

The Institutional Review Board Manual

Southwestern Assemblies of God University

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Introduction

The purpose of the SAGU Institutional Review Board (IRB) is to aid researchers academically and professionally by ensuring they conduct research on human subjects in accordance with Christian principles, federal regulations, and the best practices of the academic and scientific communities.

The main role of the IRB is to ensure that the rights and welfare of research subjects are protected. This is accomplished through the approval of all human-subjects research and the continued monitoring of previously approved studies.

How to Use This Manual

The manual is intended to assist SAGU researchers in understanding the policies and procedures that govern the use of human subjects in SAGU-sponsored research. Also included are levels of proposal review, frequently asked questions, and definitions and terms to assist researchers with their understanding of federal regulations.

The SAGU IRB Handbook has three uses: (1) assisting IRB members with their understanding of the roles and responsibilities of membership, (2) providing university researchers processes for submitting research proposals for review and implications of non-compliance with approved projects, and (3) educating the university community on the importance of ethical treatment of human research participants.

If you are unable to locate within this manual the information you are seeking, please contact the SAGU IRB Co-chair at the e-mail address or phone number listed on the IRB website: see www.sagu.edu/irb

Roles and Responsibilities of the IRB

Purpose and Authority of the IRB

The IRB is an administrative body established to protect the rights and welfare of human research subjects participating in research that is conducted (1) by or under the direction of any SAGU instructor or student in connection with SAGU academics; or (2) using any SAGU employees or students as subjects; or (3) using SAGU property or facilities; or (4) using SAGU's non-public information to identify or contact human research subjects or prospective subjects, regardless of sponsorship. This includes all research conducted at extension sites of the university.

Only projects that qualify as *research* and use *human subjects* fall within the jurisdiction of the IRB.¹ The IRB has the authority to approve, require modifications to, or disapprove all research activities within its jurisdiction, as specified by both the federal regulations and local institutional policies. Except for research projects that are judged to be exempt from further review, all IRB-approved research projects are subject to continuing review and approval by the IRB at least annually.

¹ The terms *research* and *human subjects* are carefully and specifically defined in the Code of Federal Regulations: 45CFR46.

All research² conducted by SAGU faculty, staff, and students using human subjects must have prior approval from the SAGU IRB before data-collection is initiated.

Convened Meetings

The IRB convenes monthly or as needed when applications for IRB approval have been submitted for review. The IRB may cancel scheduled meetings if no agenda items require attention by the Board.

A quorum at a convened IRB meeting shall consist of more than one-half of the total membership, including at least one member with a non-scientific focus. A voting majority of members at a convened meeting shall consist of more than one-half of the members present.

The IRB Co-chair may abstain from voting during a convened meeting unless necessary to make a quorum or to break a tie vote. IRB members may abstain from voting by personal choice. Members who have a conflict of interest³ in regard to a given application shall recuse themselves from voting and leave the room to eliminate any chance of influencing the discussion and subsequent decision. Conflicts of interest may include, but are not limited to, (1) an application in which an IRB member is the principal investigator (PI), a research-team member, or a faculty advisor; and (2) a conflict of interest as defined by University policies. In the case of such a conflict, this should be reported to the IRB Co-chair and noted in the minutes.

Approved minutes of all meetings, summarizing the results of reviews of all research applications submitted to the IRB, are sent to IRB members, Vice President for Academics, and University President. Minutes are maintained in the IRB Office on the main SAGU campus.

The IRB may conduct convened meetings by telephone or video conference provided (1) members have received copies of all documents to be reviewed, (2) a majority of the IRB members are present, and (3) discussion occurs in real time. All members must be connected simultaneously for teleconferences or video conferences. "Telephone polling" (in which IRB members are contacted individually) does not qualify as a convened meeting.

IRB Membership

Federal regulations require that the IRB will be comprised of at least five members who vary in gender, educational backgrounds, and professional expertise; diversity helps to ensure that the IRB provides complete and thorough review of research activities commonly conducted by the institution.

