted clearly to the subject. The date that the information was given, and the potential research participants' verbal refusal or consent, must be documented by the investigator.

3. CHILD ASSENT WITH PARENTAL/GUARDIAN CONSENT

Assent is typically required of minors who are recruited for research studies [45 CFR 46.408]. The assent procedure should be appropriate to the age of the child. For example, children over the age of 12 typically could be asked to read, discuss, and sign an adult consent form. If the form is to be used by both adolescent and adult participants, it can be titled "assent/consent form. Children aged 7-12 can be given verbal information about a study and asked to sign a simplified version of a consent form. Younger children should be given a verbal explanation of the study aims and procedures and asked if they are willing to participate; if verbally agreeing, a parent/guardian can give written consent.

In general, a parent or guardian is required to sign a consent form for a minor to participate in research. The IRB can waive the child assent procedure in certain circumstances, as authorized in [45 CFR 46.117(c)] and [45 CFR 46.408 a,b]. Investigators submitting IRB applications for studies involving children are advised to carefully review the DHHS Federal Code, Subpart D: Additional Protections for Children Involved as Subject in Research [45 CFR 46.401-46.409].

4. WAIVER OF INFORMED CONSENT

The federal regulations allow the IRB to modify or waive the requirement for informed consent in the following two situations:

a) a 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: 1) public benefit or service program, 2) procedures for obtaining benefits or services under these programs, 3) possible changes in or alternative to those programs or procedures, or 4) possible changes in methods or levels of payment for benefits or services under those programs, and the research could not practicably be carried out without the waiver or alteration; b) a research study that: 1) involves no more than minimal risk, 2) cannot practicably be carried out without a waiver, 3) where the waiver will not adversely affect the rights and welfare of participants, and 4) whenever appropriate, the subjects will be provided with additional pertinent information after participation [45 CFR 46.116d].

A waiver of informed consent does not absolve investigators of their responsibility to inform the study participants of the nature and benefits of the project, when this is possible. For example, in the case of a mailed survey questionnaire, information that would normally be included in a consent form is included in a cover letter. In other cases, it may be possible to give the study participants additional pertinent information about the study after participation.

CHAPTER 3. GENERAL GUIDELINES FOR RESEARCH INVOLVING HUMAN SUBJECTS

THE FOLLOWING GENERAL PRINCIPLES APPLY EQUALLY TO ALL RESEARCH INVOLVING HUMAN BEINGS, WHETHER CARRIED OUT SOLELY WITH UNIVERSITY RESOURCES OR WITH THE ASSISTANCE OF OUTSIDE FUNDS. THE UNIVERSITY ASSUMES RESPONSIBILITY FOR COMMUNICATING AND EXPLAINING THESE PRINCIPLES TO FACULTY AND FOR PROVIDING PROCEDURAL GUIDELINES.

1. Simpson University faculty, staff, and students recognize their responsibility for protecting the rights and welfare of human subjects.
2. Appropriate professional attention and facilities shall be provided to ensure the safety and well being of human subjects. No subject in a research activity shall be exposed to unreasonable risk to health or well being.
3. Research involving children (i.e., persons under 18 years of age), other legal incompetents, and persons unable to give informed consent will be approved only with the permission of a parent or legal guardian or attorney in fact. Research involving a child, another legal incompetent, or a person unable to give informed consent will not be approved if there is a significant risk of suffering without the possibility of benefit to the individual subject.
4. The confidentiality of information received from subjects in experiments or from respondents to questionnaires shall be protected, both during and after the conduct of a research activity, within the limits of the law.
5. Before a potential subject participates in research involving risk or substantial stress or discomfort, these considerations shall be carefully explained to the subject; the investigator shall be satisfied that the explanation has been understood by the subject; and the written consent of the subject, such consent containing the substance of the explanation, shall be obtained and kept as a matter of record.
6. A request by any subject for withdrawal from a research activity shall be honored promptly without penalty or without loss of benefits to which the subject is otherwise entitled.
7. The investigator shall make appropriate arrangements to make available the results of the study to the subjects, when completed. Researchers making a decision to select for study one population group over another shall, in the proposal, provide clear rationale for selecting one such group over another. In requiring rationale for such a selection, the University seeks to conform to the guidelines set forth by the NIH in the Office of Human Research Protection (OHRP) IRB Guidebook which can be accessed at **www.hhs.gov/ohrp/irb/irb_guidebook.htm.**

CHAPTER 4: RESEARCH RISKS AND LEVELS OF IRB REVIEW

I. DETERMINING THE LEVEL OF RISK

The DHHS Code of Federal Regulations [45 CFR 46.101] defines three major categories of research for purposes of IRB review and approval: 1) exempt, 2) expedited, and 3) full board review. A description of research activities that fall within each of the three categories, and the required IRB review procedures are described in Appendix A. The investigator should review the review categories in Appendix A and include the checklist for the appropriate review category with the research application and supporting documents. The IRB tracks all research conducted at Simpson University, regardless of the review classification. In all cases, the research investigator is required to prepare a research proposal before the research is begun in order to receive approval from the IRB (see Chapter 5 for application procedures).

