SOUTHWESTERN COMMUNITY COLLEGE DISTRICT
INSTITUTIONAL RESEARCH REVIEW BOARD
Application

Section 1. Type of Submission In the space provided indicate if this is a new application, a submission for modification to an existing protocol, or a renewal of an existing protocol.	
Is this submission a new application, modification, or a renewal of an existing approval?	☐ New (continue to section 2) ☐ Modification (continue to section 10) ☐ Renewal of Existing Protocol (continue to section 11)

Section 2. Personnel In the space provided include all individuals who will interact or intervene with human subjects or their private identifiable information.		
Date of Submission		
Project Title		
Principle Investigator		
Department		
Address		
Telephone Number		
Email Address		
Research with Human Subjects Training (Please attach a copy)	NIH ☐	CITI – Social and Behavioral Module ☐
Co-Investigator		
Department/ Non-SWCCD Affiliation		
Telephone Number		
Email Address		
Research with Human Subjects Training (Please attach a copy)	NIH ☐	CITI – Social and Behavioral Module ☐
Co-Investigator		
Department/ Non-SWCCD Affiliation		
Telephone Number		
Email Address		
Research with Human Subjects Training (Please attach a copy)	NIH ☐	CITI – Social and Behavioral Module ☐
Is another entity engaged in the research? (i.e., will a person who is not an SWCCD employee interact or intervene with human subjects or their identifiable private information for research purposes, or obtain informed consent?) No☐ Yes ☐		

Is another institutional review board or review committee reviewing this research proposal? No☐ Yes☐
If yes, list the institution(s):
If yes, has approval been obtained No☐ Yes☐

(Submit all documentation from the external committee for IRRB review, if applicable.)

****

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

For SWCCD 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):

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

SWCCD Sponsor:

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

Section 3. Funding or Anticipated Funding Source

☐ Not Applicable
☐ Name of External Funding Agency:
☐ Name of Internal Grant Program:

Contract or Grant Title:

Contract or Grant Number:	☐ N/A Funding is Pending

Section 4. Participant Population and Recruitment

If this research includes more than one participant group, please attach a file that describes each sample specifically.

1.Targeted Participant Population(s)

Age:
☐ Adults (age 18 years or older)
☐ Minors (less than 18 years of age)
☐ Specific age range:

Gender:
☐ No targeted gender population (i.e., males and females will be recruited)
☐ Male
☐ Female
☐ Other (please specify):

Race/ Ethnicity:
☐ No targeted racial/ ethnic population (i.e., a variety of races/ ethnicities will be recruited)
☐ American Indian/ Alaskan Native ☐ Asian ☐ Black or African American
☐ Filipino ☐ Hawaiian/ Pacific Islander ☐ Hispanic ☐ White (Non-Hispanic) ☐Two or More Races
☐ Other (please specify):

Sexual Orientation:
☐ No targeted sexual orientation population
☐ Heterosexual
☐ Sexual minority (e.g., homosexual, bisexual) please specify:

Other:
☐ Illiterate
☐ Inpatient Participants
☐ Outpatient Participants
☐ Institutionalized Participants
☐ Low Income Participants
☐ Non-English Speaking
☐ Mentally/ Emotionally/ Developmentally Disabled or Impaired Decision Making Capacity
☐ Physically Impaired
☐ Pregnant Women
☐ Incarcerated

2. Describe any participant characteristics not included above if applicable:

3. For each participant group please:
Describe inclusion criteria:

Describe exclusion criteria:

4. For each participant group please:
Provide an estimate of how many participants you will need/ expect:

5. Recruitment procedures
☐ Email distribution via
  ☐ Personal email account
  ☐ College email account
  ☐ Survey software tool (e.g., SurveyMonkey, Qualtrics, etc.)
    please specify:
☐ U.S. Mail
☐ Handout/ flyer
☐ Website ad
☐ Newspaper ad
☐ Verbal announcement
☐ Other (please specify):

(Submit all recruitment materials, written materials as well as a sample of verbal announcements (if applicable), for IRRB review and approval.)