The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Further, the IRB will also include at least one member who represents the community (i.e., a person who is not otherwise affiliated with the University). Thus, IRB members fall into three distinct categories: the co-chairs, the University-affiliated members (faculty and staff), and the non-affiliated or community members.

The IRB is authorized to invite individuals with expertise in specific areas to assist in the review of applications/issues that require expertise or perspective beyond or in addition to that available

² See footnote 1.

³ See the following section entitled Conflict of Interests.

on the IRB. Although these individuals may attend meetings and take part in the discussion of research protocols, they may not vote. Prospective IRB members may also be invited to attend one IRB meeting to learn about the IRB review process, but they may not vote at that meeting. An investigator may be invited by the Co-chair to present additional information to the IRB members about a proposed study, but the investigator may not remain in the meeting for the deliberation and vote. Due to the confidential nature of the IRB proceedings, the IRB members, invited investigators, ad hoc non-voting members invited for their special expertise, and invited prospective IRB members are the only persons authorized to attend any convened meetings of the SAGU IRB.

Member Appointments and Terms of Service

Members are appointed by the IRB, in conjunction with the Vice President for Academics for renewable three-year terms. Original members' terms will be staggered to ensure continuity and experience.

Relationship of IRB to Other SAGU Personnel

The IRB functions under the overall direction of the Vice President for Academics. The IRB maintains complete separation from academic committees in charge of various research projects that require IRB approval or review. If a member of an academic committee is also a member of the IRB, that individual will recuse himself/herself from IRB deliberations concerning that research project.

Principal Investigator

The PI is the person who assumes full responsibility for conducting the research project. This individual is ultimately responsible for (1) ensuring that the proposed research remains in compliance with federal regulations and University policies, and (2) implementing all safeguards mandated by the IRB.

IRB Job Descriptions

This section describes the general and specific responsibilities of IRB members, including details for each position or role: the IRB Co-chairs, Community Member, and Member (in general). In addition to the following details, every IRB member will complete the Collaborative Institutional Training Initiative (CITI) course entitled, "Human Subjects Research—Basic"⁴. Additional optional modules will be completed if necessary, as directed by the IRB Co-chairs.

IRB Co-chairs

Through a process of continuous evaluation, the IRB Co-chairs divide the following responsibilities between them in functionally efficient ways:

1. Presides over meetings of the fully convened IRB;
2. Ensures that the IRB carries out its duly authorized responsibilities, as required by federal regulations, state laws, and University policies;

⁴ See <https://about.citiprogram.org/en/course/human-subjects-research-2/>.

3. In conjunction with the Vice President for Academics, develops and revises IRB policies, procedures, and guidelines to stay current with regulatory changes, societal thinking (where relevant), Christian ethics, and best-practice standards;
4. Ensures that reports related to safety, noncompliance, unanticipated problems in research, and adverse events are reviewed, attended to, and reported pursuant to federal regulations, state laws, and University policies;
5. Ensures that members of the IRB are recruited, appointed, oriented, and trained, such that the IRB is duly qualified to fulfill its obligations;
6. Monitors changes in federal regulations/guidelines;
7. Oversees initial training and continuing instruction of IRB members and relevant others;
8. Ensures that the IRB carries out its duly authorized responsibilities as required by federal regulations, ethical principles, state laws, and University policies;
9. Reviews and approves for completion application submissions that qualify for review, or delegates such authority to a qualified and experienced IRB member to conduct such review and approval;
10. Communicates with applicants the decisions of the IRB, through both email and formal communication;
11. Serves as a liaison between the IRB Committee and the University research community to promote communication and understanding of the concerns of the IRB, the research community, and other HRPP (Human Research Protection Program) partners;
12. Recuses himself/herself from discussion and voting on any application in which a potential, perceived, or real conflict of interest exists.

