

- Q: Is there a way to get feedback on proposals before formal submission to the IRB?  
A: Proposals can be submitted to the Chair, or any other cooperating member of the IRB, for prior review, but such review is rarely necessary. RPAs submitted to the IRB are assigned a reviewer as soon as possible, and that reviewer contacts the project's Contact Person concerning any necessary changes to the RPA.
- Q: Are there examples of successful proposals to which students and faculty could have access? Do these examples include an array of research designs?  
A: Because RPAs are considered confidential, the IRB does not make copies of them available to the public. However, one can always request a copy of a successful RPA directly from the researcher(s) who submitted it.
- Q: Are there examples of consent forms for an array of potential research participants, including children?  
A: The RPA contains a checklist of information that should be included in a consent form. Examples of consent forms are not available from the IRB because a consent form is project specific. However, if one is conducting research similar to that conducted by another researcher, one can request copies of that researcher's consent forms directly from the researcher.
- Q: In research involving minors, is 'assent' always required from the children?  
A: The presumptive answer is "yes," but each project is different (and each project is reviewed independent of other projects). Obviously, very young children are not in apposition to provide assent. A justified request to waive 'assent' can be included in the RPA.
- Q: What is the turn-around time for a 15-week class of 20-25 students if all students submit to the IRB? This is a concern given the IRB is scheduled to meet only once a month.  
A: Turn-around time is difficult to estimate because each project must be reviewed on its own merits and there are many conditions that affect turn-around time (complexity of the project, quality of the RPA, etc.). Many projects do not require a full meeting of the IRB (this is called Expedited Review), and turn-around time for such projects is not affected by the schedule of regular IRB meetings. However, for those projects that do require a meeting of the full IRB, the IRB Chair will make every attempt to schedule additional IRB meetings to meet demands for reviews.
- Q: Do members of the IRB come to talk with classes to provide an overview and give insight into expectations?  
A: There currently exists no organized program for classroom visits. However, the IRB Chair has agreed to meet with any class within normal scheduling reservations. Other IRB members may also be so willing, and interested individuals are encouraged to contact IRB members concerning such visits.
- Q: If a faculty member does not know the answer to questions about the IRB, should the faculty member contact a member of the IRB or should the student do that?  
A: Ideally, the faculty member should contact the IRB; that way, the faculty member will know the answer for the next student who asks that question. Practically, however, it doesn't matter who contacts the IRB, so long as the answer is relayed to all members of the research team.
- Q: How are people appointed to the IRB? Can we have access to vitas of IRB members? Do all reviewers have PhDs or personal research experience?  
A: The Vice President for Academic Affairs appoints members of the IRB. Curriculum Vitae for each member of the IRB can be obtained by asking the member for a copy; presumably, each member of the IRB will comply as a matter of professional courtesy. By design, all reviewers do not have personal research experience. The federal regulations require that at least one member of the IRB be a nonscientist. The purpose of this

requirement is that each proposed project must be evaluated from many different viewpoints, not merely from the viewpoint of the scientific quality of the project.

- Q: Particularly in the College of Education, is there a good way to determine whether a project is a “research” project or something more of a “systematic inquiry” conducted just for the teacher’s own development of insight into teaching? Are there tips for making an ethical decision about which type of project it is? For example, if a project is not to be published or shared outside the college classroom setting, and there is no attempt to imply that the project could or should contribute to the professional literature, and the implications are just for SELF and not other teachers, and the teacher sets out with the goal of collecting data solely to better understand and improve classroom practices, does this mean that the teacher is probably not doing “research”?
- A: The federal regulations include the phrase “systematic investigation ... designed to develop or contribute to generalizable knowledge.” Applying the results of one project to other samples, to other situations, or to a scientific theory all involve “generalization.” In practice, it is rarely the case that someone engages in a systematic investigation without some desire for generalization. However, “generalized knowledge” is usually interpreted in the context of sharing the results with others or making the results available so that others may apply the results to different samples, situations, or theories. If a project is designed solely for the purposes of informing one’s self, and there is no intention or action to share the results of the project with others, then the project probably falls outside the purview of the IRB. However, the federal regulations require the IRB to make this determination, so the investigator is required to employ the IRB Decision Tree provided on the SVSU IRB website.
- Q: Related to a research course, given that we have 15 weeks, what should one do in the event of indecision about whether it is research or inquiry?
- A: As noted elsewhere, the IRB is tasked with deciding whether or not a project involving data collection from humans falls within the purview of the IRB. Therefore, the short answer to this question is that the project should be subjected to the IRB Decision Tree and, if necessary, submitted to the IRB as soon as possible. The Decision Tree contains questions that enable the IRB to make a very fast determination of projects in this regard, so the length of the semester should not pose a problem.
- Q: Does the committee give feedback on proposals that were not approved? What if I don’t agree with the feedback?
- A: It is rarely the case that a proposal will be rejected, although it has happened in the history of the SVSU IRB. Instead, the IRB Liaison works with the project’s Contact Person to ensure that the proposal will be approved. If the investigators do not agree with the Liaison’s feedback, they are free to request that another Liaison be assigned. The goal of the IRB is to be able to approve every proposed project. However, when investigators choose not to cooperate with the IRB, then the project could be rejected, in which case the investigators may not proceed with the project.
- Q: Do course assignments that deal with human subjects need to go through the IRB?
- A: If the project involves accessing humans and constitute a “systematic investigation ... designed to develop or contribute to generalizable knowledge,” then it needs to be submitted to the IRB. Course projects that are conducted only to provide students with experience at research procedures and do not involve producing generalized knowledge probably do not need to be submitted. Refer to the IRB Decision Tree for more clarification.
- Q: How might a faculty member teaching a research-oriented capstone course manage the submission of 20-25 proposals to the IRB? Have some faculty members been successful with this, and are there any tips that might be supplied?
- A: One suggestion is to alert the IRB Chair of the large number of incoming proposals so that the Chair can make arrangements (extra meetings, etc.) to ensure timely review of

the proposals. The review process is faster when RPAs have been completed properly, so the faculty member can speed up the process by ensuring that only adequate RPAs are submitted to the IRB. Advice from other faculty members who have supervised multiple projects simultaneously should be sought as well. Having the IRB Chair, or some other IRB Member, visit the class to explain what is required in an RPA would certainly be helpful.

Q: Is there such a thing as “retroactive” approval?

A: No. All projects must be reviewed and approved prior to data collection.

Q: What happens if I don’t go through the IRB?

A: Instances of research that has not been approved by the IRB are referred to the Vice President for Academic Affairs for action; the IRB has no enforcement mechanism; the IRB is an advise-and-consent group. Ultimately, although there are many, many steps in between, an institution that does not conform to the federal regulations can be stripped of all federal funding and denied participation in all federally funded programs.

Q: How are “competence” and “informed consent” defined?

A: “Informed consent” is generally defined as the situation in which a prospective human subject has been provided with sufficient information about the research so as to make a meaningful decision about whether or not to participate in the research. Assuming “competence” refers to the ability of prospective participants to make an informed decision, this term is usually defined both in terms of an individual’s ability to understand the information provided as well as utilize the information to make a decision. Certain individuals are legally excluded from making a decision, such as minors. The ability to understand the information presented depends upon a combination of the information processing skills of the prospective subject, the complexity of the information to be understood, and the level at which the information is presented.

Q: How is “action research” defined by the IRB?

A: “Action research” is not defined by the IRB. Different disciplines define the phrase in different ways, and the IRB is not in a position to accept one discipline’s definition over another discipline’s definition. As far as the IRB is concerned, research is research, regardless of the adjective that may be used.

Q: Is IRB-related training required before faculty can do research and, if so, where can we get the training?

A: Yes, training is required. The IRB website contains URL(s) for approved on-line training. Other types of training may satisfy the requirement, but such training needs to be approved by the IRB Chair in advance.

Q: What is “program evaluation” in comparison to “research”?

A: Program evaluation is usually defined as a systematic investigation for the purpose of determining the strengths and weaknesses of an organized effort to produce social change. When such investigations also include the purpose of developing or contributing to generalized knowledge, then, from the IRB’s perspective, program evaluation is research.

