COLBY-SAWYER COLLEGE
INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES INVOLVING THE USE OF HUMAN SUBJECTS[1] IN RESEARCH

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[1] These guidelines use the term "human subjects" to refer to individuals being studied as part of research activities. The Colby-Sawyer College Institutional Review Board suggests that investigators follow the recommendation of a professional organization for their discipline to determine the appropriate reference for human subjects/participants. For example, the American Psychological Association recommends the use of participant instead of human subject.

Institutional Review Board Policies and Procedures
Involving the Use of Human Subjects in Research

SECTION I

Institutional Review Board Policies and Procedures

Colby-Sawyer College (CSC) has established an Institutional Review Board (IRB) to review all research involving the use of human subjects and to implement institutional policies and procedures regarding such research. The use of human subjects in research imposes both ethical and legal responsibilities upon the researcher, faculty sponsor, project director, and the College to ensure that the rights and welfare of those subjects are adequately protected. The primary function of the IRB is to assist researchers in the protection of the rights and welfare of human subjects. Review and approval by the IRB is meant to aid both the subjects and the researchers by bringing scrutiny to projects by a group of peers or faculty and staff who can objectively assess the potential risk and recommend accommodations to minimize it.

All research involving the use of human subjects conducted by CSC faculty, staff, or students; or sponsored, in part or in whole, by CSC; must be reviewed and approved prior to the start of the project and then conducted in full compliance with IRB policies and procedures. According to federal regulations, "human subject" means a living individual about whom an investigator conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable personal information. "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 the investigator and subject. "Research" is defined as a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge (45 CFR 46. 102). The research, conducted on or off campus, includes questionnaires, interviews, surveys, tests, observations, and other experiments, even if the work is preliminary to a more extensive study. It includes secondary analyses of data previously collected. It also includes any systematic collection of data from human subjects that occurs in conjunction with classroom projects.

Class Assignments. Projects conducted by an entire class or as one of a series of class assignments should be proposed to the IRB using the application form contained in this document. This form requires faculty or staff approval and signifies that supervisors share responsibility with students to insure that the project protects the rights and welfare of subjects. Faculty and staff who conduct research as part of their courses or other activities should submit syllabi or descriptions of planned projects to the IRB chair.

It is the responsibility of the researcher to refer his or her project to the IRB whenever humans are used as subjects in research, even if the researcher does not consider the subjects to be at risk. Current law places the burden of liability for negligence and harm directly on the researcher and the institution. The IRB policies and procedures are formulated to protect the College, the researcher, and in the case of the students, the faculty

research advisor, from liability through imposition of minimal standards for research and through procedures for careful review of projects.

If you have questions about the policies and procedures, call the IRB chairperson or another IRB member.

A. Background

The Public Health Service Act (Title IV, Part G, Section 491 a) required the Department of Health and Human Services (DHHS) to issue regulations for the protection of human subjects of research and to implement a program of instruction and guidance in ethical issues associated with such research. The regulations are codified as Title 45 Part 46 of the Code of Federal Regulations, Protection of Human Subjects (45 CFR 46), issued on June 18, 1991. These regulations apply to all research involving human participants that is conducted or supported, in whole or in part, by the DHHS in foreign or domestic settings.

The establishment of the CSC IRB and its policies and procedures are primarily derived from 45 CFR 46. The policies and procedures are intended to provide a resource for the preparation and submission of research applications for IRB reviews. A copy of 45 CFR 46 is with each IRB member.

B. Ethical Principles and Issues for the Use of Human Subjects in Research

The current regulations in 45 CFR 46 are based on *The Belmont Report*, which was developed in the 1970's by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report presented three basic ethical principles. These principles of respect for persons, beneficence, and justice remain as essential requirements for the ethical conduct of research involving human subjects. Respect for persons recognizes personal dignity and autonomy of individuals and protection of those that have diminished autonomy. Beneficence includes an obligation to protect individuals from harm by minimizing risks of harm and maximizing benefits. Justice requires that the burdens and benefits be distributed fairly.

In addition to the aforementioned principles, the IRB will consider the following ethical issues in determining the nature of the risks and extent to which the benefits of the study justify exposing the subjects to risk:

- *Voluntary participation:*

  Participation of human subjects must be voluntary, i.e., must occur as a result of free choice, without compulsion or obligation, based upon disclosure of relevant information in a clear, concise, and understandable way. The researcher must take care to avoid coercing subjects' participation and must invite potential subjects to participate. Subjects must be made aware that not volunteering to participate will have no repercussions.

- *Inducement to participate:*

  Subjects are frequently offered some form of incentive or reward for their participation, e.g. earning extra credit points from their professor, small gifts or prizes, a chance to win money in a lottery. In general, inducements are allowable as long as they are minimal and are not more attractive to some subjects than to others. The primary ethical issue involves the extent to which an inducement might be sufficiently influential to cloud the person's judgment about whether or not participation in the study is in their own best interest.

  In cases where students may earn extra credit points from their professor, other options to earn extra credit besides research participation must be available. Preferably, faculty/staff will not do the recruiting in their own classes (although they may have one of their colleagues or research students recruit for the study in their own classes), nor should their names be associated with the recruitment procedures if recruitment will take place in their own classes. This guards against the students' perception that they may be expected to participate in a study that their own professor is conducting in order to stay on good terms with that professor.

  A second issue involves the extent to which the subjects can reasonably choose not to participate, especially in a case where subjects are approached in a large group (e.g., class) and asked to participate without standing apart from their peers. This is particularly a problem if participation involves a sensitive issue. For example, if the study focuses on AIDS and a person chooses not to participate, it might be interpreted that the person has AIDS. In such cases, the researcher/recruiter would need to demonstrate that this concern has been recognized and addressed (e.g., by providing a means for all potential subjects to appear as if they are participating even if they are not).

- *Informed consent:*

  All subjects must be properly informed about what their participation will entail. This should be initiated in the recruitment process by having the subjects read and sign an informed consent form before participating in the study. The informed consent form should include a clear and concise description of the purpose, procedures, time involved, risks, and benefits to the participant. A model form begins on page 17. For anonymous surveys, a statement that describes the nature of the research is sufficient without the subject’s signature. It also is crucial that researchers ensure to the best of their ability that the potential subjects understand what is being communicated to them. Consent must be given freely with the subject understanding the nature and consequences of what is proposed. Consent also is an ongoing process, not just a single occurrence. Researchers must inform subjects and/or guardians of any important new information that might affect their willingness to continue in the study.