6. For each participant group please:
Describe the details of the recruitment process (e.g., how are you obtaining email/ mailing addresses, where are you distributing flyers, etc.).

7. Describe how permission has been or will be obtained from outside institutions or entities to recruit, conduct research, or access records at their site (if applicable).
☐ Not Applicable

8. Describe any compensation for participation (please include the amount, how, and when it will be given, if applicable.)
☐ Not Applicable

Section 5. Informed Consent Procedures

1. **Will participants sign a written consent/ assent/ parental permission document?**
☐ Yes ☐ No

If yes,

By whom will written consent be obtained (e.g., lead researcher, co-researcher, etc.).

Describe the method that will be used to obtain voluntary informed consent/ assent/ parental permission (e.g., consent will be obtained in using a form in person, obtained verbally over the phone, etc.)

For assent/ parental permission procedures, describe how you will ensure that only minors with parental permission forms will be included in the research.

Describe how you will match or align minor assent forms with parental permission forms.

Will participants receive a copy for their records?
☐ Yes ☐No, explain why:

Submit all informed consent documents for IRRB review and approval

If no,

If participants will not sign a written consent/ assent/ parental permission document, will they receive an information sheet that provides them with what they need to know before deciding to participate including all required elements of consent? ☐ Yes ☐No, explain:

2. If potential participants or their legally authorized representatives are non-English speaking, please explain how the investigator will identify these participants and ensure their ability to understand information about the study to provide consent. ☐ Not Applicable

Section 6. Study Description

1. Provide a brief description of the purpose of the proposed research, including research questions or hypotheses, and any relevant background information. Use language a person unfamiliar with your area of research would understand.

2. Type of research, select all that apply:

☐ Faculty/independent research
☐ Student research
☐ Class project – specify course:
☐ Honor's thesis or project/ Master's thesis/ Doctoral Dissertation
☐ Other, please specify:

3. What do you plan to do with your results? select all that apply.

☐ Publish
☐ Present at conference
☐ Archive
☐ Other, please specify:
☐ Not applicable

4. Provide an estimated data collection period:

Section 7. Study Procedures

1. Select all research methods that apply:

☐ Paper surveys/ questionnaires
☐ Online surveys/ questionnaires
☐ Telephone surveys/ questionnaires
☐ Standardized written/ oral/ visual tests
☐ Interviews
☐ Focus groups
☐ Field work: (e.g., public, classroom, or worksite observations) specify:

☐ Voice, video, digital, or image recording made for research purposes
☐ Moderate exercise and muscular strength
☐ Materials (i.e., archived data, documents, records, or biological specimens) that have been collected or will be collected for non-research purposes.
☐ Materials (i.e., archived data, documents, records, or biological specimens) that are publicly available and the information is recorded so that participants cannot be identified.
☐ Materials (i.e., archived data, documents, records, or biological specimens) that have been collected for another research project.
☐ Other, please specify:

2. List and briefly describe the testing instruments, surveys, interview items, and/ or additional research materials which will be used in the research if applicable (instruments included in this item must be labeled and submitted for review):

☐ Not applicable

(Submit all materials listed above for IRRB review and approval, if applicable. The titles or labels you use in this item must match your submitted materials.)

3. Provide a detailed description of the steps you will take to test your hypotheses (provided 5.1) **from participant recruitment to data collection to analyses performed on the data.** (I.e., provide a research protocol).

4. Location of Research, select all that apply

☐ SWCCD Chula Vista campus
☐ SWCCD Crown Cove Aquatic Center
☐ SWCCD Higher Education Center at National City
☐ SWCCD Higher Education Center at San Ysidro
☐ SWCCD Higher Education Center at Otay Mesa
☐ Off campus location(s), please specify:

5. Describe your debriefing procedures (e.g., how and when will participants be debriefed about the research):

Section 8. Data Privacy and Security

1. How are participant data, records, or specimens identified when they are <u>made available or collected?</u>

☐ No identifiers (e.g., neither the researcher nor the source providing the data can identify a participant based on the information provided with the data)
☐ Direct identifiers (e.g., participant name, SSN, date of birth, email, address, or student ID number)

Who will receive access to the identifiable information?

