Institutional Review Board (IRB) Handbook

The USW Institutional Review Board (IRB) Handbook serves as a guide for students and faculty seeking approval to engage in research activity affiliated with University of the Southwest. Such approvals are required for research that includes human and animal participants, dissertations, and similar projects. Students should consult their research committee chair regarding questions and/or concerns related to specific projects.

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Guiding Ethical Principles

As an institution of higher learning, University of the Southwest is committed to highest level of ethical conduct and maintains such standards in keeping with the university mission. Research affiliated with USW, particularly that involving human subjects, is guided by and consistent with the ethical principles and standards outlined in Title 45, Part 46 of the U.S. Code of Federal Regulations https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html. Additionally, research projects associated with the university observe the ethical practices and standards outlined in the The Belmont Report – Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as well as the Declaration of Helsinki. The IRB policies and procedures outlined in this handbook apply to all university-affiliated research (funded or non-funded) that is conducted by USW students, faculty, and staff. Such research will also be consistent with the foundational ethical principles outlined below.

- The participation of human subjects in research may present ethical and civil rights questions. Such research will be appropriately reviewed and guided by the IRB and polices/procedures outlined in this handbook.
- All research activities involving human subjects must afford for the appropriate rights, health, and safety of all participants.
- Research participation must be completely voluntary and comply with requisite informed consent guidelines. Participants do not forfeit any rights by agreeing to be a part of research activities. Participants are allowed to refuse participation and/or withdraw from research activities at any time without any adverse consequences or penalties.
- The benefit derived from the research must fully and completely outweigh the risk to the participants.
- The researcher must take every reasonable precaution to safeguard personally identifiable information about the participants.
- Protecting the rights, safety, and health of participants rests with the researcher supported by USW as outlined in the IRB policies and procedures.

IRB Membership (HHS §46.107)

The Institutional Review Board will consist of at least five members, and include representation from each of the three colleges (College of Business Administration, College of Arts & Sciences, College of Education). One of the five members will serve as the chair and will be the official point of contact for the deans of each college for IRB matters. Representatives will be full-time faculty holding terminal degrees in various fields and have demonstrated both professional and academic achievements sufficient to warrant service on the board. IRB member representation will appropriately align with the university commitment to diversity, cultural awareness, academic freedom, and individual respect, with the goal of safeguarding the rights of human participants in research. Representatives must possess the knowledge and competence required for compliance with applicable legal regulations, institutional policies, and industry standards. The IRB shall make every effort to ensure members are appropriately credentialed and trained. Such efforts may include, but are not limited to, providing/requiring professional training when necessary (NIH, CITI, etc.). IRB members will be appointed for a one-year term of service and will be selected during the faculty council meeting when council officers are elected.

IRB Responsibilities and Expectations (HHS §46.108)

The IRB is responsible for evaluating potential risks to the safety and well-being of human participants for university-affiliated research projects through the IRB research application. IRB does NOT evaluate research proposals for validity, methodology, applicability, etc. The faculty chair and committee for individual student research projects are expected to evaluate research proposal content, validity, methodology, applicability, etc., prior to the submission of an IRB application. The role of IRB is to maintain the university standard of ethics in research involving human participants.

The IRB chair will serve as the primary point of contact for the deans of each college (College of Business Administration, College of Arts & Sciences, College of Education), and will be responsible for:

- scheduling and leading IRB meetings as necessary to review pending research applications;
- providing IRB members with research application information to review;
- coordinating with faculty research chair and/or college deans for research

applications under review;
- conducting a formal vote with IRB members for research applications having been reviewed;
- appointing a secretary to record the minutes of the IRB meeting that include a summary of all actions taken;
- maintaining all IRB meeting records; and
- notifying the faculty research chair and/or college dean of research approvals.

IRB members will coordinate with the IRB chair and will be expected to:

- attend meetings scheduled by IRB chair;
- review research applications provided by IRB chair;
- disclose any conflicts of interest to IRB chair and, if necessary, recuse himself/herself from the review; and
- vote on reviewed research proposal applications.

Updates to the IRB responsibilities and expectations defined in this handbook will be completed annually (as with other university handbooks) in a coordinated effort between the provost, the dean of the College of Business, the dean of the College of Arts & Sciences, the dean of the College of Education, and the IRB chair.

