SOUTHWESTERN COLLEGE

Southwestern Community College District Institutional Research Review Board (IRRB)

Guidelines and Procedures

Office of Institutional Research & Planning
Revised January 2022

Any person or entity proposing to use Southwestern Community College District students, employees, or their educational or employee records in any research must submit a proposal to the Institutional Research Review Board. Please contact Bill Abasolo, Director of Institutional Planning, Research & Grants, at (619) 216-6614 or gabasolo@swccd.edu for more information.

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SOUTHWESTERN COMMUNITY COLLEGE DISTRICT
INSTITUTIONAL RESEARCH REVIEW BOARD

Introduction

The Southwestern Community College District (SWCCD) Institutional Research Review Board (IRRB) developed this guide to assist any person or entity engaged in research (hereafter researcher) understand their responsibilities. This guide is intended to introduce researchers to the IRRB, clarify the research review process, and simplify the preparation and review of research protocols.

IRRB Mission

The mission of the IRRB is to protect the rights and welfare of human subjects participating in research. The IRRB is responsible for reviewing and monitoring all research that involves human subjects to ensure that researchers are supporting the college's mission and fulfilling their legal[1] and ethical obligations.

IRRB Accountability

The IRRB is organized in the Office of Institutional Research and Planning under the Dean of Institutional Research and Planning. The IRRB acts according to the regulations set forth by the United States Department of Health and Human Services (DHHS) that relate to the ethical standards of research involving human subjects (45 CFR 46) and all applicable state laws and institutional policies. Every 5 years, or as needed, the IRRB files a federal wide assurance with the Office of Human Research Protection (OHRP) to ensure that SWCCD is adhering to the federal guidelines as outlined by DHHS. Compliance with these federal regulations not only safeguards human subjects and the institution sponsoring the research project, but also protects the researcher.

[1] Title 45 CFR Part 46, Protection of Human Subjects.
Title 34 CFR Part 99, Family Educational Rights and Privacy (FERPA).
California Education Code, Section 76240-76246.
Southwestern Community College District Policy No. 5040, Student Records and Directory Information

IRRB Guidelines

In order to approve research involving human subjects, the IRRB review shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized by using procedures consistent with sound research design and ethical procedures.
2. Risks are reasonable in relation to anticipated benefits.
3. Selection of subjects is equitable.
4. Informed consent is obtained from each prospective subject or the subjects legally authorized representative in accordance with the federal policy for the protection of human subjects.
5. Informed consent will be appropriately documented or appropriately waived in accordance with the federal policy for the protection of human subjects.
6. When appropriate, there are adequate provisions for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

The IRRB recognizes the following definition of *minimal risk*, as defined by the Office for Human Research Protections:

> "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

The IRRB recognizes the following definition of *human subject*, as defined by the Office for Human Research Protections:

> "Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

The IRRB recognizes the following definition of *private information* and *identifiable private information*, as defined by the Office for Human Research Protections:

> "Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recoding is taking place, and information that has been provided for specific purposes by an individual and the individual can reasonably expect will not be made public (e.g., a medical record)."
>
> "Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information."

The IRRB recognizes the following definition of *research*, as defined by the Office for Human Research Protections:

> "A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

A research protocol must be reviewed by the IRRB under these guidelines if it meets all three of the following criteria:

1. It involves human subjects as defined above.
2. It is research as defined above.
3. The intention to publish or disseminate results or the possibility of publishing or disseminating results exist.

Responsible Conduct of Research

It is the responsibility of all researchers that engage in research to preserve the integrity of science. All researchers engaged in research involving human subjects must complete educational training prior to initiation of a research project and must abide by SWCCD policy and relevant government regulations for protecting human subjects. This includes the ethical principles set forth in the Belmont Report.

The Belmont Report recognizes these ethical principles;

Respect for Persons: Individuals should be treated as autonomous agents whose opinions and choices are valued. Individuals with diminished autonomy (e.g., minors, prisoners, persons with a mental disability) are entitled to additional protections. This principle embodies the concept of informed consent whereby individuals enter research voluntarily, have sufficient information to make an informed decision about participation, and are free from coercion or undue influence from the researchers.

