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| Southwestern Community College District Institutional Research Review Board (IRRB) |
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| **Policy and Procedure Summary and Application** |
|  |
| **Office of Institutional Effectiveness** |
| **Revised February 2013** |

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| *Any staff member or off-campus person or entity proposing to use Southwestern Community College District students or their student education records in any research must submit a proposal to the Institutional Research Review Board. Please contact Linda Hensley, Director of Institutional Planning, Research & Grants, at (619) 216-6686 or lhensley@swccd.edu for more information.* |

#### Southwestern Community College District

**Institutional Research Review Board**

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##### Southwestern Community College District Policy

**No. 6051**

**Students**

HUMAN SUBJECTS POLICY

Any staff member or off-campus person or entity proposing to use Southwestern Community College District students or their student education records in any research must submit a proposal to the Institutional Research Review Board. The Institutional Research Review Board will meet and either grant or deny approval of the proposal. The approval of the Institutional Research Review Board for research to be conducted in no way constitutes institutional or administrative sponsorship or requires any student or staff member to participate. The Chairperson of the Institutional Research Review Board is the Director of Institutional Research.

Approved by Southwestern Community College District Governing Board, April 12, 2000

**Southwestern Community College District Procedures**

**No. 5040**

**Student Affairs**

STUDENT RECORDS, DIRECTORY INFORMATION & PRIVACY

Outside individuals, groups or organizations who wish to submit a written and formal request for a specific research project may submit their request to the SCCD Institutional Research Board (IRB) or cognizant Vice President (s). Student records which are released for these research projects will be conducted in such a manner as will not permit the personal identification of students or their parents by persons other than representatives of those organizations to be released. Information will be destroyed when no longer needed for the purpose for which it is conducted.\*

\*Excerpt from District Procedures AP 5040

**SOUTHWESTERN COMMUNITY COLLEGE DISTRICT**

**INSTITUTIONAL RESEARCH REVIEW BOARD**

**Procedural Summary**

# Basis

In accordance with federal and state laws, Southwestern Community College District (SCCD) bears both legal (1) and ethical responsibility for helping to safeguard the rights and welfare of its students involved in all research projects conducted either:

* Under the direction of an employee or agent in connection with his or her College responsibilities.
* By a person not employed at Southwestern Community College District.
* By an outside entity.

**SCCD Employees Conducting Research**

It is the responsibility of the principal investigator and the dean/director to establish the investigator’s legitimate educational interest in conducting the research and to assure review by the Institutional Research Review Board (IRRB). Further, the dean/director serves as a point of contact to the investigator throughout their research project and is responsible for ensuring that a copy of the investigator’s final research paper is filed with the Institutional Research Review Board.

**Non SCCD Employee Conducting Research**

Similarly, non-SCCD employees and other outside entities must establish their legitimate educational interest in conducting the research and gain the approval of their institution’s faculty advisor/sponsor or authorizing official prior to submitting the request to the Southwestern Community College District IRRB. In addition, non-SCCD employees must obtain a dean/director to serve as their sponsor/point of contact throughout their research project. In addition, the SCCD sponsor/point of contact is responsible for ensuring that a copy of the investigator’s final research paper is filed with the Institutional Research Review Board.

The IRRB shall not provide retroactive approval for research that has been completed. Literature search and other work not involving SCCD students or their records may be initiated prior to IRRB review.

In the completion of routine college administrative duties, legitimate educational interest in students’ records is implied. Therefore, these duties are not subject to IRRB approval. Care must still be exercised in the analysis and dissemination of information pertaining to students or their educational records to protect students' privacy and the confidentiality of their records. To that end, college policy requires that approval be obtained prior to initiation of any research activity proposing to use Southwestern Community College District (SCCD) students (human subjects) or their student education records according to the definitions below.

**Definitions**

Research A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

[Source: 45CFR46.102 (d).]

Human Subject A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention with the individual, or (2) identifiable private information.

[Source: 45CFR46.102 (f).]

Legitimate Educational

Interest Requested information must be (1) necessary for the school official to perform appropriate tasks that are specified in his or her position description or by a contract agreement; (2) used within the context of official agency or school business and not for purposes extraneous to the official’s areas of responsibility or to the agency or school; (3) relevant to the accomplishment of some task or to a determination about the student; and (4) consistent with the purposes for which the data are maintained. Having access to education records or the information within the records does not constitute authority to share this information with anyone not given access through the written agreement. [Source: Protecting the Privacy of Student Records, Guidelines for Education Agencies. National Center for Education Statistics and National Forum on Education Statistics. 1997.]

