POLICY AND PROCEDURES

FOR RESEARCH WITH HUMAN SUBJECTS AT STATE CENTER COMMUNITY COLLEGE DISTRICT

State Center Community College District

Spring 2013

Originally compiled by

FCC Institutional Research & Effectiveness Committee

Approved by Chancellor's Cabinet 5/20/13

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Introduction

The purpose of this policy and procedures manual is to protect the rights and health of human subjects used in research investigations while promoting free inquiry and research at State Center Community College District (SCCCD) and to assure that we follow:

1. Appropriate procedures to ensure that the rights and dignity of human subjects are not violated by research projects at SCCCD; and

2. Appropriate procedures to protect the principal investigator, the investigative staff, and the college and district from potential liability in research projects involving human participants.

Ethical Principles: The Belmont Report

The basic principles that govern the Human Subject Review are described in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, also known as *The Belmont Report.*

The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, provides the philosophical underpinnings for current federal laws that govern research involving human subjects.

The primary goal of the human subject review is to ensure the protection of research subjects from undue risk and from deprivation of personal rights and dignity. This protection is best assured by consideration of the following **three principles**, which are the touchstones of ethical research involving human subjects:

1) that voluntary participation by the subjects, indicated by free and informed consent is assured;

2) that an appropriate balance exists between the potential benefits of the research to the subject or to society and the risks assumed by the subject; and

3) that there are fair procedures and outcomes in the selection of research subjects and the potential distribution of likely benefits.

SCCCD Human Subjects Review

Research projects that involve human subjects will require a review by the SCCCD's Institutional Research Group (IRG) for the Protection of Human Subjects to determine that adequate measures have been taken to protect the subjects involved in the research.

Applicability

All research involving human subjects (defined below) conducted under the auspices of SCCCD and any of its auxiliary organizations is covered under this policy.

Definitions

Research

Research is an investigation or experimentation aimed at the demonstration, discovery or interpretation of new facts; the revision of accepted theories, or laws in the light of new facts; or the practical application of new or revised theories or laws. Research includes, but is not limited to, investigations conducted by faculty members, staff, and students and includes collaboration with researchers outside the college. "Pilot studies" are defined as research.

Human Subjects

Any person who is studied in any research investigation is considered to be a human subject. Subjects may include, but are not limited to, classroom participants or voluntary participants in behavioral studies or oral or written interviews, donors of fluid and tissues, participants in a clinical setting (the "unborn" are human subjects), or students registered in a course for which academic credit is given for participation in research projects. The use of a departmental pool of subjects does not exempt the principal investigator from compliance with the **Policy and Procedures**.

Human subjects also include any living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

> **Intervention** includes both physical procedures by which specimens 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.
>
> **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect no observation or recording to be taking place. 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 known or may readily be ascertained by the investigator) in order to constitute research involving human subjects.

Faculty/Staff and Student Research

Research conducted by faculty/staff solely for assessment of course/program outcomes or improvement purpose is usually not reviewed by the IRG. Research conducted by students for a class project will also not be reviewed. However, if such research may be reasonably foreseen to involve any aspect of the ethical dimensions of this policy, the investigator must submit the project for human subject review.

Human Subjects Review Categories

A specific determination must be made in each instance as to whether the research is classified as **Exempt**, **Expedited Review**, or **Full Review** (defined below), and thus covered by different aspects of policies and procedures delineated in this document. Each investigator must provide the review board with sufficient information for an informed judgment about risk level to human subjects involved in the research.

EXEMPT Submission

Introduction/Definition

The following types of research may be exempt from extensive board review if proper procedures to assure confidentiality are evident, informed consent is provided, and participants are exposed to no more than minimal risk. Federal Register defines **minimal risk** to mean 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.

Please review the EXEMPT categories to determine if your research qualifies for EXEMPT status (pages 5-6). You will be asked to cite the appropriate exemption number next to the EXEMPT box on the Proposal Submission Form.