II. CONTINUING REVIEW OF PREVIOUSLY APPROVED STUDIES

In its initial review of a proposal, the IRB will consider the extent of continuing review needed. Federal regulations require review to occur on or before the 12-month anniversary date of the previous IRB review. All proposals shall be reviewed at least annually, but in certain research the subjects are exposed to more than usual risk; such projects will be reviewed at more frequent intervals. This review interval will be determined at the time the research is approved and may be changed at the discretion of the IRB. Principal investigators with approved protocols will be sent a reminder letter to complete the annual status report and return it to the IRB Chair or appointed member by the date indicated on the letter. The annual status report is the mechanism by which a proposal is reviewed and approved for another period of time.

The annual report submitted by the principal investigator must be processed in sufficient time for review and approval to occur before the expiration date established by the IRB (which is a maximum of 12 months from the original approval date). In each such review, the principal researcher will be required to promptly report the status of the research activity and any proposed changes in the research activity.

If the research is still in progress, the investigator will affirm that the approved research protocol involving human subjects if being followed. It is important that these reports are completed and returned in a timely manner – failure to do so will result in a suspension of IRB approval for the project. A suspension of IRB approval mandates that any work involving human subjects must be terminated until approval has been secured again and requires submitting a new application to the IRB.

CHAPTER 5: APPLICATION AND REVIEW PROCEDURES

THE INDIVIDUAL INITIATING A PROGRAM INVOLVING HUMAN PARTICIPANTS IS RESPONSIBLE FOR ENSURING APPROPRIATE COMMITTEE REVIEW BEFORE SUBMITTING A PROPOSAL OR UNDERTAKING ANY PROGRAM ACTIVITIES. THE REVIEW PROCESS AND TIME WILL VARY WITH THE CATEGORY OF RESEARCH (EXEMPT, EXPEDITED, FULL REVIEW).THE PRINCIPAL INVESTIGATOR(S) IS/ARE RESPONSIBLE FOR PREPARATION OF THE APPLICATION FOR REVIEW OF HUMAN SUBJECTS RESEARCH. THIS APPLICATION SHOULD BE PREPARED FOR ALL CATEGORIES OF RESEARCH. A COPY OF THE CONSENT FORM, SCRIPTS, OR STUDY MATERIALS MUST BE ATTACHED.

Submit the following application documents to the IRB Chair for review:

1) One electronic copy of the application via email to the IRB Chair.

2) One hard copy of the application with any documented protocol (such as the questionnaires or assessment instruments that you propose to use).

I. BASIC APPROVAL REQUIREMENTS

In accordance with the Code of Federal Regulations [45 CFR 46.109] the IRB has the authority, to approve, require modifications in (to secure approval), or disapprove all research activities. In order to approve research the IRB shall determine that all of the following requirements are satisfied [45 CFR 46.111]:

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB will take into account the purpose of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

II. REVIEW PROCEDURES

1. EXEMPT REVIEW PROCEDURES.

Investigators seeking "exempt" status for research should prepare a research proposal, using the standard application form. The proposal should clearly explain why the research is believed to be low risk and should qualify for exempt status. A copy of the consent form, scripts, or study materials must be attached.

The application for research and supporting documents should be submitted to the IRB Chair or appointed IRB member. The IRB member will review the material and determine that the research proposal meets the requirements for exempt status, or designate the proposal for expedited review or full board review. He/she will retain the proposal for record keeping purposes and notify the investigator of the outcome of the review. If the study has been approved with exempt status, a "Certification for Exemption" will be sent to the investigator. The research may proceed when the investigator receives the exempt certification. If the IRB member does not approve the exempt status for the research, the investigator will be advised of procedures to obtain the required review.

Research studies approved for exempt status are not routinely monitored by the IRB while the study is in progress. However, the investigator (or supervising faculty member in the case of student research) is responsible for informing the IRB of the completion date of the approved research study.

2. EXPEDITED REVIEW

From the viewpoint of the investigator, the procedures for expedited review are the same as those for full board review. A standard IRB application form should be completed and submitted with the necessary supporting documents. The application shall contain a complete description of the proposed research or study, including provisions for the adequate protection of the rights and welfare of prospective human research participants and assurance that the pertinent laws and regulations are observed. Samples of study materials, communications with prospective participants and any informed consent forms must be included.

The proposal is read by the IRB Chair or appointed IRB member who takes one of two actions: (i) referral of the proposal to the full board for review, or (ii) approval of the proposal with or without adding stipulations and/or recommendations.