Intervention Includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. [Source: 45CFR46.102 (f)]

Interaction Includes communication or interpersonal contact between investigator and subject; includes survey activities. [Source: 45CFR46.102 (f)]

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 (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [Source: 45CFR46.102 (f)]

IRRB The Southwestern Community College District Institutional Research Review Board (Board) established in accord with and for the purposes expressed in this policy chaired by the Director of Institutional Research.

IRRB Approval The determination of the IRRB that the research has been reviewed and may be conducted at Southwestern Community College District within the constraints set forth by the IRRB and other College and legal requirements.

SCCD

Sponsor Outside entities (non-SCCD employees) who are seeking to conduct research at Southwestern Community College District must obtain a sponsor (i.e. a SCCD dean/director) to serve as the investigator’s point of contact throughout the duration of their project; the sponsor oversees that the investigator follows the research protocols established in this IRRB packet.

Research Misconduct According to the Office of Research Integrity of the U.S. Department of Health and Human Services research misconduct means fabrication, falsification, or plagiarism in proposing, performing or reviewing research, or in reporting research results. Specifically these terms are defined as:

* **Fabrication** is making up data or results and recording or reporting them.
* **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
* **Plagiarism** is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

The function of the Institutional Research Review Board is to help assure that risks to human subjects are minimized and are reasonable in relation to the anticipated benefits, that there is informed consent, and that the rights and welfare of subjects are maintained. When considering approval of research using SCCD students or their student education records, the IRRB will first determine that all of the following criteria have been met in accordance with AP 5040 - Student Records, Directory Information & Privacy:

* Risks to subjects are minimized.
* Risks are reasonable in relation to anticipated benefits, if any, to the subjects and to the advancement of knowledge.
* Selection of subjects is equitable.
* Informed consent is sought.
* Informed consent is documented.
* Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of the subjects.
* There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. [Source: 45CFR46.111]

\_\_\_\_\_\_\_\_\_\_

(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 Composition**

The Institutional Research Review Board is composed of the Director of Institutional Research (Director, Institutional Research, Planning and Grants), two faculty members appointed by the Academic Senate Chair, and two administrators appointed by the Superintendent/President.

Chairperson: Director of Institutional Research (Director, Institutional Research, Planning and Grants)

Duties: Reviews and approves all research conducted by individuals or groups outside of Southwestern Community College District (including employees who are enrolled in educational programs outside of Southwestern Community College District) that seek to include Southwestern Community College District students or employees as subjects.

Meetings: As needed determined by IRRB application submissions.

Reports: Reports actions taken by the IRRB to the Dean of Institutional Effectiveness. An annual report is provided to the Superintendent/President regarding the status of IRRB applications received and studies performed.

# Procedures

1. After approval by the principal investigator’s department chair, school dean, and vice president, a copy of the following documents should be forwarded to the IRRB chair at least ten business days prior to the scheduled meeting of the IRRB. See attached checklist for additional details.
2. The application cover sheet signed by the appropriate officials indicating their Recommendation for Approval.
3. Abstract of the proposal.
4. Protocol statement.
5. Consent form.
6. Non-disclosure statement.
7. Instruments (questionnaires, interview guides, etc.).
8. It is the responsibility of each IRRB member to identify and avoid any situation in which he or she, either personally or by virtue of position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before the IRRB. Upon notification of a potential conflict of interest, the IRRB Chair must arrange for another reviewer.
9. After all documents are reviewed, the IRRB’s action is communicated to the investigator and respective dean. Upon receipt of IRRB approval, the investigator may initiate the activity with the students or their student education records. If appropriate, the IRRB shall require the principal investigator to debrief the research subjects at the completion of the research study.
10. IRRB action is recorded and retained in a file along with the application. The responsible individual must also maintain records of Board reviews and decisions on the use of human subjects. In addition, if the project is classified at-risk, documentary evidence of informed consent of the subject or his/her legally authorized representative must be maintained for a period of five years after termination of the project.
11. Research activities lasting more than one year are subject to annual review by the IRRB. Prior to a scheduled IRRB meeting before the expiration date of the yearly approval, the investigator will notify the IRRB if the project has been completed or if renewal is requested. If renewal is requested, the researcher must submit a status report.
12. If during the course of any research activity a change in design is made so that the research methods or techniques are different, new hazards are evident, the risk/benefit balance is altered, or the informed consent is modified in some way, a modification application must be submitted within 10 working days.