IRB Records (HHS §46.115)

The secretary of the IRB will record the minutes of each meeting and maintain the relevant IRB documentation for at least three years. Documents required to be kept on file include:

- IRB handbook updates;
- IRB meeting minutes;
- a list of all IRB members and credentials;
- research proposals and applications; and
- any direct correspondence between the IRB, deans of the Colleges, research chairs, or students.

As IRB chairs and secretaries change with terms of service transitions, the aforementioned documents on file will be transferred to the officers currently holding the positions.

Submission Procedure

All proposals to conduct university-affiliated research must be submitted to the University of the Southwest Institutional Review Board. IRB approval must be obtained *prior* to initiating the research and data collection. Investigators seeking IRB approval must complete the appropriate training regarding the protection of human subjects in research as identified by the research chair. Examples of training include, but are not limited to, NIH, CITI, or other university IRB-approved courses. Evidence of successful training course completion must be submitted to the IRB along with the research proposal and application. Upon completion of the training, the complete IRB packet will be submitted to the faculty research chair. The faculty research chair will submit the completed packet to the IRB chair, who will then schedule the review meeting with IRB. A complete IRB packet includes the following documents:

- an approved/valid certificate of completion for training regarding the protection of human subjects in research;
- the research proposal (having been approved by the college dean, faculty research chair and committee); and,
- the application for IRB approval.

All complete IRB packets should be submitted electronically to IRB@usw.edu, as this is the designated email address monitored by the acting IRB chair.

Review Criteria (HHS §46.102)

In keeping with the guiding ethical principles, all research proposals submitted to the USW IRB are evaluated according to the level of risk presented to the human participants. The objective of IRB is to weigh the risks posed to participants against the potential benefits to the academic community and the general body of knowledge. Research proposals will be reviewed in accordance with the following risk levels

1. *No Risk* – research participants will face no physical or psychological distress.
2. *Minimal Risk* – the potential physical or psychological distress that participants might face will be no greater than that ordinarily encountered in daily life.
3. *Moderate Risk* – research participants face physical or psychological distress greater than that encountered in daily life. The potential research benefits must outweigh the risk to study participants.

4. *High Risk* – research participants face severe physical or psychological distress much greater than that encountered in daily life. The distress might have lasting effects upon the participants. The potential research benefits must outweigh the risk to study participants.

Review Levels (HHS §46.104)

The USW IRB will engage in the following three levels of review. The IRB will determine the review level appropriate for each individual research proposal in conjunction with the review criteria and corresponding level of risk.

1. *Exempt Research/Review* – research that is low-risk, aligns with the six federally-defined exempt categories, and maintains participant anonymity. These research categories present the lowest potential risk to research participants and generally involve anonymous, public, and/or data without personal identifiers. Although this research is considered "exempt", it still requires IRB review. The review, however, is much less intensive than an expedited or full board review. Examples of exempt research include, but are not limited to, anonymous surveys and interviews without personally identifiable information.
2. *Expedited Research/Review* – research that is minimal risk (or less), aligns with the nine federally-defined expedited categories, and does NOT maintain participant anonymity. Examples of expedited research include, but are not limited to, surveys and interview with personally identifiable information, biological specimens, and pathological specimens with personal identifiers.
3. *Full Board Research/Review* – proposed research with human participants that does not meet the criteria for either exempt or expedited consideration is subject to a full IRB review. A full board review is the most intensive IRB process and is required for proposals that present a level of risk to participants that is greater than minimal. Examples of full board research include, but are not limited to, pharmaceutical clinical studies, research involving medical diagnosis, and investigative studies about illegal behavior or drug abuse.

Approval Criteria (HHS §46.111)

Research proposals will be subject to the following approval criteria when undergoing IRB review. The approval criteria are consistent with federally defined standards outlined in the Code of Federal Regulations HHS §46.111. Specific details of the criteria are available at

the e-CFR site (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits and importance of the knowledge that may be expected to result.
- Selection of subjects is equitable.
- Informed consent will be obtained from each participant or legal representative.
- Informed consent will be documented.
- The research proposal will appropriately provide for oversight of the collected data to ensure the safety of participants.
- The research proposal will appropriately provide for the privacy protections of participants and the confidentiality of data.
- When the proposed research involves federally-defined vulnerable populations, additional protections will be included to protect the rights and safety of these participants.
- Participants will be appropriately informed as to whether any compensation is available, and if so, the extent of the compensation and/or where further information may be obtained. If available, compensation will not be excessive and/or create a situation of coercion or undue influence.