In the case of stipulations, the approval is conditional, and the investigator must respond to the stipulations in a communication with the IRB member.

a) Upon receipt of a satisfactory response to the stipulation(s), the IRB member may then grant final approval. In this case, the primary investigator will be notified and provided with a signed copy of the first page of the application to indicate IRB approval.
b) In the case of recommendations, the IRB will provide written documentation of the recommendations as well as a signed copy of the first page of the application to indicate IRB approval. The investigator(s) may then proceed without further communication from the IRB.
c) If the board member judges the proposal to require full board review, the proposal shall be relayed to the full board and the investigator notified in writing to that effect.

3. FULL REVIEW PROCEDURES

A standard IRB application form should be completed and submitted with the necessary supporting documents. The application shall contain a complete description of the proposed research or study, including provisions for the adequate protection of the rights and welfare of prospective human research participants and assurance that the pertinent laws and regulations are observed. Samples of study materials, communications with prospective participants and any informed consent forms must be included.

When the application is received, it will first be screened for completeness. If information is missing from the application, the investigator will be contacted and requested to supply the missing information. Applications are assigned to one of the monthly Board meetings for review on a "first come, first served" basis. (See the IRB website for the Full Review Application Deadlines and review dates.) A week or more before the scheduled meeting, applications are posted on the confidential IRB website for review by board members. Applications are then further discussed and voted upon during scheduled meeting dates (see schedule posted on the IRB website). The IRB encourages Principal Investigators to be present at the IRB meetings in which their applications are being reviewed in order to answer clarification questions.

4. CONTINUATION OF PREVIOUSLY APPROVED STUDIES

The IRB will send a notice to the investigator two months before the end of a given approval period. An investigator who does not receive such a reminder should contact the IRB as soon as possible to request a copy of the Status Report. If the research is proceeding as outlined in the research protocol, the investigator is to note this on the Status Report Form. If there are any increased risks to participants, deceptive practices in the research, or if any other changes have occurred (or are expected to occur) that could affect the rights and choices of participants, the investigator shall not wait until the annual status report but shall promptly submit updated information to that effect to the board for its review.

III. IRB DECISIONS

Upon review, the Board shall make one of three determinations:

1. APPROVAL.

The IRB will notify the primary investigator and provide him/her with a signed copy of the first page of the application to indicate IRB approval. Upon receiving approval, the investigator(s) may begin the research project.

2. APPROVAL ONLY IF SPECIFIED MODIFICATIONS ARE MADE.

The IRB will explain in writing why the proposal, as submitted, is considered unacceptable. The investigator(s) will then have the opportunity to address those points of concern with the Chair of the IRB or appointed IRB member. Once the requirements are fully met the Chair or appointed member will approve the research (see Approval above).

The investigator may not take any definitive action such as recruiting participants, expending funds, or submitting a grant proposal to any outside agency that requires IRB certification until a proposal is given final and full approval by the IRB.

3. DISAPPROVAL.

If neither of the two previous options received a simple majority vote, the proposal will be considered "disapproved" by the IRB. If a proposal is not approved, the IRB will explain, in writing, the rationale for the disapproval and notice of the appeal options under this policy. Without approval the investigator shall not use any University facilities or funds for the research, nor in any way claim University sponsorship. The University will not incur any obligation to protect an investigator who proceeds with the research nevertheless.

IV. APPROVAL TIME FRAME

Research activities are approved for no longer than a period of one year and may be approved for a shorter period of time commensurate with the level of risk posed by the research and the projected project duration [45 CFR 46.109]. The approval letter sent to the investigator will specify the time period that research activities may be conducted. No research data may be collected outside of the designated time period. Research projects that cannot be completed in the approved time period will need a continuation approval (see Chapter 8).

When reviewing the initial proposal, the following criteria will be used by the IRB to determine the frequency of study review: 1) the probability or magnitude of anticipated risks to participants, 2) any medical conditions of the proposed participants and their susceptibility to problems as a result of enrollment in the protocol, 3) qualifications of the investigator and other members of the research team, 4) past history of the investigator(s) and research team in adherence to IRB guidelines, 5) specific experience of the investigator(s) in similar research protocols, 6) the nature and frequency of adverse events in similar research, 7) the general vulnerability of the population being studied, and 8) other factors deemed relevant to the IRB.

V. APPEAL PROCEDURE

If an investigator believes that the IRB review process was not fairly executed and that it resulted in an unduly restrictive decision regarding the proposed research, he/she may appeal the decision. He/she should first discuss the matter with the IRB Chair, taking care to explain the reasons for believing that the research procedures are in compliance with IRB policy and federal and state regulations. If the issue cannot be resolved satisfactorily by negotiation, the investigator may submit a written appeal regarding the decision of the IRB, in writing, to the IRB.

Upon receipt of an appeal, the IRB shall convene an ad hoc committee, constituted so as to fulfill federal requirements. A member of the current IRB may be added to the ad hoc committee to provide technical knowledge or other appropriate information. The ad hoc committee shall review the proposal, relevant minutes of the IRB, and request any expertise necessary for their deliberations. The researcher may request an appearance before the ad hoc committee. The ad hoc committee will consider the appeal, and within 60 days, communicate its decision in writing to the Provost, giving its reasoning for the decision. A copy of the decision will be given to the investigator and the IRB Chair. The decision made by the ad hoc committee is final.