**Research Misconduct**

Any and all misconduct related to institutional research shall be reported to the Director of Institutional Research (Director of Institutional Research, Planning and Grants) immediately. In addition, such discussions of potential research misconduct are considered confidential in nature. Specifically, it is the responsibility of Southwestern Community College District employees to report observed or suspected research misconduct. If an individual is uncertain whether or not research misconduct has occurred he/she should contact the Director of Institutional Research (Director of Institutional Research, Planning and Grants).

The process for investigating an allegation of research misconduct includes the following:

* Conducting the assessment and inquiry: The purpose of the assessment and inquiry is to determine whether an investigation is required.
* Appointment of Inquiry Committee: Committee includes appropriate individuals who are knowledgeable and impartial to the specific research study to be investigated.
* Investigation: The Inquiry Committee shall review all facts that are related to the Research Misconduct allegation.
* Notification/Next Steps: After completing the proceedings the Inquiry Committee shall submit a report to the Dean of Institutional Effectiveness with a recommended action.
* Upon conclusion of the inquiry, Southwestern Community College District will take appropriate institutional actions in response to the accepted findings of research misconduct, which could include termination of research project.

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### INSTITUTIONAL RESEARCH REVIEW BOARD

### Application Cover Sheet

Date submitted to IRRB:

Principal Investigator:       Title:

Title of Project:

Home Address:       Home Phone:

Email Address:

***SCCD Employees:*** Dept      Work Phone:

***Non-SCCD Employees***: College/University

Address:       Phone:

Program of study:       Faculty advisor:

***Outside Entity*:** Name of Organization:

Address:       Phone:

Names/titles of additional investigators:

Subjects: (Summary and Detail)

Duration of Research:       Projected Start Date:

History of this protocol: New Modification  Renewal

*If Modification or Renewal, does this submission differ in any way from the previously approved protocol?*  Yes  No  *If yes, describe any differences in your protocol*.

Documentation of informed consent (Describe in detail in the protocol and submit text)

I agree to follow all requirements and to adhere to the guidelines outlined in Southwestern Community College District’s IRRB Policy and Procedure Summary.

Signed Written  Other (describe)

*(e.g., Oral, Unsigned, Written etc.)*

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## Recommendations for Approval (*Signatures must be obtained prior to submission to IRRB*)

# SCCD Employees:

Principal Investigator’s Dean:

Principal Investigator’s Vice President:

# Non-SCCD Employees/Outside Entity:

* Principal Investigator’s Research Committee Chair/Faculty and/or Staff Advisor (from applicant’s institution of higher education:

\_\_\_\_\_ \_\_\_\_\_\_

(*Name) (Title & Contact email/phone number)*

* SCCD Sponsor:

\_\_\_\_\_

(*Name) (Title& Contact email/phone number)*

***All applicants must attach protocol as outlined on the enclosed “Investigator’s Checklist” and a copy of IRB approval from their home institution.***

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***For Internal Use Only* SCCD Institutional Research Review Board**

Approve  Disapprove

Signature of Chair Date

SOUTHWESTERN COMMUNITY COLLEGE DISTRICT

**INSTITUTIONAL RESEARCH REVIEW BOARD**

### Sample Consent Form

This sample is provided as a model from which a consent form can be developed. It is not provided with the intention that it be precisely emulated*. [You should include the information suggested in the brackets/italics.]* The consent form should be written in terms comprehensible to the intended subject. **One signed copy should be given to the subject and one to the investigator.**

You are invited to participate in a study conducted by *[Name of investigator and affiliation]*. We hope to learn *[State what the study is designed to discover or establish]*. You were selected as a possible participant in this study because *[State why the subject was selected]*.

If you decide to participate, we *[or Dr. \_\_\_\_\_\_\_\_ and his/her associates]* will *[Describe the procedures to be followed, including their purposes, how long they will take, and their frequency and locale]*. *[Describe the risks, discomforts, inconveniences, and benefits reasonably to be expected. If benefits are mentioned, add:]* We cannot guarantee, however, that you will receive any benefits from this study.