IRB Member

An IRB member,⁵ regardless of his/her unique designation,⁶ carries the following responsibilities:

1. Participates in IRB committee meetings, reviews and approves minutes, and completes preliminary reviews of IRB applications, as assigned;
2. Maintains confidentiality for all discussions, applications, meeting minutes, and proprietary information;
3. Ensures that the review of human-subjects research adheres to all applicable ethical standards;
4. Promotes an ethical research climate at the University;
5. Completes all required certifications on human subjects protection and regulations;

⁵ If an IRB member leaves the University or goes on leave for one year or more, the IRB Chair will appoint a replacement.

⁶ Scientist, non-scientist, or community member.

6. Recuses himself/herself from discussion and voting on any application in which a potential, perceived, or real conflict of interest exists.

IRB Non-Affiliated (community-representative) Member

A non-affiliated IRB member maintains no direct affiliation with the University, other than general interest in its educational mission. He or she carries the following unique responsibilities, *in addition to those specified above for all IRB members*:

1. Maintains sensitivity to unique community populations and cultures;
2. Represents the perspective of the community when appropriate during IRB meetings;
3. Shares relevant information about the community known to the non-affiliated member.

IRB Recording Secretary

The recording secretary summarizes the IRB's deliberations and captures all records of its decisions. He or she is present at all meetings, and later distributes the minutes to all members for review and correction. The recording secretary does enter into discussions (except to clarify the minutes) and does not vote, and is not an official member of the IRB.

IRB Review of Course-Related Research

Class Projects Involving Human Subjects

Research activities that are part of a course requirement and which require the involvement of human subjects may not require IRB review and approval. If all of the following criteria apply to a class project, IRB review and approval are not necessary:

1. The activity is designed for learning purposes only.
2. The results will not be made public through presentation outside of the classroom; specifically, the results will not be published in any form or publically presented (e.g., at a state or regional meeting of discipline-specific professionals). A capstone or project paper housed only in the sponsoring department for academic purposes is not considered publically accessible.
3. The activity involves procedure with no more than minimal risk. (The phrase "minimal risk" is defined in the following section.) By definition, research of a sensitive topic or requiring the participation of those in a "vulnerable" population cannot be considered a minimal-risk study.
4. Informed consent procedures are used during the data-collection process. (Some surveys or observational activities may require disclosure of the procedures used, instead of signature-based informed consent, or no consent at all.) See appendices A, B, and C for sample informed consent templates for three distinct research methods.
5. Data obtained during a research effort will not be identifiable in print or in any subsequent discussion or presentation of the findings. Identifiable data will be completely destroyed or purged at the end of the semester. Note that photographs, video, and audiotaped recordings all contain identifiable data

Additional information regarding class projects may be found at www.sagu.edu/irb.

Graduate-student Research Projects

All proposed research required to complete a graduate degree program (e.g., theses/dissertations) must be reviewed and approved by the SAGU IRB prior to any form of data collection with human subjects. The IRB assumes that all such projects will be conducted to contribute to general knowledge, and thus qualify as research as defined by 45 CFR 46. Note that the results of such projects DO NOT necessarily have to be published to be considered research.

Research at SAGU by an Investigator from Another Institution

An investigator from another institution who seeks to conduct research at SAGU or with SAGU students or employees is subject to the same IRB requirements as SAGU researchers. A project by an external investigator must first receive approval by an appropriate administrator (e.g., the Vice President for Academics) at SAGU. This approval must, in fact, be granted before the project can be reviewed and approved by the IRB at the investigator's sponsoring institution. That IRB's decision, with all relevant documents appended, must be submitted to the SAGU IRB Co-chairs⁷ for review by the SAGU IRB. Restrictions on data collection and data storage not envisioned by the investigator's IRB may be imposed by the SAGU IRB.

Privacy and Confidentiality

Investigators sometimes seek access to existing records in order to identify potential subjects, or in order to conduct research. If the investigator will record *identifiers* such as subjects' names (either for further record review or for personal contact), this activity requires IRB review. The SAGU IRB will determine whether the consent of subjects should be sought before the researcher gains access to the records (in some cases, a *waiver* can be granted). In determining whether it is appropriate to waive the requirement to obtain consent from these subjects, the IRB considers the sensitivity of the information being recorded, the vulnerability of the subject population, and the purpose for which the investigator wants access to the information.