(These individuals will have to sign a non-disclosure agreement)

☐ Indirect identifiers (e.g., an assigned code or pseudonym used to track participants)
Who will receive access to the identifiable information?

(These individuals will have to sign a non-disclosure agreement)

2. How will the data, records or specimens be labeled <u>when published or shared</u> (sharing includes releasing, transmitting, or providing access to any individual or entity outside the research team)**?**

☐ Not applicable (do not intend to publish/ share).

☐ Anonymized or de-identified (i.e., the participant's identifying information will be destroyed/ removed before it is shared).

☐ Coded and linked (Data is coded. The data may be linked back to participants with the code, but the code will not be shared).

☐ Identifiable data (Data such as name, date of birth, email, and address is not removed). <u>Only an aggregate form of this data is to be shared.</u>

3. Safeguarding and Storage of Data (check all that apply)

☐ Consent/ assent/ parental permission forms will be stored separately from data.

☐ Data will be kept on a password protected computer in the following location.
(Please supply building and room number):

☐ Codes for data will be stored separately from data.

☐ Data will be shared using password protected thumb drives.

☐ Data will be transmitted using encryption.

Provide additional information for any technology or medium used to store and/ or transmit data not addressed above:

Section 9. Risks and Benefits

1. **Do the data or records to be collected relate to any illegal activities** (e.g., immigration status, drug use, etc.)**?**

☐ Yes ☐ No

If yes, explain:

2. Will participants be asked to provide information or records that may be harmful to their reputation, employability, or insurability?

☐ Yes ☐ No

If yes, explain:

3. Will information or records be requested that participants might consider personal or sensitive?

☐ Yes ☐ No

If yes, explain:

4. Will the participants be presented with materials that might be considered offensive?

☐ Yes ☐ No

If yes, explain:

5. Will participants encounter stress or psychological, social, or physical risks that are greater than those ordinarily encountered in daily life or the performance of routine physical or psychological examinations?

☐ Yes ☐ No

If yes, explain:

6. Describe specific measures taken to minimize or protect participants from anticipated risks:

7. Describe any expected benefits for research participants or society.

Section 10. Modification Request: (Skip unless applying for modification) Please provide the information requested below:	
Date of Submission of original application	
Date of Modification submission	
Project Title	
Principle Investigator	
Department	
Address	
Telephone Number	
Email Address	
1. What is the status your research protocol? ☐ Active (still enrolling subjects) ☐ Closed to subject enrollment, but subjects still actively involved with procedures ☐ All research interventions completed, but research open for follow-up of subjects ☐ All research interventions completed, but research open for data analysis	
2. Is this modification being submitted in response to potentially life-threatening problem? ☐ No ☐ Yes, explain:	
3. How many subjects have participated in this study to date?	
4. How many subjects do you anticipate participating in this study?	
List and describe each proposed change and the rationale for the changes: Attach a copy of the materials that have changed, with the changes highlighted.	

Section 11. Renewal Request/ Progress Report: (Skip unless applying for Renewal) Please provide the information requested below:	
Date of Submission of original application	
Date of Modification submission	
Project Title	
Principle Investigator	
Department	
Address	
Telephone Number	
Email Address	

1. What is the status your research protocol?

☐ Active (still enrolling subjects)

☐ Closed to subject enrollment, but subjects still actively involved with procedures

☐ All research interventions completed, but research open for follow-up of subjects

☐ All research interventions completed, but research open for data analysis

2. Have there been any subject complaints filed against the study?

☐ No

☐ Yes, explain:

3. Have there been any unanticipated problems with the study?

☐ No

☐ Yes, explain:

4. Have any subjects withdrawn from the study or been withdrawn by the investigator?

☐ No

☐ Yes, explain:

5. Have there been any modifications to the IRRB approved research application or informed consent documents that were implemented without prior IRRB approval?

