

SEATTLE PACIFIC UNIVERSITY Institutional Review Board (IRB)

INTRODUCTION

Policies and Procedures for Protection of Human Participants in Research

The purpose of the SPU Institutional Review Board (IRB) is to protect the rights, health, and privacy of individuals who participate in research that is conducted through the University. Protection of human participants is the primary goal of these policies.

The policies of the SPU IRB are also designed to protect University members who conduct research, and students who conduct research under their supervision. These policies apply to all research activities that involve human participants.

Definition of Research

The definition of Research used by the SPU IRB comes from the Office of Human Research Protections (OHRP), the federal agency within the Department of Health and Human Services that oversees IRB's. Research is defined as "a systematic investigation (*i.e.*, the gathering and analysis of information) designed to develop or contribute to generalizable knowledge." Research designates "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective."

More simply put, The IRB is responsible to review and approve any proposed research with human participants that occurs ***outside of established or commonly accepted educational settings involving normal educational practices such as regular course evaluations or student assessment***. OHRP refers to this as the "common rule" when ascertaining the need for IRB review.

Any project outside of the common rule that meets ***all*** of the following criteria needs to submit an IRB application for data collection approval.

1. Systematically collects data from multiple human participants ***and***. . . .
2. Stores the data for analysis, ***and***. . .
3. Publicly presents or archives in printed / electronic form a summary of the results that will be available to others outside of normal classroom activities.¹

Implementation of the policies is a joint responsibility of the University and its members. The University, through the IRB is responsible for communicating these principles to employees, monitoring their applications, and enforcing their applications. University members are responsible for designing and conducting research according to the highest ethical principles of their own professional fields and according to University policies.

To learn more about the IRB at SPU see our website at <http://www.spu.edu/orgs/irb/>

To review federal regulations concerning research with Human Participants see <http://www.hhs.gov/ohrp/>

¹ Two common academic activities that are not considered research include student academic assessment and quality assurance surveys.

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IRB CHARTER

In accord with Federal Regulations 45CFR46², Seattle Pacific University has provided the Department of Health and Human Services an assurance that it will comply with federal regulations for human subjects' protections. This Federal Wide Assurance, known as FWA, covers the responsibilities of the University, the IRB, and investigators. Under the FWA, all research involving human subjects at SPU—not just federally funded research—is subject to IRB review and approval.

The IRB follows the Federal Regulations associated with 45CFR46. The IRB also maintains the right to adhere to University specific regulations that are not in violation of Federal guidelines.

As the signatory to the FWA, the Vice President of Academic affairs charges the IRB with the following tasks and responsibilities.

The Institutional Review Board (IRB) shall review and have authority to approve, require changes in prior to approval, or disapprove research activities involving human subjects which are conducted at or sponsored by SPU, including research activities (a) performed by SPU faculty, staff, and students, (b) performed in SPU facilities, or (c) otherwise supported by University resources which are under the control of SPU officials. The IRB shall also have the responsibility and authority to adopt appropriate procedures adequate to assure compliance with the approved consent process and other requirements for the protection of human subjects.

IRB AUTHORITY AND RESPONSIBILITIES

To fulfill the requirements of DHHS regulations and this policy, the IRB shall have the following authority and responsibilities:

1. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by federal regulations, state law, and institutional policy.
2. The IRB shall require signed informed consent by Human Subjects where required by 45CFR46.116 & 117.
3. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
4. Except when an expedited review is used, the IRB shall review proposed research at convened meetings at which a quorum of the members of the IRB are present. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.
5. The IRB shall not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

² 45 CFR 46 includes four subparts. Subpart A refers to regulations regarding the common rule. Subpart B refers to regulations regarding pregnant women, fetuses and neonates; Subpart C refers to Prisoners and Subpart C refers to Children.

6. The IRB shall ensure appropriate training for Investigators whose research includes Human Subjects.
7. The IRB shall conduct continuing reviews of research at intervals appropriate to the degree of risk but not less than once per year. The IRB shall have the authority to determine which research requires review more often than annually.
8. The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with its approval.
9. The IRB shall have the authority to suspend or terminate approval or require modification to research that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of reasons for the IRB action and shall be reported promptly to the investigator and VPAA.
10. The IRB will maintain appropriate records regarding investigator training, research projects, and federal certificates.
11. The IRB shall publish its policies and procedures that detail requirements for research with Human Subjects.
12. The IRB will ensure that the University meets its obligations for Federal Wide Assurance and make appropriate changes in light of new regulations.
13. The IRB is responsible for reporting to the Vice President for Academic Affairs any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.
14. The IRB shall report annually to Faculty Council on the status of its work.

Federal Wide Assurance and IRB Registration

In noting its adherence to Federal Wide Assurance, the Department of Health and Human Services has assigned the Federal wide assurance number **FWA00010393**³ to Seattle Pacific University. The current assurance expires July 24, 2009.

The IRB number assigned to Seattle University is IRB00002129

³ PI's applying for Federal grants will be asked to provide the FWA number, include FWA and the following 8 numerical digits.