EXEMPT Categories

The following research projects are exempt from full review by the IRG on the Protection of Human Subjects; however, there are some exceptions for special populations. Category 5 is not applicable to research involving pregnant or nursing (breastfeeding) women, prisoners, or the institutionalized mentally disabled. A standard proposal must be submitted for those reviews. Category 6 does not apply to research involving children.

1. Research conducted in established or accepted educational settings using standard educational practices, such as comparison among instructional techniques, curricula, or management methods.

2. Research involving the information taken from educational tests (cognitive, diagnostic, aptitude, achievement) that is recorded in such a manner that makes identification of the subjects impossible.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are routinely available to the investigator, and are recorded by the investigator in such a manner

that makes identification of the subjects impossible.

4. Research involving survey or interview procedures when the respondents are elected or appointed public officials or candidates for public offices.

5. Research involving the observation (including observation by participants) of public behavior in places where there is no recognized expectation of privacy.

6. Research involving survey or interview procedures that do not produce psychological stress in which the subjects are legally competent, and in which the investigator identifies him or herself stating that he or she is conducting a research survey or interview.

Categories 5 and 6 are not exempt if responses or observations are recorded in such a manner that the subjects can be identified and the information, if it became known outside the research, could reasonably place the subject at risk of criminal or civil liability, could damage to the subject's financial standing or employability, or could expose a sensitive aspect of a subject's behavior, such as illegal conduct, sexual behavior, or use of alcohol or controlled substances.

Submission of EXEMPT Proposals

EXEMPT proposals must include the following:

1. A completed Submission Form (See Appendix A, Page 13);

2. Research proposal; and

3. All instruments/materials used for your research project (including surveys, interview scripts, etc.).

Review of EXEMPT Research Proposals

1. Completed proposals should be submitted to the college/district researcher. For research which will be conducted at a specific college, proposals should be submitted to the college researcher. For research which will be conducted districtwide, proposals should be submitted to the district researcher. The college/district researcher will verify stated exemption category or categories of your research. The college researcher will notify you of the status of your proposal. You may not begin your research until you receive the approval notification from the board.

2. Once approved, your research will not need additional review unless you make modifications to your original proposal submission (see Proposal Modifications, Appendix B, page15).

3. If the college/district researcher determines that your proposal is not EXEMPT or needs clarification/modification, you will be notified and given instructions on how to proceed.

4. After your proposal is approved, the college/district researcher will inform the appropriate supervisor about your research.

EXPEDITED REVIEW Submissions

Introduction/Definition

If your project involves only minimal risk to human subjects, but does not meet one of the six exemption criteria, your project may qualify for EXPEDITED review. Federal Register defines **minimal risk** to mean 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.

Submission of EXPEDITED REVIEW

EXPEDITED protocols must include the following:

1. A completed Proposal Submission Form (See Appendix A, Page 13);

2. Research proposal; and

3. All instruments/materials used for your research project (including surveys, interview scripts, etc.).

Review of EXPEDITED Research Proposals

1. Completed proposals should be submitted to the college/district researcher for review by the college/district researcher and another IRG member. For research which will be conducted at a specific college, proposals should be submitted to the college researcher. For research which will be conducted districtwide, proposals should be submitted to the district researcher. The college/district researcher will notify you when your proposal is approved. You may not begin your research until you receive the approval notification .

2. If the IRG places a conditional approval on your proposal, you will not receive official approval until you submit the requested modifications to the IRG. Once you have met those conditions, your proposal will be reviewed again and you will be notified of the status of the review.

3. If the college/district researcher determines that your proposal does NOT qualify for EXPEDITED review and requires FULL REVIEW, you will be notified and given instructions on how to proceed.

4. Once your protocol is approved, the college/district researcher will inform the appropriate supervisor where you will conduct the research.
5. If at any time you modify your research proposal, you must submit those changes to the college/district researcher for review and approval (see Proposal Modifications, Appendix B, page15).

6. If your research continues for longer than one year, you will need to submit an

ANNUAL PROGRESS REPORT (see Annual Progress Report, Appendix C, page17).