Federal law stipulates that a person must be 18 years or older to give legal consent on his/her own behalf.

Children. Subjects under the age of 18 years may participate in research only with the signature of their parent or legal guardian in addition to their own signature. This also applies to the completion of anonymous questionnaires, since persons under 18 are not permitted legally to make the informed choice to participate. Children should have the information about participation in the research explained to them in language that they can understand (by their parent), and, if possible, they should sign their assent.

- *Identification and minimizing of risks:*

  "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102). Virtually all research involves some risk, even though it may be slight (e.g., embarrassment over a performance on a task). A risk may be of a physical, social, and/or psychological nature. The IRB will consider the extent to which the researcher(s) and/or faculty sponsor have attempted to identify the potential risks to the subject and the extent to which those risks have been minimized without interfering with the validity of the research. In cases where there is the possibility of more than minimal risk to the subject, approval will depend on the benefits of the research, the expertise and prior experience of the researcher(s) in conducting this type of research, the level of inducement to participate, the extent to which the subject is fully informed of the possible risks, and the availability of compensatory treatment or follow-up designed to alleviate any negative consequences from participation. Researchers must make all reasonable attempts to eliminate the possibility of any harm to subjects. A research procedure may not be used if it is likely to cause serious and lasting harm to subjects (e.g., health problems).

- *Adverse events*

  Primary investigators have a responsibility to report to the IRB committee immediately any and all adverse events that occur during the course of a study. An adverse event is described as a situation in which a participant is harmed either, physically or emotionally, as a direct or indirect result of a participation in a research study. Adverse events include but are not limited to the following: 1) any physical injuries that may occur during participation in a study 2) any physical injuries that may appear in the aftermath of participation in a study, 3) psychological distress or upset during the course of participation in a study or 4) any psychological distress that may result in the aftermath of participation in a study. Adverse events include activities that range in seriousness from mild to severe. Adverse events can include (but are not limited to) the following kinds of events: fainting, feeling sick,

getting hurt, or feeling distressed. Even when participants do not express serious or deep concern over adverse events, they must still be reported.

A primary investigator should take the following steps when he or she becomes aware of an adverse event. The primary investigator must contact the chair of the IRB committee about the incident. Following contact with the IRB chair, the primary investigator must complete the Adverse Events Report for the Primary investigator (see section V). If the primary investigator is a student, he or she must inform their faculty sponsor of the incident. After informing the faculty sponsor, the student should then contact the chair of the IRB and complete the Adverse Events Report for the Primary investigator (see section V). Adverse event incidents should be treated privately and discreetly.

Participants have the right to voice their concerns about adverse events to the IRB committee directly and the experimenter has the obligation to inform participants of this right. Participants who experience an adverse event are asked to report the incident to the Primary investigator of the study). If a student is the Primary investigator, participants should report the adverse incident to the faculty sponsor. If the participant is not comfortable reporting the incident to the primary investigator (or faculty sponsor), he or she is asked to contact the chair of the IRB committee. The Chair of the IRB committee will instruct the participant to complete an adverse events report form for Study Participants (see appendix).

The IRB committee will review all adverse event reports. For adverse events that are deemed of a serious nature, as measured by the extent of injury to a participant, the committee will review the event and take appropriate action.

- *Fairness*

  The research should be designed to treat all individuals fairly. The selection of subjects must be based upon fair procedures and not overburden, overuse, or unfairly favor or discriminate against any subject pool.

- *Deception:*

  In some types of research it may be necessary to withhold some pertinent information from subjects when disclosure of such information would likely impair the validity of the study. In all such cases, subjects should be told that they are being invited to participate in research in which some features will not be revealed until the research is concluded. Complete nondisclosure of information about the study or its purpose is only justified when the research solely involves observation of a person's behavior in locations where the person might reasonably expect that his/her behavior could be observed by another. In any research that involves incomplete disclosure, the following conditions must be met: 1) there are no undisclosed risks to subjects that are more than minimal; 2) there is an adequate plan for debriefing subjects, when appropriate; and 3) incomplete

disclosure is truly necessary to accomplish the goals of the research. Truthful answers should always be given to direct questions about the research; this may include telling the subject that revealing certain information may impair the success of the study.

- *Confidentiality/Anonymity/Privacy:*

  In all research involving human subjects, it is important to assure the subjects of the confidentiality of their responses. This is especially important in cases where the study involves asking the subjects personal questions about themselves or obtaining other information that might put the subject psychologically at risk, if the information were made public. Total anonymity (e.g., where the subject's name or face is never associated with his/her responses, even to the researcher) is preferable, especially in the case of extremely sensitive or personal information. This generally means that the subject must be able to provide information in complete privacy and to submit the information in such a way that it is mixed in with other subjects' data before it is retrieved by the researcher. "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. Private information must be individually identifiable to constitute research involving human subjects (45 CFR 46.102). Where it is necessary to have the subjects' names or identification numbers associated with their responses (e.g., in order to collate several sets of responses by the same subject), the subjects need to be told who will see their data and specifically how this information will be kept confidential. Subjects should also be informed how the collected data will be treated at the conclusion of the study.

- *Debriefing:*

  In most cases, it is desirable for subjects to be debriefed after their participation in the study (e.g., given further information about the study and given a chance to ask questions). There are three cases in which debriefing is required: first, when the research has involved incomplete disclosure; second, when subjects may be left with a misleading or potentially harmful perception or inaccurate information; and third, when compensatory treatment or follow-up may be needed. Such debriefing should not be treated as a substitute for informed consent prior to and during the subject's participation in the research.

  In some cases, debriefing may not be possible immediately after the study due to concern about other potential subjects finding out about a deceptive aspect of the study that would preclude further data collection. In these cases, debriefing statements or descriptions could be offered to the subjects at a later date through the mail or by other means. In rare instances, debriefing may itself pose a social or psychological risk to a subject; in which case it may be in the best interest of

the subject to forego the debriefing procedure. In most cases, however, this can be avoided by disclosing to the subjects prior to their participation that some harmful information may be uncovered in the course of the study. This would fall under the obligation to disclose any risks that are more than minimal (See *Deception.).*

- *Compensatory follow-up:*

  In cases where some physical or psychological harm might result from the subjects' participation, plans for compensatory treatment or follow-up counseling must be provided.

C. Type of Review

The type of review required depends upon the nature of the research, the subjects, and the risk imposed upon the subjects. There are three categories of reviews: exempt, expedited, and full review. Research that is exempt from review deals with non-sensitive topics and involves subjects who are able to consent to participate, and the anonymity and confidentiality of subjects is maintained. Expedited reviews apply to studies that involve no more than minimal risk, procedures that collect samples, or procedures that require the collection of data through noninvasive procedures typically used in clinical practice. Full board review will occur for all proposals that involve vulnerable subjects, sensitive behavioral research, or research where the risk of harm is greater than minimal.

In all cases the researchers must complete the application (Section II) and faculty/staff must evaluate and approve any student proposal before sending to the IRB.

1. Research that qualifies for exemption from full or expedited IRB review

All research involving human subjects that is exempt from full or expedited IRB review must maintain an adequate standard of informed consent and confidentiality of data.

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from a full or expedited review. Another stipulation is that the information on these subjects is recorded so that subjects cannot be identified directly or through identifiers linked to the subjects.

<u>Educational Research</u>

a. When research in educational settings meets conditions 1-6, or condition 7 listed below, it is exempt from IRB review. The researcher and/or school, however, may want this consent. The assent of a child should be obtained whenever possible.

   (1). The research is conducted in established or commonly accepted educational settings involving normal educational practices. Examples are 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). If the research involves educational tests (cognitive, diagnostic, aptitude, achievement), this information must be recorded so that subjects cannot be identified, directly or through identifiers linked to the subjects

(3). The research procedures do not represent a significant deviation in time or effort on the subjects' part from those educational practices already existing at the research site.

(4). The research procedures do not involve an increase in the level of risk or discomfort compared to normal, routine educational practices. For example, studies in which parenting practices are criticized or teachers' jobs may be jeopardized require an expedited or full review.

(5). Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.

(6). The research does not involve sensitive topics (e.g., sex education).

(7). The institution grants written approval for the research to be conducted.

Other Research

b. When the research involving the use of surveys, interview procedures, or observation of public behavior is not part of educational research as defined in "a", but meets all the following conditions.

(1). Information on these subjects is recorded so that subjects cannot be identified directly or through identifiers linked to the subjects.

(2). Disclosure of subject responses outside the research setting would not place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

(3). There is very low risk associated with a breach of confidentiality.

(4). The research does not deal with sensitive or highly personal aspects of the subject's behavior, experiences, or attitudes (e.g., substance abuse, detailed health history, sensitive demographic data).

(5). The research does not involve children (subjects under 18 years of age).

(6). The respondents are elected or appointed public officials or candidates for public office.

c. The research involves the collections or study of existing data, documents, records, pathological specimens, or diagnostic specimens which either are publicly available or will be recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

d. Research that involves taste and food quality evaluation and consumer acceptance studies where only wholesome foods without additives are consumed or that involves only a limited amount of consumption of a food additive at or below a level approved by the Food and Drug Administration, Environmental Protection Agency, and/or the United States Department of Agriculture.

2. Research that qualifies for expedited IRB review

Applications pertaining to some research activities that qualify for expedited review are read by only two members of the IRB. These research activities involve no more than minimal risk and only include involvement of human subjects in one or more of the following categories (carried out under standard methods). Also, previously approved (within one year or less) research with only minor changes qualifies for the expedited review. The Chair of the IRB and one other member determine whether a proposal qualifies for expedited review (see Section G.1).

a. Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth; and permanent teeth, if patient care indicated a need for extraction.

b. Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

c. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, encephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., x-rays, microwaves).

d. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and not more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

e. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is no more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

f. Voice recordings made for research purposes such as investigations of speech deficits.

g. Moderate exercise by apparently healthy volunteers (as defined by the American College of Sports Medicine). See Appendix A.

h. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

i. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the researcher does not manipulate subject's behavior.

j . Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

3. Research that requires full IRB review

Unless research qualifies for exemption from full IRB review or expedited IRB review as previously described, it requires full review by the IRB. Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Research involving these subjects, sensitive behavioral research, research involving deception, research involving the ingestion of substances, research that is potentially harmful to the subjects, or research that involves undue stress to subjects automatically requires full IRB review.

D. Student Research

These same policies and procedures apply to student research. Instructors are responsible for screening student research projects and ensuring that applications are submitted correctly and in a timely manner. Instructors are also responsible for determining that research is conducted in the manner proposed and that recommendations made by the IRB are incorporated into the research. If a project is assigned for the purpose of producing results that may be presented inside or outside of the class, or published, or may involve risk to the subjects, the researcher must comply with these policies and procedures. Submission of an application and appropriate approval must occur prior to initiating the research (e.g., data collection). The IRB will notify the faculty/staff sponsor of all decisions.

E. Cooperative Research with Another Institution

When cooperative research occurs with another institution, one institution may agree to delegate responsibility for initial and continuing review of all or a portion of the research activity to another IRB. This can occur if the other institution and IRB agree to assume responsibility for the review and if the delegating institution agrees to abide by the reviewing IRB decisions. For any portion of a research activity which CSC researchers do not delegate

to another IRB, the researchers remain responsible in complying with these policies and procedures.

Researchers and CSC IRB need to bear in mind the following when contemplating the use of another institution's IRB to review its protocols: local laws, institutional policies and constraints, professional and community standards, and population differences. Researchers should seek local IRB counsel prior to engaging in cooperative research involving the use of human subjects.

When researchers from outside the CSC community come to campus or collect data on campus and use CSC subjects the researcher should obtain approval from the CSC IRB and should determine a CSC faculty/staff member to serve as liaison and sponsor.

The agreement for IRB review of cooperative research must be documented in writing with copies to be furnished to all involved with the agreement and those ensuring compliance with IRB determination. Regardless of the agreement, each institution is responsible for safeguarding the rights and welfare of human subjects.

F. International Research

Procedures for reviewing research in foreign countries may differ from those set forth in this document and in federal regulations. Such international standards as the Nuremberg Code and Declaration of Helsinki present broad policies, but are not considered sufficient for an institution having an assurance with a federal agency such as DHHS. Because of the varied policies and procedures involved with conducting research in foreign countries, it is best that researchers discuss research projects with the CSC IRB during the planning phase of the project.