Q: What is “generalized knowledge”? Can you give examples to clarify this construct?

A: Generalized knowledge is knowledge obtained under one set of circumstances that is subsequently applied to a different set of circumstances. The most obvious example in a research context involves data collected for the purpose of testing an hypothesis deduced from a theory. Other examples in a research context include using the results of one program evaluation to design or implement another program, using the results of an investigation into one teaching technique to employ or alter that technique for a different course. The key to the concept is the use of information obtained in one particular setting to understand or produce change in another setting. Not all generalized knowledge is

- obtained through systematic investigation, and not all systematic investigations produce generalizable knowledge. In order to be generalized, for example, others must be made aware of the knowledge in some fashion. Refer to the IRB Decision Tree for further clarification.
- Q: If I am a qualitative researcher, do I need to go through the IRB?  
A: Probably yes. The key is whether or not your qualitative investigation involves humans, is systematic, and is done for the purpose of developing or contributing to generalized knowledge.
- Q: According to federal regulations, some research is “exempt”. Does this mean I do not need to go through the IRB?  
A: No, you must submit an RPA. “Exempt” is a classification that is used by the IRB to determine whether or not the IRB needs to maintain continued supervision of the research. Obviously, the IRB cannot determine whether or not research fits the “exempt” category if the IRB does not know about the research.
- Q: I plan to conduct online research. Are there any special things I need to do?  
A: At one level, there is nothing special. Online research must be reviewed by the IRB just the same as any other research. However, there probably are issues related to online research, such as informed consent, that you may need to handle differently from “in-person” research. Therefore, it may be a good idea to become familiar with information concerning justifications for waiving written documentation of consent (getting signatures on a consent form). The distinction between confidentiality and anonymity also comes to mind as something that may be relevant to online research (but not exclusively to online research).
- Q: Do I always need to have a consent form signed?  
A: The presumptive answer is “yes,” but the regulations allow for waiving this requirement if the subject’s signature poses more risk than the absence of the signature, such as in particularly sensitive projects for which knowledge that a person merely participated might be deemed damaging in some way, or for projects in which obtaining signatures places an undue burden upon the researcher that the would severely, negatively impact the likelihood of accomplishing the research.
- Q: Our program is getting ready for accreditation. As part of the accreditation process, we need to show student work samples to a board of reviewers. Can we mandate/require students to post their work to an online portfolio with the idea that their work may be shared with accreditation program reviewers? What if students don’t want to post their work? Is this an IRB issue?  
A: As stated, this does not appear to be an IRB issue. The information is not being collected for the purpose of developing or contributing to generalized knowledge. However, it’s always best to consult the IRB Chair in such circumstances to ensure that there are not issues or circumstances that bring the effort into the purview of the IRB. Note that each project must be considered on its own merits; there are almost no “blanket” statements about research that can be made.
- Q: Do ALL faculty have to take the online IRB course or just those submitting to the IRB?  
A: Any individual affiliated with SVSU who wishes to conduct human-subjects research must complete training that has been approved by the IRB. This includes anyone connected with a particular research project. However, someone who has recently completed training for one project need not complete additional training when collaborating on a different project. Faculty who do not intend to conduct human-subjects research, either individually or in collaboration with others, need not complete the training.
- Q: If I am conducting research somewhere else, do I still need to submit the project to SVSU’s IRB?

A: Yes. The purview of the IRB extends to any research conducted by anyone affiliated with SVSU. The only time you need not submit an “elsewhere” project is when your participation includes absolutely no connection with SVSU (no SVSU affiliation in the publication, presentation, or publicity release, no submission to fulfill any job requirements at SVSU, etc.)

Q: Do researchers who are not affiliated with SVSU ever have to submit their research to SVSU’s IRB?

A: Yes, if the project is conducted on SVSU’s campus or through SVSU facilities.

Q: What kinds of research need to be submitted?

A: The most straightforward answer to this question is that one should refer to the IRB Decision Tree. Generally, any research in which humans will be questioned or otherwise observed needs to be submitted to the IRB. Research involving animals other than humans should be submitted to the Institutional Animal Care and Use Committee (IACUC).