FULL REVIEW Protocol Submissions

Introduction/Definition

If your research involves more than minimal risk to subjects as defined previously, your project requires a FULL REVIEW by IRG. Research involving any of the following will also require FULL REVIEW:

- Minor subjects (children 17 years of age or younger).
- Special populations (prisoners, pregnant women, individuals with disabilities).
- The use of video- or audiotape to record subjects.
- Research studies that include monetary compensation for participants.
- Research projects that involve potentially sensitive, personal, or incriminating information or that could place participants at risk, physically, psychologically, emotionally, or legally.
- The research involves survey or interview procedures that include responses that are recorded in such a manner as to allow for identification of the participant.
- The research deals with sensitive aspects of the participant's behavior such as those instances in which embarrassment or danger would result for the participants should these behaviors become known.
- Procedures are used that might cause physical harm to research participants.
- Procedures are used that might cause emotional distress to participants.
- Participants will be administered chemical substances, including drugs and pharmaceuticals.
- Physical stimuli are administered, such as: ambient pressure, cold or wind, electric shock, gravitational fields, heat or humidity, ionizing radiation, magnetic fields, noise, nonionizing radiation, e.g. ultraviolet, visible light, infrared radiation, microwaves, vibration, etc.
- Participants are exposed to sensory deprivation, sleep deprivation, exhaustive physical activity or special diets.
- Adult participants or guardians/designees are not able to give free and informed consent.
- Participants are required to participate in activities that may be illegal or are likely to offend prevailing standards of morality.
- The research involves deception that could reasonably cause emotional or physical harm to the participants.
- Exposing subjects to graphically violent or pornographic materials.
- Placing individuals in confining physical settings or attaching other devices.
- Leaving subjects alone for periods of time longer than 20 minutes.
- Taking human tissue samples, drawing blood, or sampling any other bodily fluid.

Submission of FULL REVIEW

Protocols for research, which require FULL REVIEW by the IRG, must contain the following:

1. A completed Submission Form (See Appendix A, Page 13)

2. Research proposal; and

3. All instruments/materials used for your research project (including surveys, interview scripts, etc.).

Review of FULL REVIEW Research Proposals

1. If your project requires FULL REVIEW, you must submit your proposal to the college/district researcher one week before the IRG meeting when you would like it considered. The IRG requires your attendance at the IRG meeting to provide any clarification the group may need.

2. At the meeting, the IRG may **approve**, **conditionally approve**, **reject**, or **table** (e.g. due to insufficient information, concern about the research, etc.) your research proposal.

3. All meetings are contingent upon a quorum (including at least one member whose primary concerns are in nonscientific areas) of members attending.

4. After the meeting, the college researcher will notify you of the status of your proposal. If the IRG places a conditional approval on your proposal, you will not receive official approval until you submit the requested modifications to the IRG. Once you have met those conditions, your proposal will be reviewed again and you will be notified of the status of the review.

5. Once your proposal is approved, the college/district researcher will inform the appropriate supervisor where you will conduct the research.

6. If at any time you modify your research proposal, you must submit those changes to IRG for further review (see Proposal Modifications, Appendix B, page15).

7. If your research continues for longer than one year, you will need to submit an ANNUAL PROGRESS REPORT (see Annual Progress Reports, Appendix C, page17).

Length of Time for Review Process

1. Exempt and Expedited Proposals

When new individual research proposals reach the IRG, exemptions and expedited proposals will be processed within 10 working days.

2. Full Review Proposals

Full review proposals should be forwarded to the chair of the IRG. Investigator will be informed within the 10 days of receiving the research proposals that the proposal will be or will not be reviewed by the board. The chair has 30 days to convene a meeting of the full board.