☐ No

☐ Yes

Please submit a modification request to the IRRB's consideration during review of this renewal.

6. Have there been any breaches of subject confidentiality?

☐ No

☐ Yes, explain:

7. How many subjects have participated in this study to date?

8. How many subjects do you anticipate participating in this study?

Please provide a narrative summary of the study progress to date.

Attach a copy of the materials that have changed, with the changes highlighted.

Section 12. Assurance and Submission

Your submission certifies that as a researcher you understand and accept the following obligations to protect the rights and welfare of research subjects in this research:

COMPLIANCE WITH FEDERAL AND COLLEGE REGULATIONS AND STANDARDS

- I recognize that as a member of the research team, it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will conform with the IRRB approved protocol, IRRB policies, and all applicable federal regulations including but not limited to HHS, FERPA, PPRA, and/or HIPAA regulations.
- I understand that failure to comply with all applicable HHS, FERPA, PPRA, and/or HIPAA regulations, IRRB policies and procedures, and the provisions of the protocol as approved by the IRRB may result in suspension or termination of my research project, notification of appropriate governmental agencies by the IRRB, and/or suspension of my freedom to present or publish results.

IRRB APPROVAL OF ALL PROTOCOLS

- I will not initiate any change in protocol without IRRB approval except when it is necessary to reduce or eliminate a risk to the subject in which case the IRRB will be notified as soon as possible.
- I understand that IRRB approval is valid for no more than one year with continuing review by the IRRB required at least annually in order to maintain approval status. I will not enter subjects in the study before IRRB approval or if IRRB approval expires. In the latter case, I will immediately contact the IRRB to obtain permission to continue subjects in the research study.
- I recognize that it is my responsibility to ensure that the study has been reviewed for scientific merit and ethical content.
- I recognize that it is my responsibility to ensure that there is constant open dialogue between myself and the other research personnel to ensure that the research is conducted correctly, and the safety and protection of the subjects are ensured.
- I recognize that it is my responsibility to ensure that valid informed consent/assent/parental permission has been obtained from all research subjects or their legally authorized representatives. I will ensure that all project personnel involved in the process of consent are trained properly and are fully aware of their responsibilities relative to the obtainment of informed consent according to the IRRB guidelines and applicable federal regulations. I will use only the currently approved, informed consent form or script for recruiting subjects.
- I understand that I am part of the collaborative effort to maintain the integrity of the human subjects' research approval process and procedures to ensure continuous quality improvement and academic excellence at SWCCD.

COMMUNICATION WITH THE IRRB

- I will promptly inform the IRRB of any event that requires reporting in accordance with IRRB policies and procedures on unanticipated events involving risks to subjects or others and adverse events (serious and/or unexpected).
- I will inform the IRRB immediately of *any* significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRRB.
- I will inform the IRRB immediately if I become aware of any violations of HHS regulations (45 CFR 46), FERPA regulations (34 CFR 99), PPRA regulations (34 CFR 98), HIPAA regulations (45 CFR 164.530), or IRRB policies and procedures for the protection of human subjects.

IRRB MONITORING OF STUDIES

- I will maintain all required research records and recognize that the IRRB and federal government is authorized to inspect these records.
- I understand that, per OHRP/FDA guidelines, the IRRB will be monitoring adherence to approved research protocols. The oversight process does not end with approval of a research protocol.

PRINCIPAL INVESTIGATOR/FACULTY ADVISOR ASSURANCE

- **By submitting this request to the IRRB from my SWCCD email address**, the Principal Investigator accepts responsibility for ensuring that all members of the research team: 1) complete the required training to fulfill their study responsibilities, 2) follow the study procedures as described in the IRRB approved protocol and comply with Southwestern College's Policy and Procedure for Human Subjects and all IRRB communication and 3) uphold the rights and welfare of all study participants.

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

Print: _____ Signature: _____

Date: