Policy and Procedure for Human Research Participants
Soka University Institutional Review Board

The Soka University Institutional Review Board (IRB) is an administrative body designed to safeguard the welfare and rights of human participants in research or class projects conducted under the auspices of Soka University of America. The IRB has the authority to approve, disapprove, or require modifications to research proposals. All research conducted by Soka University faculty, staff, or students must be approved by the IRB before data collection may begin.

*Research* is defined by federal regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” *Human participant* is defined by federal regulations as “a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.”

Soka University’s IRB policies are consistent with the guidelines of the [US Department of Health & Human Service’s Office for Human Research Protections](http://www.hhs.gov/ohrp/). Much of the language in this policy is taken from their Code of Federal Regulations (CFR): *Title 45, Part 46*; Internet links are provided throughout this written policy to appropriate locations within that document. This statement of policy includes only the federal regulations relevant to the research context of Soka University (e.g., social and behavioral science research); however, research is subject to the full content of the federal regulations. Investigators should be familiar with the [Belmont Report](http://www.hhs.gov/ohrp/belmont.html), upon which the federal regulations are based.

Our policy regulations do not affect any applicable state or local laws or regulations that provide additional protections for human research participants. Research that takes place in foreign countries will be additionally subject to that country’s guidelines for protection of human participants.

CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Criteria for Approval of Research Proposals</td>
<td>2</td>
</tr>
<tr>
<td>II. Level of Review</td>
<td>2</td>
</tr>
<tr>
<td>III. Submissions to the IRB</td>
<td>4</td>
</tr>
<tr>
<td>IV. Informed Consent</td>
<td>6</td>
</tr>
<tr>
<td>V. Training for Investigators</td>
<td>7</td>
</tr>
<tr>
<td>VI. Class Activities and Projects</td>
<td>8</td>
</tr>
<tr>
<td>VII. Types of IRB Actions</td>
<td>8</td>
</tr>
<tr>
<td>VIII. IRB Membership</td>
<td>9</td>
</tr>
<tr>
<td>IX. Meetings</td>
<td>10</td>
</tr>
<tr>
<td>X. Record Keeping</td>
<td>10</td>
</tr>
</tbody>
</table>
I. CRITERIA FOR APPROVAL OF RESEARCH PROPOSALS (see 45 CFR 46.111)

The IRB will seek to ensure that the rights and welfare of human participants are safeguarded and that human participants are not exposed to unreasonable mental, physical, or emotional risk as a result of participation in research. The IRB will review proposals in light of all the following requirements:

- Risks to participants are reasonable relative to anticipated benefits of the research.
- Participants will face minimal risk.
- Informed consent will be obtained from all human participants and copies or other documentation will be retained.
- When appropriate, the privacy of human participants will be protected.
- When appropriate, additional protection will be afforded vulnerable populations.
- When appropriate, data collection will be monitored to ensure participants’ safety.

II. LEVEL OF REVIEW

On the Application Form (see Section III.A., below) the principal investigator will indicate whether the proposal seems appropriate for the Exempt, Expedited, or Full Review category; however, the IRB will determine the level of review.

A. Exempt (see 45 CFR 46.101)

Federal guidelines label as “Exempt” research that is perceived to expose participants to no risk. It is Soka University’s policy (and a recommended federal guideline) that investigators should submit to the IRB proposals that are expected to fall in the category of Exempt.

The IRB will process such proposals following the Expedited Review procedure (see Section B, below). On the Application Form, investigators must indicate which of the following categories apply to their research protocol (additional categories unlikely to apply to research conducted at Soka University may be found at 45 CFR 46.101). According to federal guidelines, research that is regarded as not having potential risk to participants includes the following:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
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 the previous point in this section, if: (a) the human participants are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

B. Expedited Review (see 45 CFR 46.110)

The Expedited Review procedure will be used for research that falls in one of the Exempt categories (see Section A, above); one of the Expedited categories, below; or for minor changes to approved Expedited-category research protocols within the approved period that involve no additional risk to participants (see Section III.C., below). In general, protocols that present no more than minimal risk to participants may qualify for Expedited Review. According to federal guidelines, minimal risk is defined as cases in which “the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

According to federal guidelines, Expedited Review may be carried out by the IRB Chair or by one or more reviewers designated by the Chair from among the IRB members. When conducting an Expedited Review, IRB members may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after a Full IRB review has been conducted. It is Soka University’s policy that all IRB members must be advised, at the next regularly scheduled meeting, of research proposals that have been approved using Expedited procedures.

The list below includes activities that are eligible for the Expedited Review procedure according to federal guidelines. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the Expedited Review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants. The categories in this list apply regardless of the age of participants. On the Application Form, investigators must indicate which of the following categories apply to their research protocol:

1. Collection of data from voice, video, digital, or image recordings made for research purposes.
2. 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 in the Exempt category. This listing refers only to research that is not Exempt.)
3. Continuing review of research previously approved by Expedited Review.
4. Continuing review of research previously approved by Full Review as follows:
(a) where (1) the research is permanently closed to the enrollment of new participants; (2) all participants have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of participants; or
(b) where no participants have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.

C. Full Review

When a research proposal presents more than minimal risk to participants, it will undergo Full Review by the board during a regularly scheduled meeting. Any subsequent protocol change must also be submitted for Full Review. Proposal materials will be distributed no later than three days prior to meetings. After discussion and an attempt to reach consensus, the committee will vote if necessary regarding overall approval or a request for changes in the protocol. The vote will be an open ballot, and the vote result will be recorded in the minutes. However, the votes of specific members will not be recorded, and such information will be considered confidential by all board members. The vote of the majority will constitute the official action by the Board; in case of a tie, the vote of the IRB Chair will break the tie.

III. SUBMISSIONS TO THE IRB

IRB forms will be submitted to a designated IRB member on each campus (Aliso Viejo and Calabasas); refer to the Application Form available on the IRB web site for those individuals’ names. Consistent with federal guidelines, a member of the IRB will automatically be excused from reviewing and voting on a proposal under any of the following conditions (and IRB minutes should reflect any such actions): (1) if an IRB member’s name is included anywhere in the proposal; (2) if an IRB member anticipates any present or future conflict of interest in reviewing a particular proposal; or (3) if an IRB member believes that he or she might not be completely objective in reviewing the proposal.

A. Application Form

Before collecting data for any research project, investigators must submit to the IRB an Application Form; questionnaires, interview scripts, informed consent forms, debriefing forms, advertisements, and any other supporting materials must be attached to the application. All applications must include the following information:

- Summary of the research objectives; Description of the research design, procedures, and hypotheses; Short description of any relevant prior research in the same area.
- Description of who research participants will be and how they will be recruited; Whether they will be compensated for their participation; Approximately how many will participate; Whether any vulnerable populations will be included.
- Description of the potential risks and benefits of the research to participants; Description and justification of any deception that might be used.
• Description of the means by which participants will give Informed Consent. There are specific requirements for the content of Informed Consent (see Section IV.A., below).
• Description of the procedures to assure confidentiality of primary data.
• Description of debriefing provided to participants.

Once research receives IRB approval, no changes (e.g., additional investigators, changes to procedure) may be made without IRB approval. Investigators who wish to make changes to an approved project must submit a Minor Protocol Change Form (see Section C, below).

B. Renewal Form

Investigators should submit a Renewal Form and current Informed Consent form when IRB approval will soon expire for a project that is not completed. It is the investigator’s responsibility to use this form to request renewal of IRB approval well-ahead of the expiration date. All research activity approved by the IRB must stop at the expiration date, even if a Renewal Form has been submitted. Renewal Forms will include the following information:

• Number of participants studied
• Whether there were any problems obtaining consent
• Whether participants made any complaints
• Whether there were any unanticipated risks
• Whether any changes are planned to the protocol that was originally approved by the IRB
• Whether any new investigators are going to work on the project
• Whether any changes are planned to the Informed Consent form

C. Minor Protocol Change Form

Investigators should submit a Minor Protocol Change Form during the approved period if they wish to make changes to the research protocol that involve no additional risk to participants (if the proposed changes entail additional risk, the research should be submitted using a new Application Form). Examples of changes that must receive IRB approval include, but are not limited to, adding additional investigators, changing the procedure in any way, or changing the Informed Consent form. Investigators may not change approved research protocols without IRB approval. Minor Protocol Change Forms will be evaluated at whichever level the research initially was approved.