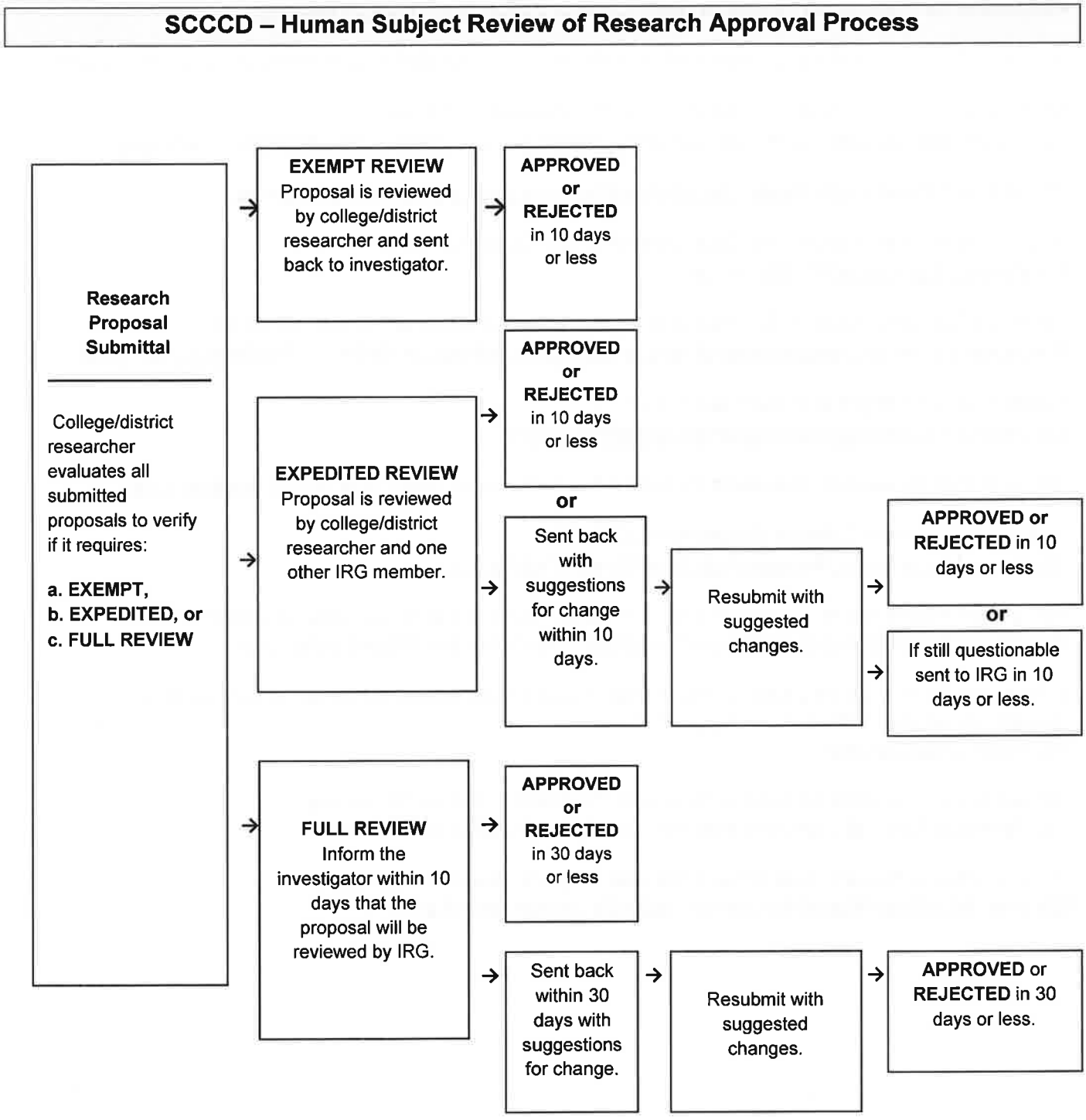
Note: Under exceptional circumstances, delays may be incurred if the IRG requires additional information from the investigator(s).