In some cases, consent cannot be waived. For example, the Buckley Amendment, also known as FERPA, requires written parental permission for release of records or identifiable information about children in public schools.

For the majority of social and behavioral science research studies, ensuring *confidentiality* is the most important procedure to minimize risk. Most researchers are familiar with the minimum standard precautions that should be taken to maintain the confidentiality of data, including coding data, separating fact sheets and consent documents from survey instruments, properly disposing of computer sheets and other papers, limiting access to identifiable data, educating the research staff about the importance of protecting confidentiality, and storing records in secured locations. More elaborate procedures may be appropriate for research involving sensitive data that may pose a greater risk should confidentiality be breached.

⁷ The SAGU IRB is led by two co-chairs who share leadership responsibility and tasks. For ease of communication, however, the singular term *chair* is used in this manual when discussing organizational structure, tasks, and responsibilities.

Special (i.e., vulnerable) Populations: Additional Protections

If the proposed research involves a population that may be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, or mentally disabled persons, additional safeguards should be included in the study to protect the rights and welfare of these subjects.

Students and Coercion

Universities afford investigators with a ready pool of research subjects: students. One problem with student participation in research conducted at SAGU is that the student's agreement to participate may not be truly voluntary. For example, students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., participating will result in receiving better grades, recommendations, employment, etc.), or that failure to participate will negatively affect their relationship with the investigator or faculty in general (i.e., by seeming "uncooperative," not part of the scientific community, etc.). When recruiting students, investigators should be aware of the possibility that students may feel pressured to participate in research, and the investigators should make every effort to make clear that participation in research is voluntary and students' decisions to participate will not affect their academic standing or their relationship with the researcher or faculty members.

Offering participation in research as a way to receive course credit (or extra credit) also presents an issue of *coercion*. There are two important issues to address: (1) participation in the research must be only one of a number of options; and (2) the other options must be roughly equivalent in terms of the amount of time and effort required. For example, participation in a 30-minute survey should not be offered as an alternative to completing a 10-page term paper.

Another issue raised by the involvement of students as subjects is *confidentiality*. As with any research involving human subjects, the researcher should make every effort to protect the confidentiality of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol. This is especially important for research involving students, since other students are often members of the research team and may be involved in data collection and/or analysis. Researchers should ensure that their research staff understands the critical importance of protecting confidentiality.

The Application for IRB Review

The Application for IRB Review is a Word document located on the SAGU IRB website;⁸ it is available in two versions: one for student researchers and one for faculty-staff researchers. It contains fillable fields to simplify completion. Student researchers should save the preferred version to their computer, answer all the questions completely, then submit the signed original proposal along with all supporting documents to their faculty supervisor for review, endorsement, and IRB submission. Faculty-staff researchers should follow the same procedures, except they should submit the complete application packet direct to the reviewing IRB Co-chairs.

⁸ See <http://www.sagu.edu/irb/>.

Supporting Documents

The following items, when applicable, must be submitted along with the signed Proposal for Initial Review:

- CITI Certificate of appropriate course completion or NIH Certificate of course completion for the Protection of Human Research Participants course;
- All data-collection instruments to be used in the study;
- Assurance(s) of institutional access to required data sources: human subjects, data stored in database(s), essential documents, records, and test scores;
- All recruitment flyers, letters of invitation to participate in the study, and similar documents;
- Informed consent template(s);⁹
- Confidentiality agreement(s) if external researcher or technician will be involved in data collection or analysis.³

Assessment and Description of Risks

All risks to which human subjects may be subjected must be thoroughly assessed and described in the application. Potential risks may be physical, psychological, emotional, social, economic, or legal. Any of these risks may result in loss of confidentiality. When answering questions about risks in the application, the researcher must consider the likelihood, severity, and nature of the risks incurred.

