SOUTHWESTERN COLLEGE

SOUTHWESTERN COMMUNITY COLLEGE DISTRICT
INSTITUTIONAL RESEARCH REVIEW BOARD

Guidelines for Informed Consent

The following guidelines are designed to help researchers create an informed consent form for their application to the SWCCD IRRB. A template for informed consent is included in this document. Informed Consent is necessary for conducting any research project at SWCCD involving human subjects as defined in the IRRB Guidelines (except those research studies categorized as exempt). Researchers may modify the parts of the template highlighted in yellow with the appropriate information.

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

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.

[Informed Consent Document Template]

[*Project Title*]

[Purpose]
You are being asked to participate in a research study about [*insert general statement about study]*. The purpose of this research is [*insert a statement of purpose]*. You were selected as a possible participant because [*explain how participant was identified]*. Please read this form and ask any questions that you may have before agreeing to be in the research.

[Information about Participants' Involvement in the Study]
The study will take place in [*building and room*]. It should take you approximately [*state the amount of time required of participants per session and for the total duration of the research*] to complete the research study.

If you agree to be a participant in this research, we would ask you to do the following things: *[List all procedures, preferably in chronological order, which will be employed in the research. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using non-technical language. Explain all procedures using language that is appropriate for the expected reading level of the participants.]*.

[Risks]
This research has the following risks: [*explain first risk, including the likelihood of the risk and any measures that will be used to minimize the risks*; c*ontinue providing the risks, as necessary*].

[Benefits]
The benefits of participation are [*explain benefits of participation that will be gained, either by the participants, society, or to the body of knowledge. Note: monetary compensation is not considered a benefit of being in the study*].

[Compensation]
You will receive the following payment/reimbursement: [*Explain the amount of payment or other reimbursement information (i.e., class credits), as well as when payment and/or reimbursement will occur. If applicable, indicate other ways participants can earn the same amount of credit or compensation. If you do not have compensation, delete this section*].

[Confidentiality]
The information in this research will be kept confidential. [*State how the data will be coded*]. Research data will be stored in a secure location. [*State why the location is secure. (e.g., locked filing cabinet/room with limited access*]. The data will be made available only to the persons conducting the research. No reference will be made in oral or written reports that could link participants to the research. [*If tape or video recordings are made, explain who will have access to them, and when they will be erased/destroyed*].

[Voluntary Participation]
You do not have to perform any activity you do not want to. You do not have to answer any question you do not want to answer. Participation in this study is voluntary. If you decide to

participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled.

Contact Information:
If there are any questions at any time about the study or the procedures, or you experience adverse effects as a result of participating in this study, please contact: *[researcher, department, telephone and email address]*.

This project has been reviewed and approved by the Southwestern Community College District Institutional Research Review Board. Questions concerning your rights as a participant in this research may be directed to Dean of Institutional Research and Planning, at (619) 216-6614 or gabasolo@swccd.edu.

Consent:
I have read the above information, and I have received a copy of this form. I hereby agree to participate in the research.

Participant's Printed Name	Signature	Date

Investigator's Printed Name	Signature	Date