G. Institutional Review Board (IRB)

1. Membership

The IRB will consist of five to seven members appointed by the Academic Vice President and Dean of Faculty. The Chair will be appointed by the Academic Vice President. Serving on the IRB will be considered the equivalent of a committee membership. Each academic department within the College that regularly carries out research with human subjects should be represented by at least one member. The IRB also must include at least one member who is not affiliated with an academic department. The Chair of the IRB will review applications with each of the other members on a rotating monthly basis. Three voting members will constitute a quorum for any full review.

If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

The IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. Researchers or faculty sponsors may also recommend such individuals. These individuals will not vote.

Members are appointed for a three year term and may be re-appointed when the term expires. The Chair should have served on the IRB for at least one year. It is recommended that no more than two members be replaced each year. The IRB chair may request that any board member who frequently does not submit reviews in a timely manner and/or misses meetings be replaced.

2. Meeting Times

The full IRB will meet regularly during the academic year. As needed, the IRB may convene during intersession or summer sessions or, in exceptional cases, may conduct business via telephone, e-mail, or mail.

H. IRB Deadlines

Applications for review by the full IRB must be submitted at least two weeks prior to the planned initiation of the research. If proposals are not received in a timely fashion, the IRB may not be able to review in time for students to complete their research. Faculty and students need to be aware that the IRB may require changes in procedures. Student projects should be submitted to the IRB by the end of the ninth week of classes in a semester. If a student project needs to begin immediately after the start of the semester, it should be submitted during the previous semester to the IRB. Proposals submitted during the summer will be acted upon at the beginning of fall semester.

I. Appeal Process

If the application is disapproved, the researcher has the right to appeal in writing to the IRB for a second hearing. Every attempt will be made to resolve the identified problem(s). Decisions of the IRB are final. Researchers, however, may appeal to the Vice President for Academic Affairs on procedural irregularities.

SECTION II

Procedures for Applying for Research

Prior to submitting an application, ensure that you understand the IRB Policies and Procedures for the use of human subjects. A description of how to prepare an application and the required forms are contained in the following pages.

Submit two copies of the application to the IRB Chair. After the application is reviewed, you will receive one of the following decisions in writing:

a. Unconditional Approval: A majority of the present voting members find the proposal acceptable and in compliance with the policies of this memorandum with no changes or modifications.

b. Conditional Approval: A majority of the present voting members approves some elements of the proposed project and requires that modifications or corrections be made in other elements to bring it into compliance with specific policies. For a project that is conditionally approved, all required changes to the protocol must be made and submitted to the IRB. Once the researcher receives final approval of the changes from the IRB committee, researchers may begin the project. The researcher or faculty sponsor will receive written notification of the Board's decision.

c. Not Approved: Less than a majority approves the proposal. This outcome will be on the basis that the proposal does not comply with the policies and/or procedures of the IRB. A specification of the reasons for rejection will be included with this outcome.

d. Tabled: The Committee requires a significant amount of additional information and/ or has a serious concern that requires outside input. A member of the Board will be assigned to discuss the proposal with the investigator.

A researcher may testify and present other evidence in support of their proposal at the Board review. The Board may request the researcher's presence at any time during the evaluation process. The Chairperson should be notified in writing at the time of submission if the researcher wishes to appear before the Committee.

The Committee shall inform the principal researcher in writing of the action taken within one week of the review date.

Please adhere to the guidelines on the application form which follows. Keep in mind that the IRB consists of persons from different disciplines, so the proposal should be written so that it is understandable to persons outside of the specific field in which the research is conducted. If you use specific terminology, explain the terms or attach a glossary. The IRB cannot make accurate judgments about risk if the exact nature of the procedures is not clear. Technical terminology often confuses the issue.

Please refer to the model informed consent form, and if necessary, the model form for children's assent to participate in research. These are contained in Section IV.

Although The IRB will respond to your request as soon as possible, please allow two weeks from the submission date for a written response.

When the research is complete, the researcher is required to complete and submit an End of Project Report to the IRB Chair.

INSTITUTIONAL REVIEW BOARD
RESEARCH PROPOSAL GUIDELINES
RESEARCH WITH HUMAN PARTICIPANTS
COLBY-SAWYER COLLEGE

Statement Governing Research with Human Participants:

The decision to undertake research is a serious one. It rests upon the researcher's individual decision about how best to contribute to science and to human welfare. On the basis of this consideration, the researcher seeks approval from the Institutional Review Board to conduct the research. The researcher carries out the investigation with respect for the dignity and welfare of the research participants and with cognizance of federal and state regulations and professional standards governing the conduct of research with human participants. [Adapted from The American Psychological Association Ethical Principle 9].

Title of the Research

Investigator:
Researcher's full name.

Faculty/Staff Sponsor:
Name and institutional affiliation of faculty or staff sponsor.

Sponsor Organization:
Organization name and address.

Funding Source [if applicable]:
Name and address of organization or individual who bears the cost of the project [if any].

Duration of the Study:
Inclusive dates.

Location:
Organization name and address for the location in which the study will be performed.

Purpose of the Study:
Explanation of the reason for the study, including the possible importance of its results.

Subjects/Participants:
Number, location, and characteristics of subjects/participants to be recruited for the study. Procedures for participant selection.

Contact Method:
Means by which the subjects/participants will be recruited. Reference to informed consent, permission forms, explanation of right to withdraw, protection of confidentiality, privacy, etc. [Attachments to the proposal]. Special precautions and permissions for subjects judged to have limited freedom of consent [mentally retarded, ill, children, elderly]. Discussion of access to subjects/participants through cooperating institution.

Procedures:

Brief but thorough description of the procedures to be used in the study and in the debriefing or information sharing process to occur at the conclusion of the study. Details are included about any instrumentation to be used, and any deception of or stress or discomfort [physical or psychological] for subjects/participants. Thorough explanation of any substances to be taken internally or applied externally to subjects.

Risks and Benefits:

A thorough explanation of possible risks [psychological, physical, social] to the subjects/participants. A description of potential benefits to the participants [including pay] and/or to the organization and the general advancement of the discipline.

Informed consent and permission:

A discussion of the steps taken to assure informed consent and to obtain the necessary permission.

Attachments [as appropriate]:

Attachments to the proposal should include the following:

Informed consent form
Permission forms
Instrumentation to be used [survey forms, description of equipment, rooms to be used, characteristics and training of observers or other research assistants]

We understand, and will abide by, applicable state and federal regulations and professional standards regarding research with human subjects. Furthermore, we agree that the research will be conducted in accordance with this proposal and that permission will be sought from the Institutional Review Board if substantive changes are to be made to the research.