Categories of IRB Review

Research Determined to Be Exempt from IRB Review

Some investigations that would otherwise merit review by an institution's IRB do not satisfy the critically important definitions of the terms *research* and *human subjects*. These key definitions are contained in the Code of Federal Regulations, and precisely define the boundaries of IRB responsibility and activity:

Human subject—a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

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” (45 CFR 46.102 (d)).

An investigator may submit an application for review that, in the judgment of the reviewing IRB Co-chair, does not involve research with human subjects, as defined above. Such a study is

⁹ Available at the IRB web page: <https://www.sagu.edu/academics-home/institutional-review-board>

exempt from IRB review; this determination will be communicated in writing to the investigator by the Co-chair.

Research Qualifying for Expedited¹⁰ Review

DHHS Regulations (45 CFR 46.110) specify the conditions under which proposed research may be reviewed by the IRB using an *expedited review* procedure. To qualify for expedited review, the proposed research must present no more than *minimal risk* to human subjects. Specifically, the research involves only those procedures described in one or more of the following categories.

1. Research involving materials (data, documents, or records) that have been collected, or will be collected, solely for non-research purposes.
2. Research requiring the collection of data from voice, video, digital, or image recordings made for research purposes.
3. 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 surveys, individual interviews, focus group interviews, oral history, program evaluation, human factors evaluation, or quality assurance methodologies.

Continuing review of research previously approved by the IRB, as follows, may qualify for expedited review:

1. Research in which minor changes in previously approved research are needed during the period for which approval is authorized;
2. Research in which (1) the investigation is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects;
3. Research in which no subjects have been enrolled and no additional risks have been identified;
4. Research in which the remaining research activities are limited to data analysis.

For both initial and continuing reviews conducted under expedited review procedures, the IRB Co-chair will document the specific category justifying the expedited review and the action taken by the Co-chair, including any required findings.

Research for which Expedited¹¹ Review Is Not Possible

The expedited review procedure **may not** be used for the following types of research:

1. Research in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing, unless reasonable

¹⁰ The term *expedited* refers to the level of review and does **not** mean that the review will be conducted quickly in all instances.

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and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal;

2. Research with human subjects specifically protect
3. Classified research involving human subjects.

Research Requiring Review by the Full Board

All proposed research that (1) is not exempt from IRB review, (2) does not qualify for expedited review, and (3) has not been reviewed by another IRB will be scheduled for review by the full IRB. A *full board review* is conducted by at least five IRB members selected by the Co-chair. Approval of the research project requires a majority vote of the selected full board reviewers.

Examples of projects requiring review by the full board include the following:

1. Research judged to likely involve greater than *minimal risk*;
2. Research involving *vulnerable populations* (e.g., legal minors, prisoners, pregnant women, mentally disabled persons);
3. Classified research.

Five decisions are possible when a project undergoes a full board review:

1. *Approved with no changes*. The research project may be initiated upon issuance of the IRB approval letter by the IRB Co-chair.
2. *Approvable with minor changes*. Such minor changes must be clearly delineated by the IRB so the investigator may easily comply with the IRB's stipulations. The research may begin after the required changes are verified and the protocol approved by the IRB Co-chair.
3. *Approvable with substantive changes*. The research may begin only after the full board has reviewed and approved the required changes to the research project.
4. *Deferred*. The IRB determines that it lacks sufficient information about the research to proceed with its review. Review of the research project halts, pending receipt of additional substantive information. The research may not proceed until the IRB has approved a revised proposal incorporating all necessary information.
5. *Disapproved*. The IRB has determined that the research project cannot be conducted because the risks presented to human subjects outweigh the potential benefits of the research.

The Application Review Process

Preliminary Review

There are three levels of review for research involving human subjects: (1) exempt from further review, (2) expedited review, and (3) full board review.