Any person who proceeds with collecting or analyzing research data, intentionally disregarding the need for official approval of the IRB for the research, will be in violation of IRB policy and will be subject to administrative sanctions, including the termination of research privileges at the University.

CHAPTER 6: CONTENT OF RESEARCH PROPOSAL

Researchers should answer the relevant questions on the application form. Proposals submitted for review shall include the following:

a) Purpose and background. A rationale explaining the purpose and background of the study must be included. This section should state the relation of the proposed research to previous scientific investigations in the field including relevant laboratory and animal studies. Adequate lay language explanations should be provided.
b) Methods. Provide a description of the research methods, with particular emphasis on procedures that pose a risk to participants, involve deception, or do not maintain the participant's anonymity to all parties beyond investigative personnel. Describe the amount of time involved and the location. Devices or activities that are not customarily encountered by the subjects in their daily living or unusual applications of such devices or activities must be described in detail. Describe questionnaires, surveys, and interviews. If the measures included in the study are not standard in the discipline then a copy of the measure must be provided.
c) Participants. Describe the potential participant pool and the means of recruitment. Justification must be provided for the use of subjects that are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

d) Potential risks and benefits. A discussion of the risks, if any, to the subject is required. Such deleterious effects may be physical, psychological, or social. Explain what steps will be taken to minimize risks of harm and to protect subjects' rights and welfare. Also describe the anticipated benefits of this research for individual subjects in each subject group and the anticipated benefits of this research for society. Explain how the benefits outweigh the risks.

e) Compensation. If subjects are to be compensated, the nature of the compensation and its influence on subject participation must be discussed. Experimental subjects may be reasonably reimbursed for their participation in an experiment. Compensation to subjects should never constitute an undue inducement or coercion. (Note: if subjects are to receive "extra credit" in a particular University course, a memorandum from the course instructor must accompany the protocol. This memorandum must clearly state the alternatives students have for earning "extra credit" if they choose to not participate in the research.)

f) Personnel. Identify all personnel who will participate in or assist in the conduct of this research. Identify each individual by name, title and responsibility in this research project.

g) Documentation of informed consent. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 45 CFR 46.116. Note: Conceptually, some sort of consent of participants is always necessary for research. See Chapter 2, Section III for a listing of the types of allowable consent procedures.

CHAPTER 7: MODIFICATION TO AN APPROVED PROTOCOL

It is recognized that changes to a research study and informed consent documents may be required as the research proceeds. However, proposed modifications must be approved by the IRB before they are implemented. The only exception to this requirement is a procedural change that may be necessary to eliminate an apparent immediate hazard to a research participant. If this occurs, the investigator must submit an amendment to the original proposal to make it consistent with the changes. If a research study is completed prior to the end of the approval period, the investigator should submit a Status Report Form to the IRB, noting the date of study closure.

Modification to a currently approved protocol requires the following:

a) A copy of the new (modified) consent form.

b) A copy of the previously approved protocol.

c) A description of the modifications to the current protocol which are desired. For these, the description and justification should proceed much as outlined for a new application; that is, the background or reason for modification, benefits, risks, etc. When positions are assumed by new personnel in the execution of the protocol (such as a change of the principal investigator), a description of the background of the individual with regard to the work described in the protocol should be given.

CHAPTER 8: CONTINUATION OF PREVIOUSLY APPROVED PROTOCOL

The IRB shall be informed annually of the status of all research. As a courtesy to investigators, the IRB will send a notice and Status Report Form to the investigator two months before the end of a given approval period. An investigator who does not receive such a reminder should contact the IRB Chair as soon as possible. If the research is proceeding in relation to participants as outlined in the research protocol, the investigator is to note this on the Status Report Form. If there are any significantly increased risks to participants, deceptive practices in the research, or if any other changes have occurred (or are expected to occur) that could affect the rights and choices of participants, the investigator shall not wait until the annual status report but shall promptly submit updated information to the IRB using a Modification Form.

CHAPTER 9: UNEXPECTED AND ADVERSE EVENTS

During the course of a research study, unexpected events and adverse reactions may occur to a study participant, other individuals associated with the participant, or to key personnel associated with the research study. An unexpected event is an undesirable and unanticipated problem associated with any aspect of the research study that may involve risks to the enrolled study participants, and/or to other individuals who may or may not be directly associated with the research study. This type of event can happen in both clinical and non-clinical (behavioral or social science) studies. An adverse event is an undesirable and unintended, though not necessarily unanticipated, result of therapy, study interventions or activities. These generally occur in clinical research and only apply to participants enrolled in the study. Investigators are responsible for ongoing monitoring of their studies for unexpected events and adverse reactions, and reporting these situations to the IRB if they arise.