Requesting Sensitive Information

Research that is determined to collect private or *sensitive information* will need to be in compliance with district Academic Regulation AR 5040 regarding Student Records and Privacy. Once the research proposal is approved through the SCCCD human subject review, such information will only be released to research conducted or sponsored by faculty/staff at SCCCD or the district. *Sensitive information* includes but is not limited to the following:

1. Student or employee records, such as name, Social Security Number and/or Datatel student/employee identification number, and personal contact information.
2. Individual student grade data.
3. Information that would lead to the statistical identification of individual persons.
4. Information relating to sexual attitudes, preferences, or practices.
5. Information relating to the use of alcohol, drugs, or other addictive products.
6. Information pertaining to illegal conduct.
7. Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
8. Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community.
9. Information pertaining to an individual's psychological well-being or mental health.
10. Information in other categories, not listed here, might also be considered sensitive because of specific cultural or other factors, and protection can be granted in such cases upon appropriate justification and explanation.

Human Subject Review Flow Chart



References

Association for Institutional Research (AIR) Code of Ethics, http://www.airweb.org

American Psychological Association (APA) Code of Ethics, http://www.apa.org/ethics/code/index.aspx

American Educational Research Association (AERA) Code of Ethics, http://www.aera.net/AboutAERA/KeyPrograms/SocialJustice/ResearchEthics/tabid/10957/Default.aspx

The Belmont Report, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

NCES (1999). Best Practices for Data Collectors and Data Providers, http://nces.ed.gov/pubs99/1999191.pdf

California Education Code (CEC) Sections 76240-76246 (Privacy of Student Records), http://www.leginfo.ca.gov/cgi-bin/displaycode?section=edc&group=76001-77000&file=76240-76246

Family Education Right to Privacy Act (FERPA), http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

The Joint Commission on Standards for Education Evaluation, http://www.wmich.edu/evalctr/jc/

Protection of Human Subjects Guidelines 45CFR46, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Policy and Procedures for Research with Human Subjects at California State University, Fresno, http://www.fresnostate.edu/academics/humansubjects/policy-procedures/index.html

Institutional Review Board (IRB) for the Protection of Human Subjects Policies and Procedures Manual, University of Wisconsin-Green Bay, http://www.uwgb.edu/irb/

Policies and Procedures for Human Research Protection, Harvard University, http://www.fas.harvard.edu/~research/hum_sub/index.html#pandp

Human Subjects Review Board Policy Manual, Roger Williams University, http://rwu.edu/sites/default/files/human_subjects_review_board.pdf

Appendix A

SCCCD REVIEW OF RESEARCH FOR THE PROTECTION OF HUMAN SUBJECTS

PROTOCOL SUBMISSION FORM

Project Information

Project Title:

Principal Investigator:

Organization or Department:

Phone: **E-mail:** **(all correspondence will be with the principal investigator)**

Co-investigator(s):

Estimated Start Date: mm/dd/yyyy
Note: This date should follow IRG review. Please allow at least 10 days for exempt or expedited reviews. Protocols requiring approval from full board will be reviewed at our next meeting.

Estimated Completion Date: mm/dd/yyyy
Note: Projects continuing for longer than one year will require an Annual Progress Report.

Determination of Risk/Review Status

For a description of the review categories, please see the *IRG Policies and Procedures Manual* or see "Determining if a Project is Exempt, Expedited or Requiring Full Review" on the -SCCCD IR website.

Check the Appropriate Review Category for this Project (check one):

- ☐ **Full Board Review**
- ☐ **Expedited Review**
- ☐ **Exempt. If exempt, indicate the exemption number: (exemption numbers can be found in the *IRG Policies and Procedures Manual* or here)**

- ☐ **Check this box to indicate that all investigators involved in this project have read *The Belmont Report* (can be found on the SCCCD IR website).**
- ☐ **Check this box to indicate that all investigators involved in this project have read the -SCCCD *Human Subject Review Policies and Procedures* (can be found on the SCCCD IR website).**
- ☐ **Check this box to indicate that you will safeguard the identify of participants and all information collected for this research.**

Signature(s)

Signing this document indicates that you have read and are familiar with the research protocol described above.