Signatures:

Investigator [s] ***Date***

Faculty/Staff Sponsor[s] ***Date***

Results of Review:

- ☐ **UNCONDITIONALLY APPROVED**
- ☐ **CONDITIONALLY APPROVED (SEE RECOMMENDATIONS)**
- ☐ **NOT APPROVED (SEE LETTER)**
- ☐ **TABLED**

Institutional Review Board Representative ***Date***

COLBY-SAWYER COLLEGE
END OF PROJECT REPORT FOR
RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Complete the following information and submit one copy to the IRB.

Project title: _____

Name of primary researcher: _____

Dept./Program _____ Phone: _____

Project dates: from _____ to _____
This is to verify that the above named research involving the use of human subjects was performed according to the procedures approved by the IRB. The research project is now complete.

There were a total of _____ participants in this research project. _____ participants voluntarily withdrew from the research project. _____ participants experienced complications, adverse reactions, or injuries resulting from participation in the research project. All records for this project will be maintained for at least one year by the researcher unless a longer time has been outlined in the research proposal.

_____ _____
Primary researcher's printed name Department/Program

_____ _____
Primary researchers signature Date

For student research:

_____ _____
Faculty research advisor's signature Date

_____

Committee use only:

Date received by IRB: _____

SECTION III

RESEARCH INVOLVING THE USE OF SPECIAL POPULATIONS

Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects. For example, the DHHS requires additional safeguards for research involving fetuses, pregnant women, and human in vitro fertilization (45 CFR 46, Subpart B), prisoners (45 CFR 46, Subpart C), and children (45 CFR 46, Subpart D). If faculty, staff, or students are associated with research involving fetuses and in vitro fertilization, they should consult with the IRB chairperson. Federal regulations, state, and local laws need to be strictly adhered to concerning these areas. For example, in some instances the DHHS requires approval by their Ethical Advisory Board prior to conducting a study.

Research involving any other special populations must follow all requirements as indicated in 45 CFR 46. The remainder of this section concentrates on proposals for research involving children, people with incapacities, and other vulnerable populations such as people with AIDS/HIV.

A. **Research Involving Children**

The special vulnerability of children makes consideration involving them as research subjects important. Special procedures are required for research involving children except for research that is conducted in educational settings as described on page 6 of the document. Whenever feasible, appropriate studies should be conducted on non-vulnerable populations or older children before young children are involved as research subjects.

What constitutes minimal risk is central to the IRB's consideration of research involving children. The IRB also must determine that adequate provisions have been made for getting the permission (assent) of children and the permission (informed consent) of their parents or guardians. The IRB's policy regarding obtaining consent and assent are as follows:

1. In most situations, parental consent is required if the research involves minors (under the age of 18). Unless the requirement is waived by the IRB, a parent or guardian must complete an informed consent form, and must receive a cover letter that describes the research and its intended use.

2. Unless the requirement is waived by the IRB, assent is required from all children. In most situations, a written form should be used to document assent. The form should include a simplified version of the contents of the informed consent. This explanation should be written so as to be understandable to the child. If the child's developmental ability does not enable him or her to understand the written explanation, documented oral assent is appropriate.

B. Research Involving Subjects with Incapacities

Incapacity refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Persons with incapacities who either have been adjudicated to lack the capacity to give informed consent or have been judged by the researcher to lack the capacity cannot participate as research subjects unless proxy consent is obtained by the their legally authorized representative. The assent of these persons must be obtained whenever possible.

C. AIDS/HIV - Related Research

A paramount concern in HIV research is confidentiality. Breaches of confidentiality could have severe adverse consequence such as loss of employment or insurance coverage, or criminal charges. If identifiers are not needed, they should not be recorded. If they are recorded, they should be separated, if possible, from the data, and combined with the data only when necessary. It also has been suggested that no lists should be retained identifying those who elected not to participate.

The procedures for obtaining informed consent need to be accurate and complete. Subjects should be informed of exactly what information will be recorded and whether any state laws require disclosure of information.

SECTION IV

MODEL FORMS FOR RESEARCH INVOLVING HUMAN SUBJECTS

A. Model Informed Consent Form

The following is a model consent form containing the elements common to many informed consent forms. You should substitute language pertinent to your research project. The italicized language is offered for example only.

Title of project:

Name of investigator: _____ Phone: _____

Invitation to Participate: e.g., You are invited to participate in this research study. The following information is provided to help you make an informed decision whether or not to participate. If you have any questions, please do not hesitate to ask.

Purpose:

e.g., We hope to learn *(in lay language, state as clearly and accurately as possible what the study is designed to do. This statement of purpose should help the subject assess the importance of the study relative to individual values.).* This research is supported by *(a grant from) (name of entity).*

Participants:

(State why this subject is eligible to participate, e.g., because you are a student, male, over 50, because you live in New London, because you have diabetes, etc. When appropriate, state criteria for subject exclusion, e.g., pregnancy, health restrictions, etc)

Procedures:

e.g., If you decide to participate in this research project, we will *(in language understandable to your population, describe the procedures to be followed, including their purposes, duration, frequency, and recovery time, if applicable. Any drug or device should be described. If a placebo is to be administered to a portion of the subjects, this information must be included, though individual subjects need not be informed as to whether they will actually receive the placebo. Quantities, such as blood to be drawn, should be stated in terms familiar to the subjects. If audio/videotaping or motion pictures are a procedure of the study, insert a statement permitting the subject to review and/or require editing of the tapes. State how the material will be used and describe the disposition of such material at the end of the study.).*

Alternatives:

(Describe alternative procedures or treatments that might be advantageous to the subject. Any standard treatment that is being withheld must be disclosed, with its relative risks and benefits. When treatment is hazardous or very unpleasant, or the quality of prolonged life is seriously at risk, the option of no treatment must be candidly presented. If no alternative drug or treatment is available, this should also be stated)

Timetable:

(Clearly identify the amount of time that will be required of the subject and the length of time that will be needed for the completion of the study.)

Risks:

(Present a fair, reasonably detailed and understandable description of any physical, psychological, social, legal, and/or economic risk resulting from the research. If there are no known risks, including discomfort, burden, or inconvenience, this should be stated.)