REFERENCES

The following colleges and University websites were used as resources for the Simpson University IRB Policy and Procedure Manual and supporting documents/forms:

Wheaton College, IL
Tusculum College, TN
Seattle Pacific University, WA
University of Washington, WA
Lindsey College, KY
Pacific Lutheran University, WA
University of Puget Sound, WA

APPENDICES

A. DETERMINING THE LEVEL OF IRB REVIEW

B. APPLICATION FOR APPROVAL OF RESEARCH

C. INFORMED CONSENT DOCUMENTS

1. General requirements for informed consent

2. Informed consent template

D. APPLICATION FOR MODIFICATION OF APPROVED RESEARCH

E. STATUS REPORT

F. ADVERSE EVENT FORM

APPENDIX A

DETERMINING THE LEVEL OF IRB REVIEW

EXEMPT REVIEW

Please read the following very carefully and refer to the definitions listed in Chapter 2 before determining if your project qualifies for exempt status:

(1) Research involving subjects which are identifiable, directly or indirectly through identifiers and/or codes linked to the subjects is NOT exempt.

(2) Research involving fetuses, pregnant women, human in vitro fertilization and prisoners is NOT exempt.

(3) Research involving children (under the age of 18) is NOT exempt, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.

EXEMPT RESEARCH CATEGORIES:

If you believe your project meets these criteria below, check off the item(s) below that qualifies this project for Exempt status.

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

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under item 2 above, if: i) The human subjects are elected or appointed public officials or candidates for public office; or ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing*: data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**

(5) Research and demonstration projects which are conducted by or subject to the approval of department agency heads, and which are designed to study, evaluate, or otherwise examine: i) Public benefit or service programs; ii) procedures for obtaining benefits or services under those programs; iii) possible changes in or alternatives to those programs or procedures; or iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
(45 CFR 46, Section 46.101(b), effective August 19, 1991).

---

*"Existing" means on the shelf and available at the time the IRB Exempt Status Application is submitted.

**Coded data which can be linked to an individual's identity by either the provider or recipient of data cannot be considered exempt and would require submission of either Full or Expedited Review Application.

If the research does not fall into one of the above categories, continue to Expedited Review

EXPEDITED REVIEW

Expedited review may be permitted for certain kinds of research that: (1) present no more than minimal privacy, psychological and/or physical risk to human subjects, and (2) involve only procedures listed in one or more of the following categories. This kind of research may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

If you believe your research meets criteria for expedited review, check each category below that applies. The IRB retains the right to change the review category when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

Check the appropriate category(ies) that applies to your research project:

(1) Clinical studies of drugs and medical devices only when one of the following criteria 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).

or

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

(2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture, as follows:
(a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts withdrawn 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.**

Prospective collection of biological specimens for research purposes by noninvasive means.

EXAMPLES:
(a) Hair and nail clippings in a nondisfiguring 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);
(e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax 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) 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) 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. Check below, as appropriate.

Provide a list of all data points that will be collected below or attach a data collection sheet.

(6) Collection of data from voice, video, digital or image recordings made for research purposes. If data collected are considered individually identifiable health information, data must be protected from inappropriate use and disclosure. Either an authorization must be obtained from the subject or a waiver of authorization must be obtained from the IRB.

(7) 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.)

If the research does not fall into one of the above categories, continue to Full Review

FULL BOARD REVIEW

Full Board review is required when research activities do not comply with the categories exempt from full board review or expedited review. Full board review is required for the categories listed below.

(1) Proposed procedures involve deception of the research participants.
(2) Research protocol presents greater than minimal risks to the research participants.
(3) Proposed research activities involve fetuses, pregnant women, and/or human in vitro fertilization.
(4) Research participants include children under the age of 18 (persons who have not attained the legal age for consent to treatment or procedures involved in research as established by California state law).
(5) Research participants include prisoners, or individuals who are cognitively impaired.

APPENDIX B

Simpson University Institutional Review Board
Application for Approval to use Human Participants in Research

NAME:	
TELEPHONE:	
E-MAIL:	
ADDRESS:	
OFFICE:	
DEPARTMENT:	
FACULTY RANK/STUDENT STATUS:	
PROJECT TITLE:	

TYPE OF PROJECT: _____Faculty Research _____Externally funded (Agency:_____)

_____Student Directed Research (Advisor: _____)

_____Thesis/Dissertation

_____Course Requirement (Course #: _____)

DURATION OF PROJECT:

Starting Date: (mm/dd/year) _____ (but not before approval is obtained)

Ending Date: (mm/dd/year) _____

I certify that the research procedures for this project and the method of obtaining consent (if any), as approved by the Simpson University Institutional Review Board, will be followed during the period covered by this research project. Any future changes will be submitted for Committee review and approval prior to implementation.