D. Miscellaneous Report Form

Investigators or others should submit a Miscellaneous Report Form to report any issue other than a protocol change. Investigators may use the form to report information about ongoing projects during the approved period (e.g., participant complaint or injury, instances of noncompliance with the approved protocol). Any Soka University student or employee may use the form to report an observation of noncompliance with federal regulations (e.g., lack of informed consent, research operating without IRB approval). According to federal guidelines, it is the investigator’s responsibility to promptly report within one week (a) any unanticipated problems involving risks
to participants or others; (b) any serious or continuing noncompliance with federal guidelines; and (c) any suspension of IRB approval (e.g., from another institution).

E. Completion Form

Investigators should submit a Completion Form when either (1) a project has been completed, or (2) a project has not started and will never start. Projects are considered completed when (1) all data has been collected, (2) identifying information (i.e., about participants’ names and contact information) in computer files has been deleted, and (3) identifying information in paper documents has been destroyed. Completion Forms will include the following information:

- Number of participants studied
- Whether there were any problems obtaining consent
- Whether participants made any complaints
- Whether there were any unanticipated risks
- Brief description of research findings

IV. INFORMED CONSENT

According to federal guidelines, except as provided in Section B, below, no investigator may involve a human being as a participant in research covered by this policy unless the investigator has obtained the legally effective Informed Consent of the participant or the participant’s legally authorized representative.

A. Basic Elements of Informed Consent (see 45 CFR 46.116)

According to federal guidelines, the following information must be provided to each participant:

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation, a description of the procedures;
- a description of any reasonably foreseeable risks or discomforts;
- a description of any benefits to the participant or to others which may reasonably be expected from the research;
- a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- an explanation of whom to contact for answers to pertinent questions about the research and the sentence: “If you have questions about your rights as a research participant, you should contact the Soka University Institutional Review Board Coordinator at 949-480-4057.”;
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled; and
- a statement that the participant will receive a copy of the form.
B. Alteration or Waiver of Informed Consent

According to federal guidelines, the IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of Informed Consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. the research involves no more than minimal risk to participants;
2. the waiver or alteration will not adversely affect the rights and welfare of participants;
3. the research could not practicably be carried out without the waiver or alteration; and
4. whenever appropriate, participants will be provided with additional pertinent information after participation.

The Informed Consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed in order for Informed Consent to be legally effective.

C. Documentation of Informed Consent (see 45 CFR 46.117)

According to federal guidelines, Informed Consent must be documented using a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy must be given to the person signing the form.

Alternatively, the IRB may waive the requirement for an investigator to obtain a signed consent form for some or all participants if it finds either:

1. that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
2. that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

V. TRAINING FOR INVESTIGATORS

Principal investigators (PIs) are expected to be familiar with the content in the OHRP’s online tutorial at: http://137.187.172.152/cbtng_oehr/cbts/assurance/module2qset1_1.asp. PIs must include in the Application Form a list of all investigators who will be involved in the research and are responsible for ensuring that all investigators are adequately trained to participate. It is the responsibility of the Principal Investigator (or faculty supervisor if the PI is a student) to:
• Be familiar with this statement of policy
• Gain IRB approval prior to collecting data
• Inform the IRB of information using the Miscellaneous Report Form or Minor Protocol Change form as appropriate
• Turn in a Renewal Form or Completion Form at the end of the approved period
• Oversee all co-investigators involved in the project

VI. CLASS ACTIVITIES AND PROJECTS

It is Soka University’s policy that class activities and projects that involve human participants are subject to IRB guidelines and procedures (even when they do not meet the federal guidelines’ definition of research; refer to the definitions of human participant and research on page 1); examples include surveys or interviews conducted on or off campus. However, if students interview an individual to use as an expert source for a research paper, IRB approval most likely is not necessary.

Class activities and projects that are designed by instructors (rather than by students) are not required to be submitted to the IRB if the activities fall in one of the Exempt categories (see Section II.A.); however, instructors are encouraged to limit recruitment of participants to students, staff, or faculty at SUA unless there is a compelling reason to recruit individuals off campus. Instructors and students are encouraged to ask an IRB member for clarification.

Course instructors have the primary responsibility of assuring that participants’ rights and well being are not violated. It is Soka University’s policy that instructors (1) inform students of the policies and procedures of the IRB; (2) review any IRB forms completed by students to ensure that they are consistent with IRB standards; and (3) monitor the activity/project to ensure compliance with ethical standards. Depending upon level of risk to participants, the IRB may require that instructors be present to supervise during data collection. Instructors should complete forms themselves or proofread and revise student materials prior to submission to the IRB. In all project materials that will be viewed by participants (e.g., surveys, Informed Consent forms), the project should be referred to as a “Class Project” and not as a research project.