Data Collection

Data collection for research involving human participants will comply with the directives outlined in this section. The principal researcher may only begin collecting data **after** the proposal application has been approved by IRB. Researchers may **not** collect data or proceed with research until written IRB approval has been received. Collecting data for research involving human participants constitutes misconduct and may result in dismissal from the institution. Once written IRB approval has been received and data collection has commenced, each research participant must agree to be part of the study and the privacy of their information must be ensured. Written documentation of informed consent must be signed by each participant or their legal guardian (a sample copy of an informed consent document is included in Appendix A). If the data collection is to be conducted within the setting of another institution/organization, a letter of approval from the institution/organization must be provided with the proposal. The researcher must obtain informed consent and the requisite approvals **before** data can be collected and the documents must contain the elements provided in the sample copy seen in Appendix A.

Regulations and References

- Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research: DHHS 45 CFR 46.110 https://www.hhs.gov/ohrp/sites/default/files/ohrp/sachrp/mtgings/2013%20March%20Mtg/approvedexpeditedreviewcategories.pdf
- Criteria for IRB approval of research: DHHS 45 CFR 46.111(a)(1-2) https://www.hhs.gov/ohrp/sites/default/files/ohrp/humansubjects/ regbook2013.pdf.pdf
- Code of Federal Regulations Title 21, Section 56.110: FDA 21 CFR 56.110 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch. cfm?fr=56.110
- Code of Federal Regulations Title 21, Section 56.111: FDA 21 CFR 56.111(a) (1-2) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch. cfm?fr=56.111
- Code of Federal Regulations PART 46—PROTECTION OF HUMAN SUBJECTS https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104
- Code of Federal Regulations Animal Welfare https://www.nal.usda.gov/awic/final-rules-animal-welfare-9-cfr-parts-1-2-and-3

Appendix A

CONSENT FORM

You are invited to take part in a research study of _____. You were chosen for the study because _____. This form is part of a process called "informed consent" to allow you to understand this study before deciding whether to take part.

This study is being conducted by _____, who is a researcher at University of the Southwest. Research gathered in this study will be used to _____.

Background Information:
The purpose of this study is to _____.

Procedures:
If you agree to be in this study, you will be asked to:

- _____.
- _____.

Voluntary Nature of the Study:
Your participation in this study is voluntary. This means that everyone will respect your decision of whether or not you want to be in the study. No one will treat you differently if you decide not to be in the study. If you decide to join the study now, you can still change your mind during the study. If you feel stressed during the study you may stop at any time. You may skip any questions that you feel are too personal.

Risks and Benefits of Being in the Study:
Participation in the study will take approximately _____ (time) to complete and will involve _____. This study could potentially benefit _____.

Compensation:
[Researcher provides information here]

Confidentiality:
Any information you provide will be entirely confidential. The researcher will not use your information for any purposes outside of this research project. Also, the researcher will not include your name or anything else that could identify you in any reports of the study.

Contacts and Questions:
You may ask any questions you have now. Or if you have questions later, you may contact the researcher via telephone (___-___-____) or email (_____@usw.edu). If you want to talk privately about your rights as a participant, you can contact the chair of the USW Institutional Review Board via email (IRB@usw.edu). USW's approval number for this study is _____ and it expires on _____.

The researcher will give you a copy of this form to keep.

Appendix A

Statement of Consent:

I have read the above information and I feel I understand the study well enough to make a decision about my involvement. By signing below, I am agreeing to the terms described above.

Printed Name of Participant _____

Date of consent _____

Participant's Written or Electronic* Signature _____

Researcher's Written or Electronic* Signature _____

Electronic signatures are regulated by the Uniform Electronic Transactions Act. Legally, an "electronic signature" can be the person's typed name, their email address, or any other identifying marker. An electronic signature is just as valid as a written signature as long as both parties have agreed to conduct the transaction electronically.