[Describe appropriate alternative procedures that might be advantageous to the subject, if any. Any standard treatment that is being withheld must be disclosed.]

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. If you give us your permission by signing this document, we plan to disclose *[State the persons or agencies to whom the information will be furnished, the nature of the information to be furnished, and the purpose of the disclosure.]*

*[If the subject will receive compensation, describe the amount or nature. If there is a possibility of additional costs to the subject because of participation, describe it.]*

Your decision whether or not to participate will not prejudice your future relations with the *[institution] [and the named cooperating agency or institution, if any].* If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty.

If you have any questions, please ask us. If you have any questions during the course of the study please contact the Director of Institutional Research (Director of Institutional Planning, Research and Grants) at (619) 216-6686. You will be given a copy of this form to keep.

**You are making a decision whether or not to participate in this study. Your signature below indicates that you have read the information above and have decided to participate in the study.**

Signature: Date

*[ Relationship to subject (this line should not appear on forms that will be given to subjects consenting for themselves.)]*

Witness (Print Name): (Signature):

Investigator (Print Name): (Signature):

Investigator’s Phone Number:

# SOUTHWESTERN COMMUNITY COLLEGE DISTRICT

**INSTITUTIONAL RESEARCH REVIEW BOARD**

**Guidelines for Informed Consent**

**Basic Elements of Informed Consent**

* The investigator must obtain the informed consent of the subject or the subject’s legally authorized representative before the investigator may involve the subject in research.
* The consent must be obtained under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
* The information must be in language understandable to the subject or representative.

The elements of information are:

* A statement that the study involves research, an explanation of the purposes of the research, and a description of the procedures, including identification of any procedures which are experimental
* The expected duration of the subject’s participation
* A description of reasonably foreseeable risks or discomfort to the subject
* A statement regarding confidentiality of records and reports
* For research involving more than minimal risk, a statement regarding compensation or treatment if injury occurs
* A statement that participation is voluntary and that the refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled
* A statement informing subjects of their right to quit the project at any time without penalty or loss of benefits to which the subject is otherwise entitled
* The name and contact information for the individual who should be contacted if questions arise about the research, the subjects rights, or if research-related injury occurs

Modification of this procedure may be permitted by the IRRB when:

* The risk is minimal
* The rights and welfare of the subjects will not be adversely affected
* The procedure of obtaining informed consent would invalidate the objectives of the research
* Alternative means of conducting the research are not available or would be less advantageous to the subject
* Whenever appropriate, subjects will be provided with additional pertinent information after participation

Persons should never be treated only or merely as means to another’s ends. If the research is to involve persons of other countries or cultures, the investigator should consider consulting the *WHO/CIOMS Proposed International Guidelines for Biomedical Research Involving Human Subjects* or regional and national research ethics committees familiar with the customs in the community in which the research is to be done.

**Documentation of Consent**

* A consent form is documentation that the process of informed consent has taken place. The form includes the elements of informed consent stated above.
* The consent form must be approved by the IRRB.
* The information must be in language understandable to the subject or representative. The subject or the subject’s legally authorized representative must have an adequate opportunity to read the form before it is signed.
* The form must be signed by the subject or the representative. A copy must be given to the person signing the form.
* The form must include the statement “I hereby agree to participate in the research” or “My signature below indicates my willingness to participate in this research project.”
* The form must not include language through which the subject waives any rights or releases the investigator, sponsor, or institution from liability for negligence.

**SOUTHWESTERN COMMUNITY COLLEGE DISTRICT**

**INSTITUTIONAL RESEARCH REVIEW BOARD**

### Non-disclosure Statement

### To Be Completed by Requestors of Access to SCCD Student Education Records

I hereby request permission to examine the following parts of the official student education records maintained by Southwestern Community College District:

I shall not:

1. Use or reveal any personally identifiable information furnished, acquired, retrieved, or assembled by me or others, under the provisions of applicable laws for any purpose other than statistical purposes specified in the

*(Title of project as proposed to IRRB)*

1. Make any release or publication whereby an individual could be identified or the data furnished by or related to any particular person can be identified;
2. Permit anyone other than the individuals authorized by Southwestern Community College District to examine the individual reports.