Name and Signature of Principal Investigator:	**Signature(s)**	**Date(s)**
1.	_____	_____

Name(s) and Signature(s) of Co-Investigator(s):

1.	_____	_____
2.	_____	_____
3.	_____	_____

Submission Instructions

For electronic submissions:

- Email a PDF of the entire proposal to the college/district researcher via email .
- The proposal must be sent as one complete document, must include all relevant forms, and must be signed by all investigators involved.

For paper submissions

- Mail the entire proposal to the college/district researcher. The proposal must include all relevant forms and must be signed by all investigators involved.

For IRG Review Use Only

Review Status

☐ **Approved**

☐ **Resubmit – Conditional approval**

☐ **Rejected**

Signature of the Reviewer_____

Date_____

Appendix B
SCCCD REVIEW OF RESEARCH
FOR THE PROTECTION OF HUMAN SUBJECTS

PROTOCOL MODIFICATION FORM

Project Information

Project Title:

Principal Investigator:

Organization or Department:

Phone: **E-mail:** **(all correspondence will be with the principal investigator)**

Co-investigator(s):

Estimated Start Date: mm/dd/yyyy

Note: This date should follow IRG review. Please allow at least 10 days for exempt or expedited reviews. Protocols requiring approval from full board will be reviewed at our next meeting.

Estimated Completion Date: mm/dd/yyyy

Note: Projects continuing for longer than one year will require an Annual Progress Report.

Protocol Modification

Please describe all modifications you will be making to your protocol including the addition or removal of investigators, changes in participant recruitment, etc.

Signature(s)

Signing this document indicates that you have read and are familiar with the research protocol described above.

Name and Signature of Principal Investigator:	**Signature(s)**	**Date(s)**
1. **Name(s) and Signature(s) of Co-Investigator(s):**	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____

Submission Instructions

For electronic submissions:

- Email a PDF of the entire proposal to the college/district researcher via email. The proposal must be sent as one complete document, must include all relevant forms, and must be signed by all investigators involved.

For paper submissions

- Mail the entire proposal to the college researcher. The proposal must include all relevant forms and must be signed by all investigators involved.

Appendix C
SCCCD REVIEW OF RESEARCH
FOR THE PROTECTION OF HUMAN SUBJECTS

PROTOCOL PROGRESS REPORT FORM

Project Information

Project Title:

Principal Investigator:

Organization or Department:

Phone: **E-mail:** **(all correspondence will be with the principal investigator)**

Co-investigator(s):

Estimated Start Date: mm/dd/yyyy

Note: This date should follow IRG review. Please allow at least 10 days for exempt or expedited reviews. Protocols requiring approval from full board will be reviewed at our next meeting.

Estimated Completion Date: mm/dd/yyyy

Note: Projects continuing for longer than one year will require an Annual Progress Report.

Project Status

Estimated Completion Date: Click here to enter a date.

Please describe the following:

1. **Any adverse events or unanticipated problems involving risks to participants or others:**

2. **Any withdrawal of participants from research or complaints about the research:**

3. **Any modifications you will be making to your original protocol:**

Signature(s)

Signing this document indicates that you have read and are familiar with the research protocol described above.

Name and Signature of Principal Investigator:	**Signature(s)**	**Date(s)**
1.	_____	_____
Name(s) and Signature(s) of Co-Investigator(s):		
2.	_____	_____
3.	_____	_____
4.	_____	_____

Submission Instructions

For electronic submissions:

- Email a PDF of the entire proposal to the college/district researcher The proposal must be sent as one complete document, must include all relevant forms, and must be signed by all investigators involved.

For paper submissions

- Mail the entire proposal to the college/district researcher. The proposal must include all relevant forms and must be signed by all investigators involved.

Appendix D

Ethical Guidelines for Research with Human Subjects
Of the American Psychological Association

The decision to undertake research rests upon a considered judgment by the individual psychologist about how best to contribute to psychological science and human welfare. Having made the decision to conduct research, the psychologist considers alternative directions in which research energies and resources might be invested. On the basis of this consideration, the psychologist carries out the investigation with respect and concern for the dignity and welfare of the people who participate and with cognizance of federal and state regulations and professional standards governing the conduct of research with human participants.