_____ _____

Principal Investigator (PI) Date Faculty Advisor (If PI is a student) Date

ACKNOWLEDGMENT OR APPROVAL: ____Approved by Committee ____Contingent ____Disapproved

X_____

Chairperson, Simpson University Institutional Review Board

PART I: PLEASE ANSWER THE FOLLOWING BY MARKING THE CORRECT RESPONSE:

1) Type of risk involved

___ None to minimal

___ More than minimal

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. There are different types of risks to which human subjects may be exposed that are inherent in various research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures that may induce a potentially harmful state or condition. Some examples are: the requirement of strenuous physical exercise; and/or subjection to deceit, public embarrassment, self-incrimination (the admission of illegal or immoral behavior), or humiliation. There is a wide range of medical, social, and behavioral projects in which no immediate physical or psychological risk for the subject is involved (e.g., those involving the use of personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data). However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, or constitute a threat to the subject's dignity, all of which pose another type of risk.

2) Deception involved?

___ No

___ Yes

Important information regarding deception: (a) A researcher should never deceive participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences; (b) Deception necessary to the study's design must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research.

3) Vulnerable participants involved?

___ No

___ Yes

Vulnerable populations are those who may have reduced capacity to consent to voluntary participation, and they include, but are not limited to, children, prisoners, the poor, pregnant women, fetuses, clinical populations or individuals who are mentally or psychologically ill or incompetent.

PART II: SUMMARIZE THE PROPOSED PROJECT INCLUDING GOALS OF PRESENT PROJECT, PURPOSE OF PRESENT STUDY, LOCATION OF THE RESEARCH AND PROCEDURES TO WHICH HUMANS WILL BE SUBJECTED. (CONSENT FORM(S), QUESTIONNAIRE(S), ADVERTISEMENTS, DEBRIEFING FORMS, ETC., SHOULD BE INCLUDED WITH THE APPLICATION.)

PURPOSE OF PRESENT STUDY:

LOCATION:

PROCEDURES:

PART III: PLEASE ANSWER ALL OF THE FOLLOWING ITEMS.

PARTICIPANTS

1. Briefly describe the characteristics of your population(s) and your participant selection procedure. Describe the size of your sample, the ethnic background, sex, age, state of health and the criteria for inclusion or exclusion of subjects. (Include rationale for use of special classes of participants such as pregnant women, children, institutionalized mentally disabled, prisoners, or those whose ability to give voluntary informed consent may be in question.) Justification is required if your participant population is restricted to one gender, ethnic group, or other specific group.

2. Who makes the initial contact with the participants? (If you want to use patients or clients of another professional, the initial contact must be made by the other professional, to protect patient confidentiality.)

3) Describe any prior personal or professional relationship that you expect may exist between any of the researchers and the potential participants. Explain how this might influence their willingness to take part in the research.

RISKS/BENEFITS

4) Identify any risk (here and in the consent form)—physical, psychological, and/or social—to which your participants may be exposed as a result of participation in your project (beyond the risks reasonably encountered in everyday life) and what safeguards you will use to protect the participants from these risks.

5) Describe any form of compensation to participants (e.g., money, grade, extra credit, etc. If money, extra credit or grade is given to students who participate in the project, what opportunity for extra credit or grade is provided to students who choose not to participate?)

6) Describe the benefits expected to be gained from this project. (This should include any direct benefits to the students as well as any general gain in knowledge.)

ANONYMITY OR CONFIDENTIALITY OF PARTICIPATION AND RECORDS

7) Describe methods for assuring anonymity OR maintaining confidentiality of research participants.

8) Describe the extent, if any, to which confidentiality of records identifying research participants will be maintained.

ANTICIPATED USE OF DATA

9) What will be the ultimate disposition of all data or samples collected or created as a result of this project? If data and/or samples are to be destroyed, indicate the method of destruction.

10) How will the data be used (i.e. publish data, present paper, etc.)?

APPENDIX C.1

Simpson University Institutional Review Board
General Requirements for Informed Consent

IN SEEKING INFORMED CONSENT THE FOLLOWING INFORMATION SHALL BE PROVIDED TO EACH PARTICIPANT. [45 CFR 46.116]

1. The fact that the study involves research.
2. The purpose of the research, the expected duration of participation, and the procedures to be followed and identification of any procedures which are experimental.
3. A description of any reasonably foreseeable risks or discomforts to the participant.
4. A description of any reasonably expected benefits to the participant or others which may reasonably be expected from the research.
5. A disclosure of any appropriate alternate procedures or courses of treatment which might be advantageous to the subject.
6. A statement describing the extent to which confidentiality of records that identifies the participant will be maintained.
7. For research involving more than minimal risk, an explanation as to whether any compensation or follow-up medical treatment will be provided if injury occurs and, if so, what that consists of and where further information about it may be obtained.
8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in event of a research-related injury to the subject.
9. A statement that participation is voluntary and that refusal to participate or to continue to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.