Beneficence: Human research must be designed and implemented to minimize harms to subjects and maximize possible benefits whether for subjects, science, or society. This principle requires that research be justified based on a favorable risk/ benefit assessment. These assessments consider:

- The probability and magnitude of psychological, physical, legal, social, and economic harms.
- The risks and benefits of alternatives to the research.
- The reasonableness of seeking certain benefits despite the risks
- Determine when the potential benefits may not sufficiently justify risks to subjects

Justice: In human research justice relates to "fairness in distribution" and "what is deserved". This principle requires that research subjects receive benefits in equal measure to the burdens of the research. Determinations about justice require scrutiny of subject selection and enrollment processes. Sample populations should be selected for reasons related to the problem being studied. Particular populations (e.g., welfare patients, racial and ethnic minorities, or persons with limited freedoms) should not be targeted because of ease of access, manipulability, or the convenience of investigators.

Reporting Complaints, Protocol Deviations, and Unanticipated Problems Involving Risks to Participants or Others

Complaints: Situations may occur during implementation of a study, after a subject withdraws or completes their participation, or after study completion that warrant assessment and possibly review by the IRRB. These include complaints from subjects or others, unapproved changes in the protocol of a study, serious events or problems experienced by subjects, new information that suggests research risks or benefits have changed, breaches of subject privacy or data confidentiality, and sponsor or other external reports that suggest a problem may exist.

Anyone (i.e., subjects, members of the community, researchers, research staff, etc.) may report complaints, potential noncompliance, or concerns related to a research project by contacting any member of the IRRB or members of the research team. Complaints may be submitted anonymously.

For non-exempt research, researchers or others who know of a complaint must notify the IRRB within five business days of learning of a complaint, deviation, potential noncompliance, or other non-life-threatening problem. If the problem may be life-threatening, it must be reported within 48 hours.

For exempt research, researchers or others who know of a complaint or problem are advised to contact the IRRB to discuss problems that may have occurred.

Protocol Deviations: a protocol deviation is any change from the study procedures as specified in the IRRB approved protocol. Examples include enrolling a participant who did not meet all inclusion/ exclusion criteria, failing to obtain or document informed consent, failing to report unanticipated problems, adding co-investigators without prior authorization, etc.

All deviations reflect a failure to comply with the approved protocol and are instances of potential noncompliance that must be reported to the IRRB. For non-exempt research, researchers must notify the IRB within five business days of learning of a protocol deviation. If the deviation occurred because of a problem that may be life-threatening, it must be reported within 48 hours.

For exempt research, researchers are advised to contact the IRRB to discuss any protocol deviations.

The IRRB provides a form for the modification of a protocol on the website. The modification approval form must be submitted to the IRRB before a modification to the approved protocol can be made unless the modification is being made in response to a potentially life-threatening problem. If the modification is in response to a potentially life-threatening problem both the modification and the problem must be reported in 48 hours.

The request for modification will be reviewed at the next convened meeting of the IRRB. Correspondence will be sent to the principal investigator and listed co-investigators regarding the IRRB's decision.

Unanticipated Problems Involving Risks to Participants: Researchers must notify the IRRB of unanticipated problems that involve risks to participants or others (unanticipated problems). Unanticipated problems may encompass physical, psychological, social, legal, and economic harms, or harms to dignity and unexpected threats to privacy or safety.

To be considered an unanticipated problem an event or situation must:

- Be unexpected in terms of nature, severity, or frequency given (1) the research procedures that are described in the protocol-related documents; and (2) the characteristics of the population being studied.
- Be related or possibly related to participation in the research
- Suggest that the research places participants or others at a greater risk of harm than was previously known or recognized.

The following incidents are likely to constitute an unanticipated problem in the context of research:

- A laptop containing identifiable subject data is stolen and the data is not encrypted
- Changes to research protocol are made without prior IRB approval to eliminate apparent immediate risks.

Researchers must notify the IRRB within five business days of learning of a non-life-threatening unanticipated problem. If the problem may be life-threatening, it must be reported within 48 hours.

The IRRB provides a form for reporting complaints and unanticipated problems on the website.