A. In planning a study, the investigator has the responsibility to make a careful evaluation of its ethical acceptability. To the extent that the weighing of scientific and human values suggests a compromise of any principle, the investigator incurs a correspondingly serious obligation to seek ethical advice and to observe stringent safeguards to protect the rights of human participants.

B. Considering whether a participant in a planned study will be a "subject at risk" or a "subject at minimal risk," according to recognized standards, is of primary ethical concern to the investigator.

C. The investigator always retains the responsibility for ensuring ethical practice in research. The investigator is also responsible for the ethical treatment of research participants by collaborators, assistants, students, and employees, all of whom, however, incur similar obligations.

D. Except in minimal-risk research, the investigator establishes a clear and fair agreement with research participants, prior to their participation, that clarifies the obligations and responsibilities of each. The investigator has the obligation to honor all promises and commitments included in that agreement. The investigator informs the participants of all aspects of the research that might reasonably be expected to influence willingness to participate and explains all other aspects of the research about which the participants inquire. Failure to make full disclosure prior to obtaining informed consent requires additional safeguards to protect the welfare and dignity of the research participants. Research with children or with participants who have impairments that would limit understanding and/or communication requires special safeguarding procedures.

E. Methodological requirements of a study may make the use of concealment or deception necessary. Before conducting such a study, the investigator has a special responsibility to (1) determine whether the use of such techniques is justified by the study's prospective scientific, educational, or applied value; (2) determine whether alternative procedures are available that do not use concealment or deception; and (3) ensure that the participants are provided with sufficient explanation as soon as possible.

F. The investigator respects the individual's freedom to decline to participate in or to withdraw from the research at any time. The obligation to protect this freedom requires careful thought and consideration when the investigator is in a position of authority or influence over the participant. Such positions of authority include, but are not limited to, situations in which research participation is required as part of employment or in which the participant is a student, client, or employee of the investigator.

G. The investigator protects the participant from physical and mental discomfort, harm, and danger that may arise from research procedures. If risks of such consequences exist, the investigator informs the participant of that fact. Research procedures likely to cause serious or lasting harm to a participant are not used unless the failure to use these procedures might expose the participant to risk of greater harm or unless the research has great potential benefit and fully informed and voluntary consent is obtained from each participant. The participant should be informed of procedures for contacting the investigator within a reasonable time period following participation should stress, potential harm, or related questions or concerns arise.

H. After the data are collected, the investigator provides the participant with information about the nature of the study and attempts to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding this information, the investigator incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant.

I. Where research procedures result in undesirable consequences for the individual participant, the investigator has the responsibility to detect and remove or correct these consequences, including long-term effects.

J. Information obtained about a research participant during the course of an investigation is confidential unless otherwise agreed upon in advance. When the possibility exists that others may obtain access to such information, this possibility, together with the plans for protecting confidentiality, is explained to the participant as part of the procedure for obtaining informed consent.

Appendix E

Research Proposal Guidelines

The proposal format for research investigations involving human subjects is included in this section. Researchers should provide sufficient elaboration in order to facilitate a speedy review.

Researchers need to type all responses and be as non-technical as possible, avoiding jargon. Researchers should also keep in mind that the proposal will be read by people outside of their field. Unless otherwise indicated, all questions must be answered for specific projects.

A. Faculty/Staff/Graduate Student New Individual Research Projects

1. Project Description

State the purpose of the research and rationale. Indicate what participants will be told, what will be done to them, and what they will have to do.

2. Participants

If the subjects are from a special population, such as children and prisoners, researchers should see Section XIII of this document before writing a proposal. If the participants are mentally or physically disabled, or are institutionalized, particular care is required to ensure that participation is not coerced and participants' rights are protected. If advertisements are used to recruit subjects, copies of the ads must be included with the proposal.

3. Research Procedures and Methodology

This section provides a comprehensive description of the research methodology including:

- Setting of the research study
- Procedures
- Data collection
- Data analysis
- How participants will be affected by the research.