10. Where appropriate, one or more of the following elements of information shall also be provide to the participants:

a) a statement that the particular treatment or procedure may involve risks to the participant that are currently unforeseeable.

b) a statement that any significant new finding developed during the course of the research which may relate to the participant's willingness to continue participation will be provided.

c) anticipated circumstances under which participation may be terminated without the participant's consent.

d) any additional costs to the participant that may result from participation in research.

e) the consequence of a participant's decision to withdraw from the research and procedures for the orderly termination of participation.

f) the approximate number of participants in the study.

11. Furthermore, this information shall:

a) be in language understandable to the participant or the participant's legally authorized representative.

b) be conveyed under circumstances that all the participant or the participant's legally authorized representative sufficient opportunity to consider whether to agree to participate.

c) not include exculpatory language through which the participant or the participant's legally authorized representative is led to waive any of the participant's legal rights or release the investigator or University from liability for negligence.

For IRB Office Use Only

Date Received:
[ ] Approved
[ ] Conditional Approval
[ ] Denied
[ ] Withdrawn

IRB Chair Signature: _____ Date: _____

APPENDIX C.2

Simpson University Institutional Review Board
Informed Consent Template

PROJECT TITLE:	
PRINCIPAL INVESTIGATOR: [NAME AND DEPARTMENT]	
RESEARCHERS: [IF APPLICABLE, LIST ALL INDIVIDUALS BY NAME WHO WILL OBTAIN INFORMED CONSENT FROM PARTICIPANTS]	

RESEARCHERS' STATEMENT

You are invited to participate in a research study conducted at Simpson University. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

[Provide a brief background and describe the purpose of the activity in lay-language.]

STUDY PROCEDURES

If you decide to participate in the study, [Describe the procedures involved, including the amount of time involved, and location. Describe questionnaires, surveys, and interviews and describe or provide examples of the most personal and sensitive questions you will ask. State that participants may refuse to answer any question or item in any test, inventory, questionnaire, or interview. If activities are to be audio- or videotaped, state this.]

RISKS, STRESS, OR DISCOMFORT

[Include information on the psycho-social and physical risks, including side effects, stress, discomforts, breach of confidentiality, or the invasion of privacy that might result from each procedure. Example: "There are no known major risks to your participation in this research study. It may be inconvenient for you to fill out a long questionnaire. Some of the questions on the survey may cause mild emotional discomfort."]

[If appropriate, state how side effects will be handled and whom the subject should contact in the event of study-related injury, illness, or distress.]

[If you will make recordings of subjects, and you will keep the recordings indefinitely, share them with other researchers, or use them in presentations or publications, explain that subjects will be given an opportunity to review the recordings and delete any portions. In addition, describe the measures taken to secure the recordings]

BENEFITS OF THE STUDY

The potential personal benefits that may occur as a result of your participation in this study are [describe the potential benefits to the participant]. The researchers anticipate that society may benefit from this study by [describe the possible benefits to society].

OR

There [may be/ will be – select the appropriate phrase] no personal benefit from participating in this study other the information provided to you about (the topic area) and the experience of participating in research. However, the researchers anticipate that, in the future, society may benefit from this study by [describe the possible benefits to society].

COMPENSATION

[This section may be eliminated if it does not apply.]

You [will/will not] be compensated for participating in this research project. [Clearly describe the monetary (total amount, average total amount, amount per visit, amount per hour, etc.) or non-monetary compensation.]

ANONYMITY

[Only if applicable] Records of information that you provide for the research study and your personally identifying information (name or other characteristics) will not be linked in any way. It will not be possible to identify you as the person who provided any specific information for the study.

CONFIDENTIALITY

[Only if applicable] Records of your participation in this study will be held confidential as far as is permitted by law. [If information will be released to any other group or agency, for any reason, state the name of the agency, the nature of the information, and the purpose of the disclosure.] Individual participants' data will be kept separate from identifying information and [state how confidentiality will be preserved, e.g., will be linked only by a code that will be kept in locked storage to which only the researcher(s) will have access. If the data will be retained with links to identifiers, state the date when the link will be broken.] The records from this study will be available for review by members of the Institutional Review Board at Simpson University (a committee that reviews and approves research studies). It is possible that these records could contain information that personally identifies you. In the event of any report or publication from this study, your identity will not be disclosed. Results will be reported in a summarized manner in such a way that you cannot be identified. [Describe any limits to confidentiality (for example if study procedures may elicit information about child abuse, elder abuse, or harm to self or others). You might state, "All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities."]

VOLUNTARY PARTICIPATION

Taking part in this research study is voluntary. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. [For studies involving survey, questionnaire, or interviews, include a statement that the participant is free to skip any questions that s/he would prefer not to answer.]

You are encouraged to ask any questions, at any time, that will help you to understand how this study will be performed and/or how it will affect you. You may contact the principal investigator [state your name and contact telephone number (faculty only) or e-mail address] or the investigator's faculty advisor [state professor's name and a contact telephone number or e-mail address.]

SUBJECT'S STATEMENT

Your signature indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation without penalty. You will receive a copy of this form.