All applications (with supporting attachments) undergo preliminary review by the IRB Co-chair, who determines the level of review applications will undergo. Prior to the formal review by the

IRB, the reviewing Co-chair may request additional information about the proposed research project and any of the mandatory attachments. The Co-chair may also invite *ad hoc* reviewers to assist in the review process when additional expertise is necessary; such reviewers serve as non-voting consultants.

For a quick overview and timeline, investigators should access the IRB Review Process Checklist found on the SAGU IRB website (www.sagu.edu/irb).

1. A project may fall within ***exempt from further review*** category after examination by the IRB Co-chair. In such cases, the IRB Co-chair will document the specific category of research which justifies the exemption.
2. Projects may be eligible for ***expedited review*** if they involve no more than ***minimal risk*** to subjects. The IRB Co-chair determines the appropriate level of review and category for the project. In those cases where projects appear to be eligible for expedited review, the Co-chair may conduct the expedited review or may assign the project to one or more experienced members of the IRB for expedited review. If an IRB member has conducted the expedited review, the IRB Co-chair reviews the submission and the IRB member's evaluation and makes a final determination about the proposed research subject.
3. Initial or continuing review of projects that involve more than ***minimal risk*** or a ***vulnerable population*** or which do not fit into the categories for exempt or expedited review must undergo a ***full board review***. A full board review is conducted by at least five IRB members selected by the IRB Co-chair. Approval of the research project requires a majority vote of the selected full board reviewers. The IRB Co-chair may invite *ad hoc* reviewers to assist in the review of proposed research projects for which additional expertise may be necessary, but such reviewers may not vote. In order for a given project to be approved, it must receive the approval of a majority of those voting members selected for full board review.

Proposal Approval Notification

Once the IRB has reviewed the proposed research study,¹² the investigator will be notified of the IRB's decision via an IRB Approval Letter signed by the IRB Co-chair. If any changes or clarifications or additional documents are required, these items will be communicated to the investigator from the IRB Co-chair by an e-mail message sent to the address provided in the IRB proposal. The investigator will submit all revised or additional documents or requested clarifications to the IRB Co-chair. Approval of a proposed research project is not granted until all conditions required by the IRB have been satisfied.

If the investigator does not reply to the IRB's requested changes within 120 days, the IRB proposal file will be closed and a new IRB proposal will be required for any further review of the proposed research project by the IRB.

Conditions of Approval and Length of Approval Period

Approval of a project by the SAGU IRB applies only to the procedures described in the proposal and reflected in any documents submitted to the IRB for review. Investigators must secure prior

¹² Whether such review was performed by the IRB Co-chair, a designated IRB reviewer, or the full board.

written approval from the IRB for any changes (major or minor) in the approved procedures or documents. These are termed *modifications*.

Investigators must also immediately report to the IRB any unanticipated problems that arise in connection with the involvement of human subjects. These are termed *adverse events*.

Approval for projects is valid only until the expiration date indicated in the approval letter. All research projects must be reviewed by the SAGU IRB no less often than annually. The length of the approval period is determined by the IRB Co-chair and is based on degree of risk to human subjects involved in the research. For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB Co-chair may determine the appropriate approval period. In making this determination, the IRB Co-chair will consider whether the protocol involves high risk/potential benefit ratio. The approval letter from the IRB will specify the date of expiration of IRB approval.

Continuing Review

DHHS regulations require that the IRB conduct continuing review of all human subjects research at intervals appropriate to the degree of risk, but not less than once per year [45 CFR 46.109].

In conducting continuing review, the IRB will review, at a minimum, the protocol and any amendments as well as a status report on the progress of the research, including (a) the number of subjects accrued; (b) a description of any adverse events or unanticipated problems involving risks to subjects or others, withdrawal of subjects from the research, or complaints about the research; (c) a summary of any recent literature, findings, or other relevant information, especially information about risks associated with the research; and (d) a copy of the current Informed Consent document.

For projects which qualify for continuing review under the expedited review procedure, the IRB Co-chair will conduct the continuing review.