GENERAL POLICES

- 1.1 The University complies with the terms of Federal Wide Assurance for research with Human subjects for all research protocols regardless of their source of funding. The University has voluntarily applied the common rule and subparts B, C, and D of HHS regulations 45 CFR part 46 to all research regardless of source of support.
- 1.2 The University recognizes the Belmont report as its statement of principles for the protection of the rights and welfare of human subjects in research.⁴
- 1.3 The University and its employees recognize their responsibility for protecting the rights and welfare of human participants. The University requires Researchers to provide and / or document written and oral informed consent with each participant where appropriate.
- 1.4 The IRB convenes once a month during the nine-month academic year. Applications for full review during June through August may be delayed the IRB chair can not call a voluntary quorum of members during the summer months.
- 1.5 No participants will be exposed to unreasonable risks to health and welfare. Appropriate research procedures and facilities help protect participants' safety.
 - 1.5.1 The IRB reserves the right to deny approval for research which may cause harm to participants or violates University Community standards and policies
- 1.6 Research that entails risk or substantial mental and/or physical discomfort will be carefully explained to participants. The researcher must document that participants understand the potential risks or discomforts, as well as potential benefits, prior to their participation.
- 1.7 Research involving legal minors (less than 18 years of age), adult legal dependents, and other at risk populations covered under 45CFR46 subparts B, C, & D who maybe unable to give informed consent may be approved if the study involves no risk to welfare or suffering and the study may directly benefit the participants.
- 1.8 PI's follow HIPAA guidelines for the concerning the deidentification of personal information when collecting or using archival data.
- 1.9 Research material including informed consent and recruitment material should be clearly labeled as Seattle Pacific University research if sponsored by Seattle Pacific University.
- 1.10 IRB study number and expiration date must be clearly labeled on all Informed consent documentation and recruitment material.
- 1.11 Subjects may withdraw from any part of or all research activities at any time. A withdrawal will bring no penalty or loss of benefits to which participants are otherwise entitled.
- 1.12 Data gathered in research will be anonymous or confidential. Confidentiality extends to data collection, interpretation, storage, publication, and disposal.
- 1.13 Records (including signed informed consent documents) and data pertaining to research that is conducted using human subjects must be retained by the PI for three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the Academic department, IRB, SPU or external agency or organization supporting or conducting the research during this time period.
- 1.14 IRB documents are stored with the approving IRB member during the active data collection. Once data collection is closed, the IRB documents are transferred to the Chair of the IRB who will confidentially store IRB documents for three years.
- 1.15 Researchers who submit research proposals that carry greater than minimal risk must demonstrate training in regards to research with human participants. This demonstration

⁴ <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>

can include training certificates from on-line or off site training programs or syllabus that with specific IRB training module(s).

- 1.15.1 All members of the research team must have on record with the IRB chair documentation that they have received adequate training on conducting research with Human Participants.
- 1.16 No researcher shall undertake a project that is covered by this document without following the procedures listed below.

IRB MEMBERSHIP

- 2.1 The University Institutional Review Board (IRB) is a standing University faculty committee.
- 2.2 The Institutional Review Board reports to the Vice President of Academic Affairs.
- 2.3 The IRB will be comprised of no fewer than five members: all of whom are knowledgeable in the issues of human research, not entirely men or women, one of whom has primary concerns in scientific areas, one of whom has primary concerns in non-scientific areas, one of whom is not affiliated with the college, none that have any conflicting interest with any project to be reviewed. At least three members will hold faculty contracts, one of whom will chair the board.
 - 2.3.1 The IRB will provide an ad hoc Prisoner's advocate for any proposed research that wishes to use a prisoner population
- 2.4 Appointments to the IRB will be made by the VPAA per the federal regulations upon the recommendations of the appropriate Deans. IRB members should accept this appointment with the understanding that they will serve at least three years. Given the large knowledge base associated with serving on the IRB, terms on the board are considered continuous until a member requests to be replaced.
 - 2.4.1 Requests for replacement to the IRB should be made to the IRB chair at the end of Spring Quarter.
- 2.5 All IRB members have documented training associated with their roles in the committee. IRB members will participate in some form of IRB training at least every three years. The IRB chair will be responsible for the documentation of IRB member's training.

IRB MEMBER ROLES AND RESPONSIBILITIES

- 3.1 IRB members collaboratively develop, approve and revise IRB research policies, roles and responsibilities in conjunction with federal guidelines, University policies, their IRB charter and in consultation with best practices of other Academic IRB organizations.
- 3.2 IRB members commit to attending monthly IRB meetings
- 3.3 IRB members review IRB applications to ascertain level of appropriate IRB review
- 3.4 IRB members individually review and approve research which is exempt from expedited or full IRB review.
- 3.5 IRB members contribute to the review of IRB applications that require expedited or full review.
- 3.6 IRB members track approved research studies by providing the following information in the database.
- 3.7 IRB members communicate with PI's regarding any IRB decisions
- 3.8 IRB members follow-up within the time period allotted to a study to insure that data collection ends within the time frame allowed by the approved IRB application.
- 3.9 IRB members maintain their appropriate level of IRB knowledge through training and continuing education.
- 3.10 IRB members must be familiar with Office of Human Research Protections documents including
 - 3.10.1 The Belmont Report
 - 3.10.2 Common Rule
 - 3.10.3 45 CFR 46 subparts B,C & D
 - 3.10.4 Criteria for Federal Wide Assurances

IRB CHAIR ROLES AND RESPONSIBILITIES

- 4.1 The IRB Chair is responsible for the administration of policies and procedures related to the protection of the rights and welfare of human subjects in research. Ensure compliance with all federal, state, and local regulations and applicable institutional policies. Provide administrative and educational leadership to the IRB and Investigators who work with Human Subjects. Ensure the review and tracking of IRB applications. Communicate with all IRB stakeholders.
- 4.2 Responsibilities for IRB Review
 - 4.3.1 Provide initial review and where appropriate approval for unit IRB submissions.
 - 4.3.2 Provide expedited review for IRB applications that fall under criteria for expedited review
 - 4.3.3 Chair full IRB reviews.
 - 4.3.4 Provide continuing reviews of ongoing research including protocol changes.
- 4.4 Administrative Duties
 - 4.4.1 Maintain all IRB documents including
 - 4.4.1.1 Annual IRB tacking system.
 - 4.4.1.2 IRB User Guide
 - 4.4.1.3 IRB Application
 - 4.4.1.4 Informed Consent Template
 - 4.4.1.5 PI Communication template
 - 4.4.1.6 Non-Compliance Form
 - 4.4.1.7 Adverse Impact Form
 - 4.4.2 Communicate with Principal Investigators regarding the status of their IRB approval including closure or continuation of IRB approval after review.
 - 4.4.3 Act as the liaison between the IRB committee and Office of Academic Affairs (OAA).
 - 4.4.4 Coordinate problems, issues and decisions among IRB members and when necessary, with OAA.
 - 4.4.5 Track and take action based on adverse events reporting.
 - 4.4.6 Work with OAA to ensure appropriate IRB membership including community member and prisoner advocate.
 - 4.4.7 Work with OAA to ensure appropriate response for non-compliance.
 - 4.4.8 Insure adequate storage of IRB records.
 - 4.4.9 Insure adequate IRB minutes
 - 4.4.10 Insure appropriate retention of IRB documentation.
- 4.5 Policies and Procedures
 - 4.5.1 Establish and periodically evaluate the policies and procedures of the IRB in conjunction with IRB members.
 - 4.5.2 Oversee the administrative operations of Research Coordinators and IRB members

- 4.5.3 Maintain institutional assurances mandated by federal, state and local laws regarding human research subject protections including federal IRB registration and federal wide assurances.
- 4.5.4 Maintain and revise as necessary IRB application, Informed Consent template, Decision letter templates, review template and other IRB documents
- 4.6 Communication and Education
 - 4.6.1 Chair monthly IRB meetings.
 - 4.6.2 Ensure provision of meeting minutes and decision documentation.
 - 4.6.3 Work with OAA to maintain SPU IRB web site.
 - 4.6.4 Ensure appropriate opportunities for training for IRB Members, Research Coordinators and Investigators within the SPU community.
 - 4.6.5 Periodically review exempt and expedited reviews for quality assurance.
 - 4.6.6 Serve as policy and decision resource for IRB members
 - 4.6.7 Ensure own professional development regarding IRB regulations and communicate pertinent changes to SPU research community. Join appropriate guilds, distribution lists and attend IRB forums for professional development
 - 4.6.8 Must be familiar with Office of Human Research Protections documents including
 - 4.6.8.1 The Belmont Report
 - 4.6.8.2 Common Rule
 - 4.6.8.3 45 CFR 46 subparts B,C & D
 - 4.6.8.4 Criteria for Federal Wide Assurances

CRITERIA FOR SPU IRB RESEARCH REVIEW

- 5.1 Any research project involving human participants with Seattle Pacific University faculty, staff, or students serving as principle investigator (PI), must be reviewed by the IRB. This includes any study with human participants who may not be part of the SPU community. Research in the following categories must be submitted to a research coordinator for review
 - 5.1.1 Research that is part of a university course or degree requirement.
 - 5.1.2 Research that is conducted for or sponsored by a university office;
 - 5.1.3 Research that is conducted for or sponsored by a college, school, or university committee
 - 5.1.4 Research that is conducted for or sponsored by a university faculty member as part of his/her professional role or expectations at the university.
 - 5.1.5 Any previously approved study in which data collection tools or processes have been amended.
- 5.2 Any research project that specifically targets SPU community members as the population of interest must be reviewed by the SPU IRB. PI's who are not members of the SPU community, who wish to collect data specifically from SPU must work with a Faculty or Staff sponsor and submit an IRB for approval.
 - 5.2.1 The IRB will review the application and may approve the study based on its previous approval if the other IRB holds an active Federal wide Assurance number.
- 5.3 SPU community members who are not PI's on research studies reviewed by other IRB's need not have the study reviewed by the SPU IRB unless the study collects data from the SPU community. In that case, the IRB recommends that the PI receives IRB approval from the PI's organization and then submit the SPU application to the SPU IRB.
 - 5.3.1 The IRB will review the application and may approve the study based on its previous approval if the other IRB holds an active Federal wide Assurance number.

TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH

- 6.1 Training in the responsible conduct of research (RCR) is required for PI's and Research assistants who have direct contact with human subjects and are:
1. Applying for a NSF or NIH grant, or
 2. Conducting research with more than minimal risk requiring expedited or full review (If a documented informed consent is required for your study),
 3. Conducting research with children outside of normal everyday activities;
 4. Conducting research with prisoners or other vulnerable populations.

- 6.2 PI's must have training if their research falls into the above categories even if they do not have direct contact with research participants and are only supervising research assistants

Researchers can receive training through the following web site.

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

- 6.3 For NSF or NIH grant writers, you need a more complete RCR training. Go to The *Collaborative Institutional Training Institute's* website to register for their online course <https://www.citiprogram.org/>
When prompted for which course to take, check the box that reads CITI Social and Behavioral Sciences RCR Course For The Unaffiliated Learner:

- 6.4 Certificates of RCR training from other institutions may be eligible to meet this requirement. Check with the Chair of the IRB.

- 6.5 PI's are responsible for ensuring that all members of their research team who will have contact with participants in the above categories have certificates of completion on file with the chair of the IRB. PI's can turn in the certificates with their IRB application or note that the certificate is on file with the IRB chair.

- 6.6 The certificate is valid for 5 years

TRAINING IN THE ROLES AND RESPONSIBILITIES OF BEING AN IRB MEMBER

- 7.1 All IRB members are required to complete training on the roles and responsibilities of being an IRB member. This training is required every five years.
- 7.2 The Academic officer is required to complete training associated with his responsibilities every five years
- 7.3 The training can be found at <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

IRB APPLICATION

- 8.1 All PI's must submit, in writing, on paper, the IRB application for Human Subjects Review which is found on the SPU IRB web site.
- 8.1
- 6.8 As the IRB application is updated frequently, the PI must insure that he or she uses the latest edition of the application posted on the website.
 - 6.8.1 IRB applications that not are completed with the appropriate application will be returned to the PI.
- 6.9 The IRB application consists of the following sections. PI's should ensure that all sections are completed in as much detail as to allow the IRB to ascertain the risks and benefits to the Human subjects
 - 6.9.1 Title of the Project:
 - 6.9.1.1 The title of the project does not need to be the same working title for proposed publication or the title given to the project on the informed consent. However the title must reflect the elements of the study and must be used consistently on all communication and documentation regarding the study.
 - 6.9.1.2 Provide the estimated start and stop dates for data collection
 - 6.9.2 Contact Information
 - 6.9.2.1 The PI must list everyone who will have contact with Human subjects in the collection of data and e-mail contact information (SPU e-mail account where possible). If additional research assistants are added to the research project the PI must notify the IRB member with the appropriate information.
 - 6.9.2.2 The PI provides the expected start and stop date for data collection understanding that the IRB will initially approve the study for one year duration.
 - 6.9.2.3 If the PI is an SPU student or someone who is not a member of the SPU community, a faculty / staff sponsor name and signature must be listed.
 - 6.9.2.4 The PI or study sponsor must provide the date of his or her signature
 - 6.9.2.5 If the study will work with at risk populations, the PI must provide evidence of training regarding research with human subjects for self and each of the researchers as part of the IRB application, or note that their training is on file with the Chair of the IRB.
 - 6.9.2.6 Once the IRB member receives the application, he or she should sign it and note the date that they received the study
 - 6.9.3 Purpose of study: The PI must provide specific and concise detail so that the IRB can match the procedure and informed consent to the purpose. Citations should be matched with a reference section as an appendix
 - 6.9.4 Sample / Population:
 - 6.9.4.1 Describe the sample size and demographic requirements and location of recruitment for the participants. Explain the rationale for using this

population. Note if you are using a special population such as prisoners, children, the mentally disabled or others whose ability to give voluntary consent may be in question.

6.9.4.2 Who will recruit subjects and how? Ensure that you include any written recruitment material or verbal scripts of oral recruitment statements.

6.9.4.3 Identify steps taken to avoid coercion including dual relationships (i.e., faculty/staff, therapist/client).

6.9.5 Research Procedure.

6.9.5.1 Describe the materials, measures and / or, apparatus that you will use for this study. Attach the materials that you are going to use in the exact format that participants will receive.

Include any recruitment material (both written and scripted for verbal instructions).

If you are using a web-based survey, include the screen shots of the material.

If you are using any type of coding protocol, include a copy of your coding sheet.

If you are using questionnaire, include a copy in the exact format that the participants will use.

If you are using copy-written material provide documentation that you have permission to use or reproduce the material for your study.

6.9.5.2 Describe in detail the research procedure and / or protocols. Ensure that you explain in an active verb tense a) where, b) when, c) how the data will be collected and d) by whom. If you are conducting a study with an intervention, provide written instructions, transcript of verbal instructions and any other protocol. Identify any procedures that are experimental with potentially unknown risks or outcomes.

6.9.5.3 Are you planning to use the research data for other activities / research outside of this study? If so, are other uses clearly labeled in the confidentiality section of the informed consent form?

6.9.6 Time Frame: What is the total time that participants will spend in this study? If participants will give data multiple times, how long will they spend in each session and how many sessions will they participate in?

6.9.7 Risks

6.9.7.1 Describe and assess any potential risks--physical, psychological, social, legal or other--and assess the likelihood and seriousness of such risks.

6.9.7.2 If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

6.9.7.3 Describe procedures, including confidentiality safeguards, for protecting against or minimizing potential risks and an assessment of their likely effectiveness.

6.9.8 Benefits

6.9.8.1 Assess the potential benefits that may be gained by any individual participant, as well as benefits which may accrue to society in general as a result of the planned work.

6.9.8.2 Specify any compensation such as monetary or academic credit that you may offer as part of the study.

6.9.9 Confidentiality

6.9.9.1 How will you maintain confidentiality? How will you store the raw and /or electronic records for the three years that SPU requires data and other research records to be stored?

6.9.9.2 If data is subject to HIPAA, how will you de identify medical data?

6.9.10 Consent Documentation

6.9.10.1 Describe consent procedures to be followed, including how and when documented informed consent will be obtained vis a vis the rest of the data collection procedure. Ensure that it is clear to the participant that SPU is the sponsoring institution (where appropriate) and that the language used in the informed consent is clear and can be easily understood by the participants

6.9.10.2 If working with vulnerable populations (children, prisoners, mentally ill or any other participants who may have difficulty giving informed consent) describe how consent or assent will be obtained?

6.9.10.3 If documented informed consent will not be obtained, specifically point this out and explain how you will communicate participants' rights

6.9.11 Deception: If any deception (i.e., withholding of complete information) is required for the validity of this activity, explain why this is necessary and attach debriefing statement.

INFORMED CONSENT

To respect the rights of research participants, it is important to provide participants with as much information as feasible in order for them to make an informed decision to participate in the research. To this end, research that is not exempt from IRB overview must provide basic information for participants to make informed consent to participate in research.

Research that poses no more than minimum risk to participants does not require documented informed consent. It does, nevertheless require the PI to provide the following elements of information.

CRITERIA FOR TYPE OF IRB REVIEW

Data collection that is exempt from any IRB Review

SPU community members who are interested in collecting the following types of academic data do not need IRB approval. Data collection in academic settings that consists of the use of educational 1) tests (cognitive, diagnostic, aptitude, achievement), 2) survey procedures, 3) interview procedures, or the observation of academic public behavior that will be used to assess student or educational staff performance.

Data collected for quality assurance. If a study is being completed for quality Assurance purposes and not research, encourage the data collectors to add the following line at the end of their research invitation: "This survey has been reviewed by the SPU IRB (MM/YYYY) and approved for quality assurance use."

Exempt From Full IRB Review

EXEMPTION #1 (45 CFR 46.101(b)(1)):

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

EXEMPTION #2 (45 CFR 46.101(b)(2)):

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

EXEMPTION #3 (45 CFR 46.101(b)(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 paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

EXEMPTION #4 (45 CFR 46.101(b)(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 subjects cannot be identified, directly or through identifiers linked to the subjects.

EXEMPTION #5 (45 CFR 46.101(b)(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: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

EXEMPTION #6 (45 CFR 46.101(b)(6)):

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

More specifically, if PI's are conducting research in the classroom, review the documents with these guidelines⁵

Research involving the use of educational tests is ordinarily exempted at 38 CFR 16.101(b)(2).

- (1) When the subjects are **adults**, this exemption applies **UNLESS**:
 - (a) information is recorded in an identifiable manner (either directly or indirectly using codes or other identifying links); **AND**
 - (b) disclosure of the information would place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

(Note: The research is exempt unless both (a) and (b) apply; i.e., the research is exempt unless the information collected is both identifiable and sensitive, except in the case of children, as follows.)
- (2) This exemption applies to research involving **children**, EXCEPT that:
 - (a) research involving survey or interview procedures with children is NOT EXEMPT; and
 - (b) research involving observation of the public behavior of children is NOT EXEMPT if the investigator participates in the actions being observed.
- (3) If not exempt under the conditions described above, research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior is exempt where:
 - (a) the subjects are elected or appointed public officials or candidates for public office; or
 - (b) federal statutes require confidentiality without exception.

(Note: Condition (b) regarding federal statutes rarely applies. The IRB should consult with ORCA and OHRP if it receives an exemption request based on absolute confidentiality under a federal statute.)
- (4) If not exempt under the conditions described above, the IRB may often utilize expedited procedures for review and approval of research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or the observation of public behavior.

⁵ Material Adapted from Marshall University
<http://www.marshall.edu/research/ori/Sop/Behavioral%20and%20Social%20Science%202002-16-03.htm>

Expedited Reviews

Behavioral and Social Science research qualifies for expedited review as long as the research presents no greater than minimal risk to subjects and fits one (or more) of the nine expedited categories.

A. Research Involving Existing Data and Documents.

Minimal risk research involving materials, (including data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes, may be reviewed using expedited procedures. (*Note: The intent is to define two categories here, each appropriate for expedited review.*)

- (1) Non-exempt research involving materials that have already been collected (for any previous research or non-research purpose) at the time when the research is proposed.
- (2) Non-exempt research involving materials that will be collected in the future for a non-research purpose.

B. Research Involving Data from Voice, Video, Digital, or Image Recordings Made for Research Purposes.

The IRB may utilize expedited procedures to review research that involves the collection of data from voice, video, digital, or image recordings made for research purposes.

C. Research Involving Individual or Group Characteristics or Behavior or Research Employing Survey, Interview, Oral History, Focus Group, Program Evaluation, Human Factors Evaluation, or Quality Assurance Methodologies.

The IRB may utilize expedited procedures to review the following:

- (1) Research on individual or group characteristics or behavior, or
- (2) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- (3) This category covers a wide range of non-exempt social and behavioral research activities when they present no greater than minimal risk to subjects. Examples include, but are not limited to, research on perception, cognition, motivation, identification, language, communication, cultural beliefs or practices.

D. Research Involving Deception or Withholding of Information.

The IRB applies both common sense and sensitivity to the review of research involving incomplete disclosure or outright deception. Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that, when appropriate, the subjects shall be debriefed. (Debriefing may be inappropriate, for example, when the debriefing itself would present an unreasonable risk of harm without a corresponding benefit.) The IRB makes sure that the proposed subject population is suitable.

Deception can only be permitted where the IRB documents that a waiver of the usual informed consent requirements is justified under the following criteria and the IRB must find and document that all four of the following criteria have been satisfied:

- (1) The research presents no more than minimal risk to subjects.
- (2) The waiver or alteration shall not adversely affect the rights and welfare of the subjects.

- (3) The research could not practicably be carried out without the waiver or alteration.
- (4) Where appropriate, the subjects shall be provided with additional pertinent information after participation.

In making the determination to approve the use of deception under a waiver of informed consent, the IRB considers each criterion in turn, and documents specifically, in the IRB minutes and/or in the IRB protocol file, how the proposed research satisfies that criterion.

An IRB member can request full review of a study even if it falls within an expedited category if he or she believes that other members' feedback of the protocol would be helpful in the review of the application.

Use these categories when you are deciding to approve under expedited review. *Research qualifies for expedited IRB review by reason of minimal risk to participants if it meets ONE OR MORE of the Following criteria⁶:*

- _____ (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - _____ (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - _____ (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- _____ (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - _____ (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - _____ (b) from other adults and children⁷, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- _____ (3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- _____ (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and

⁶Source: 63 FR 60364-60367, November 9, 1998

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

⁷ Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#).

effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- ____ (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- ____ (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- ____ (7) 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 survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)
- ____ (8) Continuing review of research previously approved by the convened IRB as follows:
 - (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis.
- ____ (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
- ____ (10) Participants engage in physical activity testing or training when condition (a) or (b) is met.
 - ____ (a) Selection criteria place them at low risk for complications according to ACSM criteria.
 - ____ (b) Selection criteria place them at moderate risk but only light- or moderate-intensity activity is demanded.

Full Review

Full IRB Review is necessary when the research involves any of the following:

1. Prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively impaired adults as subjects;
2. The collection or recording of behavior which, if known outside of the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing to the subject;
3. The collection of information regarding sensitive aspects of the subject's behavior such as drug or alcohol use, illegal conduct, or sexual behavior;
4. Research that does not fall into any of the categories defined as exempt in [45 CFR, Subtitle A, Part 46.110](#)

IRB REVIEW PROCESS

- 2.2 All research within the categories listed above will be reviewed. All reviews start with the RC. There are three levels of formal review of research projects:
1. Review by the RC and exempted from further review by the IRB.
In certain cases when standard and well known research processes and information gathering techniques are used, the RC can exempt a study from further review. However, no person other than an RC can exempt a study, and no RC can exempt his or her own study or one they direct.
 2. Review by the RC and an expedited review by the University IRB Chair.
When an RC decides further review is needed, the proposal is forwarded to the chair of the University IRB. That person can either approve the study or forward it for review by the entire IRB.
 3. Review by the RC, the University IRB Chair and full review by the IRB.
If the A member of the University IRB determines that review by the full IRB is required, he or she provide a copy of the application to the Chair who will ensure that all members receive a copy and place the review on the agenda for the next meeting.
- 2.4 The researcher, principal researcher of a team, or supervisor of a student researcher delivers the research proposal in approved IRB format as well as copies of any supporting research protocols and/or measurement instruments to the RC of the researcher's academic unit or office. A school research or thesis committee may review the proposal and give feedback on it before the RC reviews it.
- 2.5 The RC reviews the proposal and determines the necessary level of review (Section 2.2) for the research. The RC completes the Checklist for Research Proposals and the Essential Information for Consent form and notifies the researcher of the level of review necessary.
- 2.6 Research sponsored by an RC will be reviewed by another RC or a University IRB member.
- 2.7 Any research project is subject to continuous review by the IRB and may be investigated by the IRB at any time at the IRB's sole discretion. The RC and/or the University IRB will monitor the research and decide when and if it needs review.
- 2.8 The IRB approves studies for one year. The PI is responsible for contacting the IRB to inform when the data collection phase of a study is complete. An IRB approval will automatically expire after one year. If a PI needs more than one year to complete data collection, He or she must file a request for an extension with the IRB six weeks before the expiration date of this study. If the PI wishes to continue with the study but does not file the extension request before the expiration date, the PI must file a new IRB application.
- 2.9 If the PI files for an extension, he or she will be required to use his or her original IRB number with an R attached at the end. The expiration date is modified to one year from the original expiration date. This modified IRB number and new expiration date must be added to any recruitment material and / or the informed consent.