In this section describe any illegal activities and/or deception that may be involved in the research. Also include why these methods are necessary. The use of deception in no way reduces the need for informed consent. Deception includes not only the presentation of false information to subjects, but also the intentional withholding of information in a manner designed to mislead subjects. Under no condition can deception involve the withholding or falsification of information likely to affect the willingness of subjects to participate in the research.

- If monetary payment is used, it may be considered a benefit to the subject. However, neither the amount of payment nor the method of disbursement should present problems of coercion or undue influence. Such problems might occur, for example, if the entire payment were contingent upon completion of the study or if the payment were unduly large.

- Finally, in an appendix include any informal and formal testing instruments, surveys, questionnaires, etc. Citations are also necessary if you are using published materials.

4. Consent Procedures

Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. Submit a copy of the written consent form. See *Section IX* for informed consent procedures. For subjects not able to provide informed consent themselves, written informed consent must be obtained from others (e.g., parents, guardians, etc.) *Section IX* also addresses informed consent of children and prisoners. In all cases, describe how informed consent will be obtained. If the subjects are children or challenged mentally/emotionally, describe how their "assent" will be obtained.

5. Data Confidentiality

Maintaining anonymity is an ethical consideration. Describe how you will report the findings of the research while maintaining participants' confidentiality.

6. Risks /Discomfort to the Participants

Participants are at risk if they are exposed to the possibility of physical, mental, or social discomfort, harm or danger, or otherwise beyond minimal risk. If subjects are at risk, describe all steps to minimize risk, and, if necessary, attach a justification for these procedures based on the scientific literature.

7. Benefits of the Study

Anticipated benefits to any one individual or society should be described such that a risk/benefit judgment may be made.

8. Signatures

All investigators must read and sign the cover sheet assuring compliance with the ethical code for researchers.

9. Appendix

Attach any additional sheets, along with any supporting documents (e.g., consent forms, instruments, questionnaires, tests, interview protocols, etc.) to the Research Proposal Form, if appropriate.

Appendix F

Meeting Protocols for Full-Review of Human Subjects Research

- Research that will present more than minimal risk to the subjects must be reviewed at a convened meeting of the college's IRG.
- At the meeting, the investigator is required to be present at the IRG meeting when the project is reviewed.
- The review begins with a short (maximum of five minutes) summary of the research by the investigator, after which board members ask any questions they have.
- When a student presents a research proposal to the IRG, his or her faculty advisor must also attend the meeting.
- Proposals must be submitted to IRG at least ten working days before an IRG meeting for review at that meeting.
- The number of proposals to be reviewed at each meeting may be limited due to time constraints and the complexity of other items on the agenda.
- The proposal will be accepted for review in the order received. If the IRG is not able to review a proposal in a particular month, it will be given priority for review in the following month.
- The IRG may approve, table, reject, or require modifications to secure approval of the proposal.
- Changes that are substantive in nature must be brought back to the IRG at a convened future meeting.
- All meeting discussions are confidential and cannot be disclosed to others.

Appendix G

Guiding Principles for Data Collection, Storage, Sharing, and Use to Ensure Security and Confidentiality

- Data should be acquired, used, disclosed, and stored for research and educational purposes only.
- Investigators should collect the minimum amount of personally identifiable information necessary to conduct research.
- Investigators should protect the privacy and security of personally identifiable data.
- Data collection and use policies should reflect respect for the rights of individuals and community groups and minimize undue burden.
- Investigators should have procedures to ensure the quality of any data they collect or use.
- Investigators have the obligation to use and disseminate summary data to relevant stakeholders in a timely manner.
- When the research data are disseminated, data are shared only in a highly aggregated format. No individual data should be identified for any form of data sharing.
- Investigators should share data for legitimate research and education purposes and may establish data-use agreements to facilitate sharing data in a timely manner.
- Research data should be maintained in a secure environment and transmitted through secure methods.
- Minimize the number of persons and entities granted access to identifiable data.

Reference:

Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2011

http://www.cdc.gov/nchhstp/programintegration/docs/PCSIDataSecurityGuidelines.pdf