Noncompliance

Noncompliance means significant failure by a researcher to abide by SWCCD policy and relevant government regulations for protecting human subjects in research. Instances of noncompliance would include, but are not limited to, beginning research before securing IRRB approval, misuse or non-use of approved consent forms, failure to secure IRRB approval before introducing changes in an on-going protocol, and continuing to gather study data from subjects after IRRB approval expires.
For information about who may report and how to report incidents or actions that may constitute noncompliance, see the above procedure for Reporting Complaints, Protocol Deviations, and Unanticipated Problems.

Ramification for Noncompliance

Ramifications for noncompliance with SWCCD policy and relevant government regulations for protecting human subjects in research includes:

- Funding may be withheld: Federal and most private sponsors require IRB approval as a condition of funding.
- Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication.
- Liability issues arising from unapproved research may become the responsibility to the researcher. Researchers conducting unapproved research are deemed to be acting outside the scope of authority granted to them by SWCCD.
- Suspension of research: SWCCD may suspend all research activities for an indefinite time frame as a disciplinary measure or may require the mandatory destruction of all research data collected during a project.
- Disciplinary action in accordance with SWCCD policy.

Suspension or Termination of IRRB Approval

The SWCCD IRRB has the authority to suspend or terminate IRRB approval of research that is not being conducted in accordance with IRRB requirements or that may pose unexpected, serious harm to participants. This authority is retained regardless of whether the research was approved via Full Review, Expedited Review, or is classified as Exempt.

The IRRB considers the best interests of research participants in deciding whether to halt a research study temporarily or permanently. The IRRB will require that procedures for withdrawal of enrolled participants consider their rights and welfare (e.g., planning for medical care, transfer to another researcher, or continuation under independent monitoring).

Suspension by the IRRB: Suspension is a determination made by the SWCCD IRRB to temporarily withdraw IRRB approval for some or all activities of a currently approved research study.
The convened IRRB may suspend approval for some or all activities for a research project. The research may be suspended following a report of a problem, during an investigation of noncompliance or unanticipated problem, or following review of noncompliance or unanticipated problem.

The IRRB Chair has the authority to suspend some or all research activities immediately if exceptional participant safety issues are identified. This authority is only exercised if an action is required prior to a convened meeting, and it is not feasible to assemble an emergency meeting. When this authority is exercised, it will be reported at the next convened IRRB meeting. Correspondence will be sent to the Principal Investigator as well as listed co-investigators regarding the IRRB's decision.

Termination by the IRRB: A fully convened IRRB may terminate a research project when it determines that cessation of all research activities is in the best interest of participants. Studies may be terminated during IRRB review for noncompliance or an unanticipated problem. Correspondence will be sent to the Principal Investigator and all listed co-investigators regarding the IRRB's decision.

IRRB Review of Research

The SWCCD IRRB reviews human subjects research at the following three review levels:

1. Exempt Review – To qualify, research must fall into one of eight federally-defined exempt categories. These categories present the lowest amount of risk to subjects because they involve collection of anonymous or publicly available data or conduct of the least potentially harmful research experiments.
2. Expedited Review – To qualify, research must fall into one of the nine federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects.
3. Full Review – All research that do not fall into either the exempt or expedited review categories or deal with special concerns or vulnerable populations. Full Review requires that all members of the IRRB be convened at a scheduled meeting.

Correspondence will be sent to the Principal Investigator and all listed co-investigators regarding the IRRB's decision.

Review Categories

Exempt Research: the exempt process is much less rigorous than an expedited or full IRRB review. To qualify, research must fall into one of the eight federally defined exempt categories. These categories present the lowest amount of risk to potential subjects because they involve either collection of anonymous or publicly available data or conduct that is the least potentially harmful to human subjects. Research activities that fall under any of the federally defined exempt categories may not be subject to IRRB requirements (e.g., annual reviews, informed consent, etc.). However, it is strongly suggested that informed consent always be used.
Only the IRRB Chairperson may determine which protocols may be subject to limited review or may be exempt from review by the IRRB. Researchers who believe that their research meets the criteria for one of the following categories may request exempt review on their application. The IRRB reserves the authority to require proposal modifications regarding human subject's protection before approving the research as exempt.

Exempt Categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:
    a. Research on regular and special education instructional strategies.
    b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) *if at least one* of the following criteria is met:
    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
    c. The information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).