TRACKING IRB APPLICATIONS

- 3.1.1 Study Number for the academic year
 - 3.1.1.1 IRB Reviewer
 - 3.1.1.2 Name of the PI
 - 3.1.1.3 E-mail of the PI
 - 3.1.1.4 Name of the University sponsor if the PI is a student or not a member of the SPU community
 - 3.1.1.5 Name of the study
 - 3.1.1.6 Date that the IRB received the application
 - 3.1.1.7 Date the IRB or IRB member(s) provided feedback for the application
 - 3.1.1.8 Date of Final approval
 - 3.1.1.9 IRB number
 - 3.1.1.10 Date of approved IRB modifications
 - 3.1.1.11 Date for renewed IRB's

ACCEPTING IRB APPROVALS BASED ON FWA RECIPROCITY

Sometimes SPU community members conduct research in other organizations or agencies that also require IRB approval from their own board. In general the SPU IRB will accept reciprocity for studies that have been approved by other agencies that have federal wide assurance. However, we reserve the right to not accept if we believe that we do not have the resources to monitor the study. For example, if a member of the SPU community wishes to investigate the efficacy of a drug through a clinical drug trial, even though they may have received IRB permission elsewhere, if they are the principle investigator and their main identity is here at SPU, the SPU IRB would not accept the reciprocity.

If a researcher needs to get dual IRB approval, we recommend that the PI seek out the other IRB approval before submitting their documentation to SPU.

Once the study is approved by the other agency, the PI must submit all their prior IRB documentation to the IRB board here at SPU. The PI needs to make sure that the FWA # and expiration date is available somewhere in the documentation. If the IRB application was accepted under expedited review, the study can be submitted to the local research coordinator. If the study was accepted under full review, it should be submitted to the Chair of the SPU IRB. The IRB does not need to convene for the secondary review. However, data should not be collected until it is also approved by the SPU IRB.

Once the IRB is approved based on reciprocity, the study is treated as a local research protocol. The PI is responsible for letting the SPU IRB know if there are any adverse events, when data collection is repeated etc. The IRB reserves the right to monitor the study in compliance with 45 CFR 46.

The informed consent document would need to show that the research was sponsored by SPU, and faculty contact information if the research is conducted by a student. IRB@SPU.EDU also needs to be on the consent for contact information. The two IRB numbers and expirations dates also need to be on the informed consent.

COMMUNICATING IRB DECISIONS

All communications with PI's must be documented and added to each study's file. Communication should occur through e-mail and then printed out to add to the study's file. This includes any communication prior to approval, such as asking for revisions, and then, approval, revisions and renewals. In this section, you will find text templates for communicating decisions. All IRB communication and decisions must be communicated in writing. PI's can not act on any decisions until they are documented, logged in the data base and stored with the study's file so it is not possible to give verbal consent.

Request an IRB Application Revision

Subject: IRB Revision required

Dear Ms. Randa

I have reviewed your IRB application titled “***Pilot study for the effects of Alcoholics Anonymous Twelve step program on shame and guilt in the individual suffering from alcoholism***” and require the following revision(s) and/or clarifications to your application before completing the review.

Application:

Informed Consent:

Protocol / Measures:

Please address these revisions by submitting a revised IRB application for further review. Your new IRB application must include all required content⁸

Sign as member of IRB

⁸ Use your judgment on this. Depending on how much revision is necessary, you can ask them just to submit a new packet. You can also decide if they can communicate to you via e-mail or if you will need them to provide hard copies.

Exempt Review⁹

Subject: IRB Approval – IRB # 070802011(Exempt)

Dear Mr. Bartholomew¹⁰,

Your research project "*Group Behavior and Law breaking in cyclists*," has been approved under exempt IRB review. This study was approved under exempt review as it met the following criteria.¹¹

- 3. ☒ Research uses survey or interview procedures or observations (including observations by participants) of public behavior AND at least one of the following conditions exist:
 - a. ☒ Human participants cannot be identified directly or through identifiers code or numbers
OR
 - b. ☒ The participants' responses or the observations recorded, if they became known outside research, cannot reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employment
OR
 - c. ☒ The research does not deal with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol

Your approval is in effect until **10/08/2008**. Your study has been assigned IRB number: **IRB # 070802011**.

To complete your documents please add your IRB # and expiration date to you study's written recruitment material and invitation to participate in the research project¹².

Please contact me when you have completed collecting data for your study so that I can close your file. If you need more than one year to complete data collection, you must file a request for an extension with me six weeks before the expiration date of this study. Your request for an extension can be written or communicated through e-mail and must include a report on the status of your study. Otherwise you will need to file a new IRB application to continue with data collection after the expiration date.

Use your study number in any further communication regarding this study.

This is the only documentation that you will receive regarding your study's approval. Please print it out and add to your study's documentation.

Best Wishes in the Completion of your Research

Sign as member of IRB

⁹ There is no need for a documented informed consent form with an exempt review

¹⁰ If the PI is a student, e-mail the faculty sponsor also

¹¹ Place the section of the IRB checklist that you used to determine its exempt status here

¹² Edit as appropriate. For example, exempt research is not required to have a documented informed consent document.

