Southwestern Christian University
Institutional Review Board

1. STANDARD OPERATING POLICIES AND PROCEDURES

The IRB shall follow regulations and guidance of DHHS, FDA, and institutional policies to facilitate the protection of the rights and welfare of human participants. The IRB shall oversee and review research and maintain it in a uniform manner, regardless of changes in personnel. Written standard operating policies and procedures (SOPs) foster the highest quality and integrity of the review and oversight of research involving human participants and for the adequate documentation of such oversight.

SOPs provide the framework for the ethical and scientifically sound conduct of human research. The policies are general statements of principles within the SOPs and provide overall ethical guidance. The standard operating procedures are specific, detailed directives for implementation of the policies.

2. RESEARCH EXEMPT FROM IRB REVIEW

All research involving the collection of data about living individuals through intervention or interaction with those living individuals or by collection of those individuals' private identifiable information shall be reviewed by the IRB. An investigator is ***NOT*** empowered to make the determination of whether a research project is exempt from IRB review. The investigator shall forward all human participant research projects to the IRB, and the IRB shall determine if the research project is exempt from review. The IRB Chair or Vice-Chair makes the determination of exemption based on regulatory and institutional criteria, except as specifically noted below.

2.1. EXEMPT RESEARCH PROJECT CRITERIA

Research projects in which the involvement of human participants will be in one or more of the following categories are exempt from IRB review:

2.1.1. Research conducted in established or commonly accepted educational settings involving normal educational practices, 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.

c. Research relating to Instructor end-of-course surveys

Additionally, the research must meet the following:

- The research is not FDA-regulated
- The research does not involve prisoners as participants.

2.1.2. Research involving the use of educational tests (cognitive, diagnostic, aptitude achievement), survey procedures, interview procedures, or observation of public behavior, unless:

a. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the subjects; and

b. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. NOTE: The Department of Veterans Affairs (VA) also includes loss of insurability in this category.

Additionally, the research must meet the following:

- If the research involves children as participants, the procedures do not involve survey procedures, interview procedures, or observation of public
- behavior where the investigators participate in the activities being observed.
- The research is not FDA-regulated
- The research does not involve prisoners as participants.

2.1.3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is *not exempt* under 2.1.2 above if:

a. The human participants are elected or appointed public officials or candidates for public office; or

b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Additionally, the research must meet the following:

- The research is not FDA-regulated
- The research does not involve prisoners as participants.

2.1.4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants, and:

Reviewed materials exist at the time the research is proposed

- The research is not FDA-regulated
- The research does not involve prisoners as participants.

2.1.5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads and which are designed to study, evaluate, or otherwise examine:
a. Public benefit or service programs;

b. Procedures for obtaining benefits or services under those programs;

c. Possible changes in or alternatives to those programs or procedures; or

d. Possible changes In methods or levels of payment for benefits or services under those programs.

Additionally, the research must:

- Be conducted pursuant to specific federal statutory authority.
- Have no statutory requirements for IRB review.
- Not involve significant physical invasions or intrusions upon the privacy interests of the participant.
- Have authorization or concurrence by the funding agency.
- Not be FDA-regulated.
- Not involve prisoners as participants.

2.1.6. 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Additionally, the research must not involve prisoners as participants.

2.2. **Exempt Research Project Review**

Protection of participants in exempt research includes:

- that the research involves no more than minimal risk to participants
- selection of participants is equitable
- if there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data
- if there are interactions with participants, there will be a consent process that will disclose such information as:
    - that the activity involves research
    - a description of the procedures
    - that participation is voluntary
    - name and contact information for the investigator

- there are adequate provisions to maintain the privacy interest of participants

3. PROCESS REVIEW

3.1.1 Exempt Review / Determination Procedure

3.1.1. Upon initial review of the research project, the IRB Chair may request verification and/or additional Information from the investigator in order to determine whether exemption is appropriate. The IRB will communicate this request to the investigator in writing.

3.1.2. The IRB Administrator records the date of the exempt determination in the database, generates an anniversary date for renewal, generates the approval letter, and forwards the approval letter to the investigator.

3.1.3. The IRB chair will determine if it is exempt. If not exempt, the committee will meet to approve.

3.2 Renewal of Exemption Procedure

The IRB shall send a letter to the investigator on an annual basis to determine if the research project remains active and continues to meet the qualifications for \ exempt status.

3.2.1 Ongoing surveys will receive approved renewal date
3.2.2 Approved applications will receive notification by letter.

4. RESEARCH SUBMISSION REQUIREMENTS

4.1. POLICY FOR SUBMISSION

IRB members often rely solely on the documentation submitted by Investigators for initial and continuing review. Therefore, this material must provide IRB members with enough information about a study to assess whether it adequately meets the IRB's criteria for approval.

All materials submitted to the IRB for review must include the appropriate documentation and information necessary for adequate review. IRB staff will be responsible to check each submission for the appropriate materials.

4.1.1 Submission Requirements for the Initial Review of a New Research Project

4.1.1.1 Investigators applying for initial approval of a proposed social behavior research protocol must submit:

- Informed consent document or waiver of informed consent document indicated on the IRB application.

4.1.1.2 Additional required items if applicable:

- Questionnaires and assessment instruments
- Participant Study Instructions

4.1.2 Submission Requirements for Continuing Review

Investigators requesting renewal of an approved research project must submit:

- Completed Application for Continuing Review

4.1.3 Submission Requirements for Amendments to Currently Approved Research Projects

Investigators requesting approval of revisions to previously-approved research projects must submit:

- Completed Protocol Modification Form indicating revisions, signed by the Investigator
- Copies of all documents being revised with changes indicated. (i.e., protocol, informed consent document, advertisement)
- Submissions must highlight changes made to original data submitted

4.1.4 Action Taken If Documentation is Not Adequate or Additional Information is Required

If the IRB or IRB staff determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or the Investigator may be required to answer questions or explain the details of the study in person to the IRB. The IRB will not review incomplete submissions.

4.2. PROCESS REVIEW

4.2.1. Submission of a New Research Project

4.2.1.1. Upon receipt of a New Research Project, IRB Staff review the submission for completeness of required documents and confirm education requirement status of key personnel.

4.2.1.2.The IRB Administrator evaluates claims for exemption from IRB review and presents the study to the IRB Chair or designee for review and final determination.

4.2.1.3. If the documents submitted for initial review are not adequate, a pre-review letter or email is sent to the Investigator describing the required additional information. It may also be determined that the Investigator may be required to attend the IRB meeting to answer questions or explain the details of the study.

4.2.2 Submission of a Continuing Review, Amendment, Unanticipated Problem Involving Risks to Participants or Others and Protocol Deviations

4.2.2.1 Before a Continuing Review is scheduled for IRB review, the IRB Administrator conducts a preliminary review to determine if information and materials submitted by the Investigator present an adequate description of the proposed research. If deficiencies are noted, the IRB Administrator contacts the Investigator for resolution.

4.2.3 Committee Convene

4.2.3.1 The Committee is scheduled to meet twice each academic year on the second Tuesday of September and the second Tuesday of March.

4.2.3.1.1 Applications should be submitted prior to this meeting in order to be considered. Applications received after the scheduled meeting date will be held until the next regularly scheduled meeting.

4.2.3.2 Additional meetings may be scheduled at the discretion of the IRB Chair and will only be scheduled in rare urgent situations.

4.2.3.2.1 Proper planning on behalf of departments, individuals, or moderators does not constitute an urgent situation for the committee to meet beyond its regularly scheduled meeting times.

4.2.3.3 A majority of the committee must be present in order to accept an application.