Benefits:

(Present a fair, reasonably detailed and understandable description of any benefit that might result from the research. If the individual will receive no direct benefit, this should be explicitly stated. Describe potential societal benefits in this section)

Compensation for Participation:

(Any compensation for participation should be clearly stated. Cash payments should be stated in dollar amounts, and any conditions such as partial payment or no payment if early termination and bonuses for completion should be stated. If compensation will be in the form of academic credit which will be awarded for research participation, the amount and type of credit should be clearly stated as well as any conditions that must be fulfilled in order for credit to be awarded. The nature, amount and method of payment of compensation must not constitute undue inducement of the subject. When establishing the amount/type of compensation, the researcher should consider the background and socioeconomic status of the subject population. Compensation for children involved in research is generally discouraged.)

In Case of Emergency Contact Procedure/Emergency Care and Compensation in Case of Injury

These sections are required for research involving greater than minimal risk. They deal with research related injuries and adverse reactions. If your research involves such risk to the subjects, seek counsel in writing these sections as they legally obligate the College.

Confidentiality:

e.g.. Any information obtained during this study which could identify you will be kept strictly confidential. This information may be published in professional (or scientific) journals or presented at professional meetings, but your identity will be kept strictly confidential. *(State the way in which the subject's confidentiality will be maintained. State the persons or agencies to whom the information from the study will be furnished, the nature of the information to be furnished, and the purpose of the disclosure. State how data will be stored after the study is complete).*

Right to Refuse or Withdraw:

e.g., You may refuse to participate and still receive the care you would receive if you were not in the study. You may change your mind about being in the study and quit after the study has started. If the study design or use of the data is changed, you will be informed and your consent obtained for the revised research study.

Questions:

e.g., If you have any questions at this time, please ask them. If you have additional questions later, *(give name of the principal researcher or assistant)* we will be happy to answer them at *(Give an address and phone number,- in some instances, a 24-hour number should be included).* If you have concerns about this research study that you are not comfortable discussing with the principal researcher, you may also contact the Chair of the Institutional Review Board at Colby-Sawyer College (*Include contact information for the current chair of IRB found on the IRB Blackboard site).*

You will be given a signed and dated copy of this form to keep.

Your signature below indicates that you have voluntarily decided to participate in this research project as a subject and that you have read and understand the information provided above.

_____ _____

Subject's signature Date

_____

Subject's printed name

My signature as witness certifies that the subject voluntarily signed this consent form in my presence. (required only for research with greater than minimal risk)

_____ _____

Witness signature Date

_____

Witness printed name

In my judgment, the subject is voluntarily and knowingly giving informed consent to participate in this research study.

_____ _____

Investigator's signature Date

_____ _____

Investigator's printed name Date

B. Model Informed Consent Form: Anonymous Survey

Title of Project: Colors and Moods

Name of Investigator: Patti

Invitation to Participate:
You are invited to participate in this study. The following information is provided to help you make an informed decision whether or not to participate. Please read this form thoroughly before deciding if participation in the study is appropriate for you. If you have any questions about the study, please do not hesitate to ask me.

Purpose of the study:
I hope to learn if viewing different colors affects an individual's mood.

Participants:
Because you are a Colby-Sawyer College student, you have been randomly selected to participate in this study. Students who are under eighteen years of age are not eligible to participate in this study.

Procedures:
If you choose to participate in this study, you will be randomly assigned to a group and given a questionnaire to complete. Once you complete the questionnaire, please return it to me in the attached self-addressed envelope.

Timetable:
The questionnaire should take approximately fifteen minutes to complete.

Risks:
There are no known risks associated with this study. However, if while reading or completing the questionnaire you experience emotional distress and would like to discuss those feelings, the counseling staff at Baird Health and Counseling Center is available to help you. You may contact the Baird staff at 526-3621.

Should you experience any adverse events defined as physical or emotional harm as a direct or indirect result of participation in this study, report the event to the investigator, the sponsor of the study or the Chair of the Institutional Review Board.

Benefits:
As an individual, you will receive no direct benefit from the study. However, the information you provide will contribute to the general knowledge and literature of this topic. As a participant in this study, you are invited to the Senior Scholars Symposium_____.

Confidentiality:
As your name or any other identifying information will not appear on the questionnaire, the confidentiality of your responses will be protected. Any information you provide will be reported as part of the general research and not separated out. Once this study is completed, the questionnaires will be stored in my faculty sponsor Dr. _____'s office for two years before they are destroyed.

Right to Refuse or Withdraw:
Your participation in this study is completely voluntary. Should you choose not to participate in this study or change your mind once the study has begun simply submit a blank questionnaire. However, since your

questionnaire has no identifying information on it, it will be impossible to withdraw from the study once your questionnaire has been submitted.

Informed Consent:
By completing and submitting this survey, you indicate your consent to participate in the survey. If you do not wish to participate in the survey, simply place the blank survey in the envelope.

Questions:
If you have any questions at this time, please ask them. If you have additional questions later feel free to contact me, _____ 526-XXXX, or Dr. _____ at 526-XXXX and we will be happy to answer them. We can also be reached care of Colby-Sawyer College, 541 Main Street, New London, NH 03257.
If you have concerns about this research study that you are not comfortable discussing with the principal researcher, you may also contact the Chair of the Institutional Review Board at Colby-Sawyer College (*Include contact information for the current chair of IRB found on the IRB Blackboard site).*

Please keep this form for your records.

C. Model Informed Consent Form: Research with Intervention

Title: The effect of vertical jump on shot accuracy

Name of Investigator:

Invitation to Participate:
You are invited to participate in this study. The following information is provided to help you make an informed decision whether or not to participate. Please read this form thoroughly before deciding if participation in the study is appropriate for you. If you have any questions about the study, please do not hesitate to ask me.

Purpose of the study:
I hope to learn if practicing a series of short vertical leaps will improve shot accuracy at the three-point line.

Participants:
Because you are a Colby-Sawyer College student and a member of a three-on-three basketball team, you have been selected to participate in this study. Students who are under eighteen years of age are not eligible to participate in this study.

Procedures:
If you choose to participate in this study, you will be randomly assigned to either the control group or the intervention group. Initially, you will be given five basketballs and asked to shoot them sequentially from the three-point line. The percentage of shots you make will serve as the baseline for this study. If you are in the control group, you will be asked to return to the testing facility within the next three days and repeat the shots and your percentage will be recorded. If you are in the intervention group, you will be asked to return to the testing facility within the next three days. You will be asked to complete a series of five short leaps, each leap a bit greater than the last. Then you will be asked to shoot five baskets from the three-point line and your percentage will be recorded and compared with your previous percentage.

Timetable:
The time needed to participate will be approximately twenty minutes per session for the control group and the intervention group.

Risks:
The risks associated with this study are minimal. It is possible that you may experience pain in your shins while completing the intervention portion of the study. As I am trained as a first responder, I would be able to help ice your injury. Additionally, the nursing staff at Baird Health and Counseling Center is available to help you. You may contact the Baird staff at 526-3621.

Should you experience any adverse events defined as physical or emotional harm as a direct or indirect result of participation in this study, report the event to the investigator, the sponsor of the study or the Chair of the Institutional Review Board.

Benefits:
The benefits associated with this study could include you becoming more accurate as a three-point shooter. The information you provide will also contribute to the general knowledge and literature of this topic. As a participant in this study, you are invited to the Senior Scholars Symposium _____.

Confidentiality:
Any information obtained during this study, which could identify you, will be kept strictly confidential. Any information you provide will be reported as part of the general research and not separated out. Once this study is completed, it will be stored in my faculty sponsor Dr. _____'s office for two years before it is destroyed.

Right to Refuse or Withdraw:
Your participation in this study is completely voluntary. You may change your mind about being in the study and quit after the study has started. If the study design or use of the data is changed, you will be informed and your consent obtained for the revised research study.

Questions:
If you have any questions at this time, please ask them. If you have additional questions later feel free to contact me, _____ 526-XXXX, or Dr. _____ at 526-XXX and we will be happy to answer them. We can also be reached care of Colby-Sawyer College, 541 Main Street, New London, NH 03257. If you have concerns about this research study that you are not comfortable discussing with the principal researcher, you may also contact the Chair of the Institutional Review Board at Colby-Sawyer College (*Include contact information for the current chair of IRB found on the IRB Blackboard site).*

You will be given a signed and dated copy of this form to keep.

Your signature below indicates that you have voluntarily decided to participate in this research project as a participant and that you have read and understand the information provided above.

_____ _____
Participant's signature Date

_____
Participant's printed name

In my judgment, the subject is voluntarily and knowingly giving informed consent to participate in this research study.

_____ _____
Investigator's signature Date

_____
Investigator's printed name

D. Model Informed Consent Form: Consent and Assent Procedures with Children

When recruiting children for a study, researchers must develop the following:

a) letter to parents or guardians
b) parental consent form to allow the child to participate in the study
c) separate parental consent form if the parent is also being asked to participate, and
d) child assent forms or protocols.

Assent procedures with children need to take into account the child's developmental level. Developmental level refers to the child's ability to understand what they are being asked to do and to express their desire or refusal to participate.

Typically, in cases where young children are tested, parents have the option of remaining in the room with the child; have the ability to observe the child from another room, to be in an adjoining room, or to view a videotape of the procedure. Please note, in cases where a parent gives consent for a child to participate and a child refuses to provide assent, the child cannot be included in a study. Parent and child must both agree to be involved in the study.

For preverbal children or children with limited verbal and comprehension abilities (usually children from birth to 2 years): Only parental consent is required. However, in cases where the child grows very upset and can not be soothed, it is incumbent on the researcher to stop the study a) until the child can be comforted and settle, b) reschedule the child, c) terminate the procedure altogether. It is not necessary to stop a study if a child shows minor irritation or fussing.

For children between 2-5: Although written assent is not possible to obtain from younger children who do not yet know how to write their name, researchers must submit a copy of the verbal protocol that will be used to explain the study to a child. The explanation must be in basic, simple child friendly terms. The child should be given a sense of what the procedure requires them to do, roughly how long it will take and the fact that the child can refuse to participate or stop participating at any time. In cases where children receive a gift or token for participating, children who discontinue their participation midway through the procedure should still receive the token.

For children between the ages of 5-7: Children in this age range can understand a procedure that is described to them. Researchers must read the protocol to the child. Even though the child can not sign their name, a researcher can ask a child to place a checkmark on the assent form if he/she wishes to participate or an "X" if he or she does not want to participate. Some researchers may also choose to record their assent conversation with the child.

For Children between the ages of 7 and 17: A written child assent form must be provided to child participants between 7-17 years of age. For children between the ages of 12 and 17 the assent form is very similar to an adult or parental consent form.

Child Assent :

The sample assent is for a project that involves understanding how children perceive their interactions with their mother and father. Children, will be asked to a) answer questions about their interactions with their parents and b) engage in a "role play " activity using a doll house whereby children are given a scenario and need to act out an ending to the story.

Sample for the Assent. (appropriate for a 3.5-5 year old)

Hi! My name is _____ and I work here in your school. What's your name? You know what? Today I brought in some special toys and I wanted to know if you want to play a game with me and with the toys. I'm going to ask you some questions about your mommy and daddy and then I'll tell you a story and we can play with some dolls when I tell you the story. How does that sound?

Your mommy is right here and she said it would be ok if I asked you to play. (Best if mother is nearby). This game will only take us about 10 minutes to play. You know what? You get to decide if you want to play this game or not. You don't have to play this game if you don't want to and if you start playing and you want to stop you can stop whenever you want.

Do you think you might want to play this game with me for a while or would you rather stay in the room and continue what you were doing?

<u>Sample for the Assent</u>.
5-7 year

Hi! My name is _____ and I work here in your school. What's your name? You know what? Today I brought in some special toys and I wanted to know if you want to play a game with me and with the toys. I'm going to ask you some questions about your mommy and daddy and then I'll tell you a story and we can play with some dolls when I tell you the story. I just want to know how you think and feel –this is not a test and there are no right and wrong answers—it's only about your feelings so I want you to tell me whatever you feel.

Your mom and dad said it would be ok to ask you if you wanted to play this game and your teacher also told me I could ask you if you wanted to play. This game will only take us about 10 minutes to play. You can decide if you want to play this game or not. Whatever you decide is ok with me. If you decide to play and then you feel like you don't want to play anymore, we can stop playing whenever you want.

If you think you want to play this game, I'm going to ask you to make a check mark over here (show the child where) and if you don't want to do this, I'm going to ask you to make an "X " over here (show the child where).

√ **X**

I do _____want to play this game **I do not _____want to play this game**

Child's name: _____

Parent's name:_____

Parent's signature:_____

Researcher's name: _____

Researcher's signature:_____

Date: _____

Sample Child Assent for an adolescent

Title of project: _____

Name of investigator: _____ Phone: _____

Invitation to Participate: My name is _____and I study how children and think and feel about their relationships with parents and friends. I want to know if you would like to be a part of my study. You are eligible to participate in this study because I am interested in understanding how people your age think and feel about their parents. Your parents have already given their permission for you to participate in this study. If you have any questions at any time, please feel free to ask.

Purpose: We are interested in understanding why the teenagers years are hard for some teens and easier for others. In this study, we hope to learn whether childhood memories and experiences of the time teenagers have spent with their parents affects the relationships they have with their parents now as teenagers.

Procedures: If you want to be a part of this study, we will ask you to answer a series of questions about your happiest and your most difficult memories with your mom and your dad. An interviewer will also ask you some questions about the relationship you have with your mom and dad now. This will only take one 1hour session to do. The interviewer will audiotape your answers.

Right to Withdraw: You can decide if this is something you do or do not want to do. You can decide to start the study and stop whenever you want—you do not need to do the whole thing if you don't want to.

Compensation: (optional) : If you decide to do this study, you will get a free pass to six flags theme park. If you start the study and stop in the middle, you will still receive your pass.

Confidentiality: Anything that you tell us we will not tell your teachers or your parents what you have said. There are no right or wrong answers and you will not get in trouble for anything you say. We will tell your parents and teachers about what all children your age believe or think but they will have no way of knowing exactly what you think and feel. If you tell us something that makes us worried (e.g., that you will hurt yourself or someone else,) then we have to tell your parents—but this is the only time we would tell them exactly what you have said.

Risks: Sometimes it is hard for teens to feel comfortable telling these things to another person. Sometimes thinking about good and bad times with your parents can make you feel sad or angry. If you feel this way during the study you can stop answering questions, or skip any questions you don't want to answer or you can stop doing the study whenever you want. If you feel upset, the school guidance counselor will be in the room and available during and after testing.

Benefits: The reason we are doing this study and asking people your age how you think and feel about your relationships with your parents is because we hope to learn more about what makes the teen years for so many kids your age. If we can learn more about the kinds of good and bad things that many teens remember from their childhood, we can help parents understand what kids do and do not like.

You and your parents (or guardian) will be given a signed and dated copy of this form to keep.

I _____(child's name) have voluntarily decided to participate in this research project and I have read and understood what I will be asked to do. I also understand that I can stop participating whenever I want.

_____ _____

Participant's signature Date

_____

Subject's printed name

_____ _____

Investigator's signature Date

_____

Investigator's printed name

Adverse Events report form for Study Participant

Date: _____

Name: _____

Contact Information: (phone number and e-mail) _____
_____

Please complete this form if an adverse event has taken place in the context of a study in which you have participated. An adverse event is defined as any circumstance that has caused you to suffer physical or emotional injury as a result of your participation in a study. Please identify the study you participated in and the primary investigator of this study. Please describe the adverse event. Please be as specific as possible.

Name of Study: _____

Primary Investigator: _____

Adverse event:
_____
_____
_____
_____
_____
_____
_____
_____
_____

Did you report the adverse event to the experimenter?

Yes **No**

Participant's Signature: _____

Please return the completed form to the Chair of the IRB.
(*Include contact information for the current chair of IRB found on the IRB Blackboard site)*

Adverse Events Report Form for the Primary Investigator

Date: _____
Name: _____
Names of Primary investigator(s): _____
Name of Faculty Sponsor (if applicable): _____
Contact Information: (phone number and e-mail): _____
_____

Project Name and Number: _____

Please complete this form if an adverse event has taken place in the context of a study that you have conducted. An adverse event is defined as any circumstance that has caused a participant to suffer physical or emotional1njury as a result of their participation in your study. Please identify the study you conducted. Please describe the circumstances under which the adverse event took place and what you did to address the participant's situation. Please be as specific as possible.

Name of Participant(s) involved in the event:
_____

Description of the Adverse event:

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_____
_____

Primary Investigator's Signature: _____

Please return the completed form to the Chair of the IRB.
(*Include contact information for the current chair of IRB found on the IRB Blackboard site)*

Appendix A

ACSM (1995). Guidelines for Exercise Testing and Prescription. Williams and Wilkins.

ACSM Risk Stratification

Apparently Healthy: Individuals who are asymptomatic and apparently healthy with no more than one major coronary risk factor.

Increased Risk: Individuals who have signs or symptoms suggestive of possible cardiopulmonary or metabolic disease and/or two or more major coronary risk factors.

Known Disease: Individuals with known cardiac, pulmonary, or metabolic disease.

Major Coronary Artery Disease Risk Factors

1. Age — Men>45years; women>55years or premature menopause without estrogen replacement therapy.
2. Family History — MI or sudden death before 55 years of age in father or other male first-degree relative or before 65 years of age in mother or other first-degree relative.
3. Current Cigarette Smoking
4. Hypercholesterolemia — Total serum cholesterol > 200 mg/dl or HDL < 35 mg/dl
5. Hypertension — Blood pressure > 140/90 mm/Hg
6. Diabetes mellitus — Both IDDM and NIDDM
7. Sedentary Lifestyle

References

Federal Guidelines:

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U. S. Department of Health, Education, and Welfare.

Protecting Human Research Subjects, Institutional Review Board Guidebook,

National Institutes of Health, Office of Extramural Research, Office for Protection from Research Risks.

Protection of Human Subjects, Title 45 Code of Federal Regulations Part 46, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks.

IRB policies of College Miserecordia were used to develop the guidelines. College Miserecordia guidelines used the policies of the other five institutions listed below.

Amended Policies and Procedures Pertaining to Research Involving the Use of Human Subjects, Northern Illinois University, Institutional Review Board.

College Miserecordia, Institutional Review Board Polices and Procedures Involving the Use of Human Subjects in Research

Guidelines for Proposal Development and Review, All-College Review Board for Human Subjects Research, Ithaca College.

Human Subjects in Research: Institutional Review Board Policies and Procedures, Office of Research and Sponsored Programs, Central Michigan University.

Policies and Procedures of the Institutional Review Board for the Protection of Human Subjects, University of Scranton

Texas Woman's University Application to Human Subjects Review Committee, Human Subjects Review Committee, Texas Woman's University.