Expedited Review

Subject: IRB Approval – IRB # 070802026 (Expedited)

Dear Mr. Bartholomew¹³,

Your research project **“Influence of confederate "yay-saying" and prosocial non-verbal behaviors on participant opinion making”** has been approved under expedited IRB review.

. This study was approved under expedited review as it met the following criteria¹⁴

“_____(7) 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 survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101](#)(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

You may collect data until **11/16/2008**. Your study has been assigned the IRB tracking number **070802026**.

As part of your IRB approval, you are required to use this number and expiration date on any information regarding this study. To complete your documents add your IRB # and expiration date to any of your study's informed consent, debriefing and written recruitment material.¹⁵

Please contact me when you have completed collecting data for your study so that I can close your file. If you need more than one year to complete data collection, you must file a request for an extension with me six weeks before the expiration date of this study. Your request for an extension can be written or communicated through e-mail and must include a report on the status of your study. Otherwise you will need to file a new IRB application to continue with data collection after the expiration date.

If you plan to undertake changes in the protocol, you are required to submit a memo to me outlining the proposed changes. You may not change any protocol until you receive permission from the IRB.

As part of its review and oversight charter, members of the SPU IRB may request to inspect the data collection process and the confidential records from this research project.

If a subject experiences any adverse effect as part of this research protocol, you must contact the chair of the IRB at IRB@spu.edu immediately, detailing the adverse effect and the action that you took as the principal investigator. Failure to report an adverse effect within 24 hours may lead to the suspension this study.

By collecting data under this IRB application, you agree to be in compliance with Federal and SPU policies regarding the conduct of research with human subjects. Failure to comply with requirements associated with this study must be reported immediately to the Chair of the Institutional Review Board. Failure to comply with IRB policies may lead to adverse consequences as noted in the SPU IRB policies.

This is the only documentation that you will receive regarding your study's approval. Please print it out and add to your study's documentation.

Please use your study number in any further communication regarding this study.

Best Wishes in the Completion of your Research

Sign as member of IRB

¹³ If the PI is a student, e-mail the faculty sponsor also

¹⁴ Use the criteria under expedited reviews

¹⁵ Edit as appropriate

Full Board Review

Subject: IRB Approval – IRB # 070802026 (Full Review)

Dear Mr. Bartholomew¹⁶,

Your research project “**Influence of confederate "yay-saying" and prosocial non-verbal behaviors on participant opinion making**” has been approved under full IRB review. The full review took place (MM/DD/YYYY). Further details on this full review can be found in the meeting’s IRB minutes which are on file with the Office of Academic Affairs.

You may collect data until **11/16/2008**. Your study has been assigned the IRB tracking number **070802026**.

As part of your IRB approval, you are required to use this number and expiration date on any information regarding this study. To complete your documents add your IRB # and expiration date to any of your study’s informed consent, debriefing and written recruitment material.¹⁷

Please contact me when you have completed collecting data for your study so that I can close your file. If you need more than one year to complete data collection, you must file a request for an extension with me six weeks before the expiration date of this study. Your request for an extension can be written or communicated through e-mail and must include a report on the status of your study. Otherwise you will need to file a new IRB application to continue with data collection

If you plan to undertake changes in the protocol, you are required to submit a memo to me outlining the proposed changes. You may not change any protocol until you receive permission from the IRB.

As part of its review and oversight charter, members of the SPU IRB may request to inspect the data collection process and the confidential records from this research project.

If a subject experiences any adverse effect as part of this research project, you must contact the chair of the IRB at IRB@spu.edu immediately, detailing the adverse effect and the action that you took as the principal investigator. Failure to report an adverse effect within 24 hours may lead to the suspension this study.

By collecting data under this IRB application, you agree to be in compliance with Federal and SPU policies regarding the conduct of research with human subjects. Failure to comply with requirements associated with this study must be reported immediately to the Chair of the Institutional Review Board. Failure to comply with IRB policies may lead to adverse consequences as noted in the SPU IRB policies.

This is the only documentation that you will receive regarding your study’s approval. Please print it out and add to your study’s documentation.

Please use your study number in any further communication regarding this study.

Best Wishes in the Completion of your Research

Sign as member of IRB

¹⁶ If the PI is a student, e-mail the faculty sponsor also

¹⁷ Edit as appropriate

Communicating Revisions

Subject: IRB Revision Approval # 070802007

Dear Ms. Langhofer¹⁸

I have reviewed and approved the requested revisions to your project 'The relationship between spanking and adult report of religion, depression, anxiety and stress' to include the changes in script, survey items and recruitment material¹⁹, based on your previous piloting. The IRB number and expiration date remains the same. At the end of this period, if you wish to extend the study for an additional year, please provide a report on the status of this study when you request the extension. Your request should be made in writing or through e-mail communication six weeks before the expiration date.

All other requirements of your study's approval remain the same.

Best Wishes in the Completion of your Research

Sign as member of IRB

¹⁸ If the PI is a student, e-mail the faculty sponsor also

¹⁹ Put in here whatever recruitment / research documents or protocols that you have approved for revisions

Communicating an Extension

Subject line: IRB Extension Approval # 060702028R

Dear Dr. Bikos,

I have reviewed and approved your request for a one year extension for your research project titled “**Expatriate and spousal adjustment.**” Your new IRB number is **060702028R**. Your extension is granted until **3/16/2009**. This new number and expiration date must be listed on your informed consent, and any recruitment material.

The IRB only approves renewals for one year. If you wish to renew your IRB after this expiration date you will need to submit a another request for extension and another report on the status of your study. The IRB may require a new application if the protocols have changed significantly since your original IRB application. If the IRB requests a new application, please use the latest IRB application provided on the IRB web site.

All other requirements of your study’s original approval remain the same

Best wishes in the completion of your research.

Sign as member of IRB

Communicating an approval based on FWA Reciprocity

Dear Ms. Robertson,

I have reviewed and approved your study, "Students' attitudes of spiritual / religious issues in counseling; A comparison to the ASERVIC spiritual competencies" based on the University of Central Florida Institutional Review Board's (FWA00000351), approval of your study dated May 29th, 2008. As noted in your review board's letter you may collect data at SPU until 5/28/2009.

While your IRB did not require it. We require all informed consent documents to include their IRB number and expiration date. Please add SEB-08-05662 and expiration 5/28/09 to your informed consent document.

Please work with your SPU study sponsor, Dr. Cher Edwards to collect your data

Best wishes on your project

Sign as IRB member

ADVERSE EVENTS

Under Federal-Wide Assurance requirements, Investigators must report any adverse events that occur to human subjects during the course of research, even if it does not appear on face value that the adverse event was caused by the research itself. Federal regulations define adverse events as “unanticipated problems” involving risks to study participants or others. These events can be, physical, emotional or cognitive in nature.

In the case of an adverse event, the PI must complete the research Adverse Event Reporting form found on the SPU IRB web site within 24 hours of the event and submit to the chair of the IRB. The PI must suspend all research activity until the SPU IRB communicates any remedial action to the PI.

The SPU IRB will review the adverse event. If the IRB determines that the adverse event increased the research risk beyond the risk identified in the informed consent but was not likely to cause serious harm to the participant, the IRB may request the following Actions which may include but not limited to:

1. Education for Investigators.
2. Modification of informed consent
3. Modification of study protocols.

If the IRB determines that the adverse event increased the research risk beyond the risk identified in the informed consent and caused or could have caused harm to the participant, the IRB will work with OAA to determine the appropriate action.

NON-COMPLIANCE

Under Federal-Wide Assurance requirements, all research conducted with Human Subjects by the SPU community must comply with appropriate Federal regulations, State law and institutional policy. Failure to comply with the appropriate regulations signifies non-compliance with SPU's IRB policies.

There are three types of non-compliance

1. Non-compliance: Failure to comply with applicable Federal Regulations, SPU IRB policies and procedures found in this document or the IRB User Guide and / or other SPU institutional policies and procedures. Collecting data after an IRB approval as expired is an example of non-compliance

2. Serious Non-compliance: An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and /or welfare of a subject. Collecting data without IRB approval would be an example of serious non-compliance

3. Continuing Non-Compliance: A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness to comply with Federal Regulations, SPU IRB policies and procedures and / or other SPU institutional policies and procedures.

Procedure for Reporting potential non- compliance or research misconduct

All reports of alleged non-compliance or inappropriate involvement of humans in research will be investigated by The SPU IRB. Such reports should be directed initially to the Chair of the IRB.

Process for Non-compliance

1. IRB Chair will accept all reports of potential non-compliance from all sources
2. IRB chair will document the non-compliance and review the report with the IRB members to determine if there is non compliance and if so bring the complaint to the full IRB to determine if it is non-serious, serious or continuing.
3. The IRB chair will notify the Principal investigator in writing study activities must be suspended until a plan of action is approved by the IRB.
4. If the IRB determines that the action is non-serious, the following action will be taken.
 - a. If necessary, request additional information.
 - b. Formulate a corrective action plan.
 - c. Forward this plan in writing to the Principal Investigator.
 - d. Document the action plan and where appropriate add to IRB study file.
5. If the IRB determines that the action is serious and / continuing, the following action will be taken.
 - a. If necessary, request additional information.
 - b. If required by FWA, report the serious and or continuing non-compliance to appropriate federal agencies and research sponsors as required by FWA.
 - c. In conjunction with OAA determine the appropriate sanction and notify the Principal Investigator. In the case of serious and / continuing non-compliance, any communication and sanction will be issued through OAA.

Sanctions

Sanctions the IRB and / or OAA may consider and include in the notification to the Principal Investigator are:

1. Require study approval by the IRB
2. Disallow data that has been collected under non-compliance to be used in a research project.
3. Require additional investigator or study staff education
4. Require changes in study design or methodologies

5. Suspend or terminate any or all of study activities including recruitment, research or any follow-up activities.
6. Modify review cycle
7. Request PI communication with participants that their data was collected while study was under non-compliance.

If a complaint of non-compliance is received for completed research without an active IRB number, the complaint will be reviewed initially by the IRB and if found to be serious, it will be forwarded to OAA who will review it as a possible breach of Academic Integrity.

- 5.1 Failure to comply with Institutional Review Board (IRB) policy: Research investigators are the most frequent source of noncompliance with human subjects regulations. The most common lapses in investigator compliance include unreported changes in protocols, misuse or nonuse of the informed consent document, and failure to submit protocols to the IRB in a timely fashion. Problems such as these are often caused by communication difficulties. With investigator goodwill, these cases can be resolved by the Research Coordinator (RC) in consultation with the IRB chair without jeopardizing the welfare of research subjects.
- 5.2 Occasionally, an investigator will either avoid or ignore filing an IRB. Such cases present a more serious challenge to the IRB and to the institution. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the RC will contact the IRB Chair who will act promptly to halt the research, take appropriate remedial action regarding any breach of regulatory or institutional human subject protection requirements. This action will vary depending upon the nature of the research study. The Chair of the IRB will refer the matter to the VPAA who will address the question of the investigator's fitness to conduct human subject research. In addition, any serious or continuing noncompliance with DHHS human subjects regulations or the determinations of the IRB must be promptly reported to OHRP[Federal Policy 45CFR46.103(b)(5)].

RESEARCH COORDINATORS

- 3.1 The Research Coordinator (RC) informs faculty or staff about research policies and procedures and monitors research projects in the academic unit or office. The RC is also the school or office liaison with the University Institutional Review Board (IRB).
- 3.2 The Dean of each academic unit will designate at least one faculty member to be RC for that school. The Vice Presidents will designate one RC for non-academic University offices. The length of appointment will be at least 12 months, so as to provide continuous coverage of the projects.
- 3.3 The RC should have education in basic research designs he or she is likely to review.
- 3.4 The RC attends in-service education sponsored by the VPAA's Office on research, especially sessions on ethics and law.
- 3.5 The VPAA's Office will accord special work load consideration for RCs whose schools are particularly active in research. Some schools generate more research than other schools. Special considerations for RC's in the busiest schools will encourage them to get involved and stay involved in the process.