3. (i)Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
b. Any disclosure of the human subjects responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination required by 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
    a. The identifiable private information or identifiable biospecimens are publicly available.
    b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
    c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
    d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits

or services under those programs, possible changes in or alternatives to those programs or procedures, or
possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

a. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:
    a. If wholesome foods without additives are consumed; or
    b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 46.116(a)(1) through (4), (a)(6), and (d).
    b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117.
    c. An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
    d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Expedited Review: the expedited review process is less rigorous than a full IRRB review. To qualify, research must fall into one of the nine federally defined categories. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that reviewers may not disapprove research. Research may be disapproved only after review in accordance with the non-expedited procedure.

Expedited Categories: Research involving no more than minimal risk and involving only procedures listed in one or more of the following categories may qualify for expedited review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/ approved for marketing and medical device is being used in accordance with its cleared/ approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 7 week period and collection may not occur more frequently than 2 times per week; or
    b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

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

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

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened IRB as follows:
    a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (ii) the research remains active only for long-term follow-up of subjects; or
    b. Where no subjects have been enrolled and no additional risks have been identified; or
    c. Where the remaining research activities are limited to data analysis

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the

IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full IRRB Review: is reserved for research that involves greater than minimal risk. Research that does not fall into one of the above exempt or expedited categories. Any survey or interview that is likely to place human subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing requires full review. Examples of this include survey research that involves sensitive questions or information about sexual or illegal behavior.

Continuing Review: If data gathering continues for more than twelve months, federal regulations require that research be subject to a "continuing review." Researchers should use the SWCCD Continuing Review/Progress Report. This form is also to be used if changes in the research protocol occur within any given twelve-month period.

Researchers must submit a Continuing Review/Progress Report explaining the current status of the research project on or before 12 months. Notification of continuing review will be sent to the investigator 30 days prior to the review date. Continuing Review/ Progress Reports must be submitted to IRRB for review by the IRRB Submission Due Date the month of the studies expiration. After the IRRB has reviewed the Continuing Review/ Progress Report form it will contact the Principle Investigator and co-investigators and notify them of its decision.

Assessing if a research study requires more than Continuing/ Annual Review will be dependent upon the IRRB's assessment of risk to participants based on the submitted research protocol and any reported complaints, unanticipated problems, or non-compliance.

Procedures for Submitting Research Protocols

1. Complete the Human Subjects in Research Training

Before researchers engage in research that involves human subjects at SWCCD they must complete the National Institute of Health training modules.

Please see the link: https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html

Upon completion of this training, the researchers will be able to print out a "Completion Certificate". This certificate must be included as part of the protocol or on file in the Office of Institutional Research & Planning to be reviewed by the IRRB. No protocol will be approved without this certificate accompanying the protocol or on file in the Office of Institutional Research and Planning.

2. Complete the appropriate research protocol form(s) and submit it to the IRRB by the submission due date posted on the SWCCD IRRB website.

Please see the link: https://www.swccd.edu/administration/institutional-research-and-planning/research-and-survey-requests.aspx

Specific Protocol Requirements

Each of the following items relevant to the proposed research must be submitted by the submission due date posted on the SWCCD IRRB website.

1. A complete Application with all required information and appropriate signatures.

2. A complete Research Protocol. This will include the purpose of the proposed research, procedures, subjects, potential benefits, potential risks, precautions taken to minimize risk, a detailed description of data to be collected. This is in the application under section 6.

3. Informed Consent form(s) where applicable. Research that is classified as exempt does not require informed consent (but it is strongly recommended). This is in the application under section 4.

4. IRB approval from originating "Home" institution. If your research originates from another institution that is not in SWCCD then IRB approval from that institution will be necessary (if applicable). If your home institution does not have an IRB but uses another institution's IRB, then approval from that IRB will be needed. This is in the application under section 2.

5. A signed Non-disclosure statement for all researchers.

6. A copy of all instruments to be used in communicating with students, including questionnaires, cover letters, interview guides, etc. This is in the application under sections 4, 5, and 7.

7. A copy of supporting materials/ appendices that the investigator believes necessary (e.g., letters of agreement) for a thorough review of the proposed research.

8. Human Subjects in Research Training certification must be included or on file in the Office of Institutional Research and Planning. This is in section 2.