***I agree to follow the above referenced criteria regarding my use of Southwestern Community College District’s student education record information and am fully aware of the Southwestern Community College District’s research misconduct procedures.***

Signature:

Please Print:

Name:

Title: School:

Date:

# SOUTHWESTERN COMMUNITY COLLEGE DISTRICT

**INSTITUTIONAL RESEARCH REVIEW BOARD**

# Investigator’s Checklist

Each of the following items relevant to the proposed research must be submitted at least ten business days prior to the scheduled meeting of the IRRB.

## A. Application cover sheet

The attached cover sheet bearing appropriate signatures.

## B. Abstract

A one-page summary of the protocol, including potential risks, risk management procedures and potential benefits.

## C. Protocol

New applications should include, in the following order, the applicable information:

1. Purpose and background
   1. Previous work in field (brief references to literature)
   2. Justification for study involving humans
   3. Specific aims of research
      1. Hypotheses, questions to be answered, data to be tested or gathered
      2. Relevance to continuing work in the field
2. Method section
   1. Procedures to be performed
   2. Special procedures (radioisotopes, electrical equipment, etc.)
   3. Frequency and duration of each procedure
   4. Location of study
   5. Mechanism for maintaining confidentiality (example: substituting codes for names). Include storage and access of identifying data and how long data are to be kept. Federal regulations require research records to be retained for at least 3 years after the completion of the research ([45 CFR 46](http://www.virginia.edu/vpr/irb/sbs/resources_regulations_subparta.46.115.html)).
3. Subjects
   1. Number
   2. Source and recruitment procedures
   3. Criteria for inclusion and exclusion
   4. Rationale for using special groups whose capabilities to provide informed consent may be absent or limited
   5. Discussion of potential problems involving the subject group
4. Potential benefits
   1. Benefits to the individual subject or patient, if any
   2. Benefits to the population from which the subject is drawn
   3. Benefits to science, society, humanity in general
5. Potential risks – physical, psychological, social, legal (including violations of normal expectations)
6. Precautions taken to minimize risks including a clear statement to the subjects that participation is voluntary
7. Compensation of subjects
8. Detailed description of data to be extracted from SCCD-maintained student education records, including the proposed use of the data
9. Academic background and experience of investigator(s)
10. Legitimate educational interest of the investigator(s)

Modified applications should include:

* 1. Modifications requested
  2. Effect of modification on benefits, risks, risk management and consent process
  3. New consent form, if applicable

*If modifications are substantial, submit complete new protocol.*

## D. Consent form for studies involving risk

The signed, written consent form should be in language appropriate to the subjects. Guidelines for Informed Consent and a sample form are attached. Minimally, the consent form must include the following.

1. Name of investigator and affiliation
2. Purpose of research (including larger social purpose, if appropriate)
3. Procedures (including time involved and locale)
4. Potential risks and discomforts
5. Potential benefits
6. Where applicable, alternative treatments, their risks and benefits
7. Extent of confidentiality
8. Statement regarding voluntariness of participation and freedom to withdraw without jeopardy
9. Assurance of investigator’s readiness to answer questions (including phone number)
10. Where applicable, terms of compensation
11. When physical risk is a possibility, phone number to call if injured from participation
12. Where applicable, provision for guardian’s or physician’s consent

For studies not involving signed written consent, submit cover letter of text of statement to obtain voluntary participation of subjects.

## E. IRB approval from originating “Home” institution

Please provide the IRB approval for your research project that has been authorized by your institution.

## F. Non-disclosure statement

The attached non-disclosure statement bearing appropriate signatures.

## G. Instruments

A copy of all instruments to be used in communicating with the students, including questionnaires, cover letters, interview guides, etc.

For projects requiring annual renewals, submit status report including:

1. Number of subjects studied, and approximate number refusing
2. Experience of subjects, especially untoward events
3. Scientific progress
4. Proposed modifications, if any, and effect on risks, benefits and consent process
5. Copy of the current or proposed consent form

Most protocols run several pages. Answer all of the points that pertain to your study as concisely as possible. If you have any questions, please contact the committee chairperson.

Please note: you must obtain IRRB committee approval before initiating any activity with the subjects. Literature research and other work not involving human subjects may be conducted prior to committee review. Any changes to the approved research project must obtain IRRB approval and cannot be implemented without approval.