Appeal

PIs may appeal IRB decisions regarding serious or continuing noncompliance by submitting a brief summary outlining the reasons for the appeal to IRB. PIs who appeal such decisions must attend the convened IRB meeting in which the appeal is reviewed.

Suspension or Termination of Approval

The IRB has the authority to suspend or terminate approval of research that is not conducted in accordance with IRB requirements or is associated with unexpected serious harm to participants, adverse events, unanticipated problems, or serious or continuing noncompliance. Researchers must not recruit participants, enroll participants, or collect data in any form when research studies have been suspended or terminated. Data collected during periods of suspension or termination must be discarded and may not be used in any capacity for research projects. Any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to investigators, faculty advisors of student investigators, the academic unit administrators, the Vice President of Academics, OHRP, and the funding agency head.

Reporting Critical Incidents

Investigations Regarding Possible Non-Compliance

The most common lapses in investigator compliance include unreported changes in the IRB-approved protocol or consent documents, misuse or non-use of the IRB-approved Informed Consent documents, lapse in approval for continuing review, and failure to obtain IRB approval prior to starting research activities.

When unapproved research or procedures are discovered, the IRB and SAGU will act promptly to halt the research; assure remedial action regarding compliance with federal, local, and institutional human subject protection requirements; and address the question of the investigator's fitness to conduct human subject research.

Reporting of Suspensions, Terminations, or Non-Compliance

As soon as possible, but no later than within 10 days of determination by the IRB, suspensions, terminations, and/or non-compliance findings will be reported in writing to the Vice President for Academics, who, within 20 days of receipt of such a report, must also notify in writing the relevant faculty advisor, Dean any applicable regulatory body and OHRP of any suspensions, terminations, and/or instances of serious or continuing non-compliance.

Closeout of IRB Protocol

Exempt studies are closed at the time an exemption is granted. Investigators who have received approval for an expedited or full-review study must submit a request to close their file when approved research projects are completed. Close-file requests should be submitted prior to the expiration date of the study.

An application file must also be closed when the investigator is no longer at the University, unless a modification is approved to change the investigator on a study. Any exception allowing an investigator no longer affiliated with SAGU to maintain an active IRB approval must be approved by the appropriate Dean and Vice President of Academics. The close file request must include the number of participants accrued, a summary of unanticipated problems and/or adverse events, participant complaints, withdrawals, and a summary of amendments and modifications since the last review.

Researchers must submit copies of signed consent forms to the IRB upon completion of projects or be granted an exception by the IRB for this requirement. Original signed consent forms should be retained by the investigator. Consent forms placed on file with the IRB will be handled with the confidentiality of the subjects in mind. Graduate students who have conducted research as required by degree plans will be cleared to graduate when all signed documents are received by the IRB and the Graduate School has been notified.

IRB Records

The IRB will prepare and maintain adequate documentation of IRB activities. The following documents, in particular, will be maintained:

- Copies of all research applications reviewed, scientific evaluations that accompany proposals, approved informed consent documents, progress reports, and reports of adverse events/unanticipated problems;
- Minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; votes on these actions including the number of members voting for, against, and abstaining; the basis for required changes in or disapproval of research; and summaries of the discussion of controverted issues and their resolution;
- Records of continuing review activities;
- Copies of all correspondence between the IRB and the investigators;
- List of IRB members and copies of their vitas;
- Written procedures for the IRB; and
- Statements of significant new findings provided to participants.

The records maintained by the IRB will be retained for at least four years from the file closed date. All records will be accessible for inspection and duplication by authorized representatives of the Department of Health and Human Services at reasonable times and in a reasonable manner.

Appendix A: The Belmont Report

The **Belmont Report** attempts to summarize the basic ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees.

The Belmont Report requires that research on human subjects be conducted according to certain basic ethical principles. The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

2. Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

3. Justice. Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Appendix B: Office of Human Research Protections Registration Details

IORG#: IORG0008713

Approval: Approved for use through October 31, 2018

Institution: Southwestern Assemblies of God University

Additional details are available on request.