VII. TYPES OF IRB ACTIONS (see 45 CFR 46.109)

All IRB actions and notifications will be made in writing. The IRB shall review and have the authority to approve, require changes, or disapprove the research according to the following:

A. Approve

The research proposal is approved as submitted.

B. Changes Required

If a minor aspect of the research protocol needs clarification or elaboration, or if the Informed Consent form requires minor modification, the IRB will ask the principal investigator to make
the appropriate changes. In such cases, approval will be granted after the principal investigator provides written documentation to answer any questions and/or rewrites the Informed Consent form, and the IRB is satisfied that the issues have been resolved.

C. Disapprove, Suspend, or Terminate

The IRB will disapprove a research proposal if it poses undue risk to participants and/or if the anticipated risks outweigh anticipated benefits. A research proposal may be disapproved only after a review by the full IRB has been conducted. Consistent with federal guidelines, if the IRB decides to disapprove a research activity, it shall include in a written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

According to federal guidelines, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination or approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator and appropriate institutional officials (see 45 CFR 46.113).

D. Renew (Continuing Review)

Consistent with federal guidelines, the IRB will conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but at least once per year, and shall have authority to observe or have a third party observe the consent process and the research. Protocols that have higher risk to benefit ratios may be reviewed more often than annually. In addition, such projects may need verification from sources other than the investigator(s) that no material changes have occurred since the previous IRB review. For ongoing research, investigators must submit a Renewal Application Form and current Informed Consent form prior to the expiration date of IRB approval (see Section III.B).

VIII. IRB MEMBERSHIP (see 45 CFR 46.107)

According to federal guidelines, IRBs must be composed of at least five individuals of diverse backgrounds, taking into consideration such things as race, cultural background, and gender. IRB members must have expertise and experience suitable for evaluating research protocols commonly conducted at the institution. IRB members must also be aware of community attitudes, relevant institutional and federal regulations, and standards of professional practice. At least one member must have a background in a nonscientific area, and at least one member must be unaffiliated with Soka University. In addition to these federal guidelines, it is Soka University’s policy that there be at least one member from the Calabasas campus who works with thesis students. In addition, it is Soka University’s policy that there be one student member. It also is our policy that a majority of IRB members have terminal degrees in a scientific field.

It is Soka University’s policy that IRB members’ terms will be staggered as either one or two years such that there never will be complete turnover of committee members in a given year.
(student and community members generally will have one-year terms). The outgoing IRB Chair will submit to the Provost for approval the names of committee members and corresponding terms for the next year. The Chair is required to have served on an IRB committee in the past and to have a terminal degree in a scientific field. The Chair will be annually elected by committee members by majority vote and then submitted to the Provost for approval.

Consistent with federal guidelines, the IRB may consult an individual or individuals with particular expertise or competency to assist in review of a proposal. These individuals may not vote, however. Consulting an expert is especially recommended if the reviewed research will involve a vulnerable population (e.g., children, pregnant women, handicapped persons).

IX. MEETINGS

Formal IRB meetings will be convened by the IRB Chair as needed, and at least once per semester. Emergency meetings may be convened, as appropriate. According to federal guidelines, at least half of the members of the IRB, including one non-scientist, must be present in order to constitute a quorum and proceed with proposal reviews and IRB business.

X. RECORD KEEPING (see 45 CFR 46.115)

It will be the responsibility of the Chair or someone designated by the Chair to adequately document all IRB activities, including:

- Copies of all forms (e.g., application, minor protocol change, miscellaneous report, renewal, completion, and Informed Consent)
- Copies of all correspondence between primary investigator and the IRB, and records of actions taken regarding proposals
- Minutes of IRB meetings, including information on attendance, actions taken, vote tallies, reasons for requiring changes to protocols, and reasons for disapproving research
- Procedures governing IRB activities, including any changes made by IRB members (e.g., changes in the number of members or requirements for the Informed Consent form)
- A list of IRB members, including their names; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution (see 45 CFR 46.103).

The Chair will ensure that copies of all such records are stored in the Registrar’s office on the Aliso Viejo campus. In particular, when a project is approved by the IRB, a copy of the Application Form will be made available for review by the IRB Signatory Official. Records will be retained for three years after the completion of a project. All records must be accessible for inspection and copying by authorized representatives of the US Department of Health and Human Services at reasonable times and in a reasonable manner.