Participant's name (printed): _____

_____ _____

Signature of participant Date

RESEARCHER'S STATEMENT

I have discussed the above points with the participant or, where appropriate, with the participant's legally authorized representative, using a translator when necessary. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

Signature of researcher Date

APPENDIX D

Simpson University Institutional Review Board
Application for Modification of Approved Research

DATE:	
IRB TITLE	
IRB APPROVAL EXPIRATION DATE	
PRINCIPAL INVESTIGATOR NAME	
PRINCIPAL INVESTIGATOR SIGNATURE	
E-MAIL	
SCHOOL/DEPARTMENT	
FACULTY SPONSOR NAME AND SIGNATURE	

INDICATE THE TYPE OF CHANGE/ADDITION AND ATTACH ALL APPLICABLE DOCUMENTS:

Purpose	Population
Recruitment/Advertisements	Consent/Assent
Research staff	Site or locations
Change(s) to Study Procedures	Other: _____

BRIEFLY SUMMARIZE THE CHANGE(S).

DESCRIBE THE RATIONALE FOR THE CHANGE(S):

WILL THESE CHANGES AFFECT THE OVERALL RISK TO SUBJECTS IN THIS STUDY?

DO THE CHANGES TO THE STUDY PROMPT CHANGES TO THE CONSENT FORM(S)?

No.

Yes: Attach a copy of the revised consent form(s) with changes tracked or highlighted as well as a clean copy.
Use this space to further describe consent form changes if necessary:

For IRB Office Use Only

Date Received:
[ ] Approved
[ ] Conditional Approval
[ ] Denied
[ ] Withdrawn

IRB Chair Signature: _____ Date: _____

APPENDIX E

Simpson University Institutional Review Board Status Report

DATE	
IRB TITLE	
IRB APPROVAL EXPIRATION DATE	
PRINCIPAL INVESTIGATOR NAME	
PRINCIPAL INVESTIGATOR SIGNATURE	
E-MAIL	
SCHOOL / DEPT	
FACULTY SPONSOR NAME AND SIGNATURE	

A. RESEARCH ACTIVITY STATUS

1. *RENEW* IRB application because:

2. *CLOSE* IRB application because:

B. SUBJECT NUMBERS

1. NO. OF SUBJECTS APPROVED TO COMPLETE THE RESEARCH	
2. NO. OF SUBJECTS ENROLLED SINCE INITIAL IRB APPROVAL	
3. NO. OF SUBJECTS ENROLLED SINCE LAST IRB APPROVAL	
4. NO. OF SUBJECTS ACTIVELY INVOLVED IN RESEARCH PROJECTS	
5. NO. OF ADDITIONAL SUBJECTS NEEDED TO COMPLETE RESEARCH	

C. SUMMARY

Provide a summary of the research progress to date. If you have not yet enrolled subjects, please explain why.

D. ADVERSE EVENTS AND OTHER PROBLEMS:

Provide this information about adverse events and/or other issues surrounding non-compliance for the approval period since your last status report by answering the questions below. If there were no adverse events or other problems, write "None."

1. Number of adverse events that were *related to research procedures, serious, and unexpected :*

   _____ Explain:

2. Number of adverse events that were related to research procedures and expected, but more severe or occurred at a greater frequency than expected :

   _____ Explain:

3. List the adverse events that were related, non-serious, but unexpected in the table below:

EVENT TYPE/DESCRIPTION	NUMBER OF EVENTS	NUMBER OF SUBJECTS AFFECTED
EXAMPLE: NAUSEA	3	2

4. Does the occurrence of any of the adverse events listed above suggest that the risk(s) to subjects are greater than described in your initial IRB application?

   [ ] Yes [ ] No [ ] Not applicable

   If yes, provide an explanation:

5. Number of other problems (*unanticipated problems, protocol violations, protocol deviations*)_

   _____ Explain:

6. List the adverse events that were *related, non-serious, but unexpected* in the table below:

EVENT TYPE/DESCRIPTION	NUMBER OF EVENTS	NUMBER OF SUBJECTS AFFECTED
EXAMPLE: NAUSEA	3	2

7. Does the occurrence of any of the adverse events listed above suggest that the risk(s) to subjects are greater than described in your initial IRB application?

   [ ] Yes [ ] No [ ] Not applicable

   If yes, provide an explanation:

8. Other problems (e.g., protocol violations and protocol deviations)

   _____ Explain:

9. Number of complaints: _____

   Describe each complaint, and explain how you handled each one.

10. Number of subject withdrawals: _

    For each withdrawal, explain:

    - why the subject chose to withdraw, or
    - why you withdrew the subject from the research, and/or
    - how the withdrawal affects your subject enrollment numbers for the past year as well as your overall enrollment totals.

For IRB Office Use Only

Date Received:
[ ] Approved
[ ] Conditional Approval
[ ] Denied
[ ] Withdrawn

IRB Chair Signature: _____ Date: _____