

SVSU Institutional Review Board (IRB) Decision Tree: To Submit or Not to Submit

The following questions were designed to help researchers decide whether or not projects must be submitted to the IRB. If, after answering the questions, you remain uncertain, then you should contact the IRB Chair (see the IRB website) to discuss your project in more detail. Please note that projects must be approved prior to any interaction with subjects/participants.

Projects completed solely to train students how to conduct research, such as exercises in a methods course that will not be presented or otherwise distributed outside of the classroom, need not be submitted to the IRB. However, projects through which students demonstrate how well they have learned to do research, such as Capstone and Thesis projects, should be submitted to the IRB unless the following questions yield a negative answer. You should also know that federal regulations apply both to quantitative and to qualitative research, and that they apply to single-subject and case-study projects.

Human Subjects Involvement

The first step is to determine whether or not your project involves “human subjects” as defined by federal regulations. Not all projects involving humans need to be submitted, but all projects in which humans participate should be considered for submission unless the following questions yield a negative answer.

- 1) Does the project involve direct (face-to-face, telephone) interaction with one or more humans, such as giving them instructions, interviewing them, or giving them surveys or questionnaires?
 - a) NO: proceed to question 2.
 - b) YES: proceed below to the decision tree for generalized knowledge.
- 2) Does the project involve indirect interaction with one or more humans, such as a general request to log onto a website to complete a questionnaire or a “blind mailing” to respondents?
 - a) NO: proceed to question 3.
 - b) YES: answer the following question:
 - i) Is there **any** way for anyone on the research team to know or to figure out the identity of any of the individuals who are providing the data?
 - (1) NO: data are entirely anonymous; you need not submit this project.
 - (2) YES: proceed below to the decision tree for generalized knowledge.
- 3) Does the project involve analyzing existing tissue, blood, or other samples obtained from humans?
 - a) NO: proceed to question 4.
 - b) YES: answer the following question:
 - i) Is there **any** way for anyone on the research team to know or to figure out the identity of any person who provided samples?
 - (1) NO: samples are entirely anonymous; you need not submit this project.
 - (2) YES: proceed to the decision tree for generalized knowledge
- 4) Does the project involve accessing existing or archived data obtained from humans, regardless of whether you produced the archive or the archive was produced by someone else?
 - a) NO: if you’ve reached this point in the process, then your project does not meet the definition of “human subjects” used in the federal regulations; you need not submit this project.
 - b) YES: answer the following question
 - i) Is there **any** way for anyone on your research team to know or to figure out the identity of any of the individuals who provided the archived data?
 - (1) NO: data are entirely anonymous; you do not need to submit this project.
 - (2) YES: proceed to the decision tree for generalized knowledge.

Generalized Knowledge

If you have reached this point, then your project involves human subjects in a manner defined by the federal regulations. The regulations do not require that all human-subjects research be submitted to the IRB; only human-subjects research for which there is intent to develop or to contribute to “generalized knowledge” must be submitted. Even if your project has multiple purposes (research, evaluation, assessment, etc.), the key to the “generalized knowledge” test involves whether or not **one** of your pur-

poses is to develop or to contribute to generalized knowledge. The existence of additional purposes is not relevant to the issue of generalized knowledge. That is, if your project includes the purpose of generalized knowledge **and** is conducted as part of an assessment process or a program evaluation, then you still need to submit it; the assessment or program-evaluation purposes do not exclude your project from consideration. The following questions will enable you to decide whether or not your project falls under this requirement of generalized knowledge.

- 5) Is **one** of the purposes of your project to test an hypothesis derived from a theory?
 - a) NO: proceed to question 6.
 - b) YES: answer the following question
 - i) Do you intend or hope to publicize the results through publication, presentation (including posters), posting on a website, and/or generally disseminating a “white paper.”
 - (1) NO: the results are for your personal use only; you need not submit this project.
 - (2) YES: you must submit your project to the IRB.
- 6) Is **one** of the purposes of your project to describe a phenomenon of interest to others?
 - a) NO: proceed to question 7.
 - b) YES: answer the following question
 - i) Do you intend or hope to publicize the results through publication, presentation (including posters), posting on a website, and/or generally disseminating a “white paper.”
 - (1) NO: the results are for your personal use only; you need not submit this project.
 - (2) YES: you must submit your project to the IRB.
- 7) Is **one** of the purposes of your project the application of a theory or practice in order to solve a problem of interest to others?
 - a) NO: proceed to question 8.
 - b) YES: answer the following question.
 - i) Do you intend or hope to publicize the results through publication, presentation (including posters), posting on a website, and/or generally disseminating a “white paper.”
 - (1) NO: the results are for your personal use only; you need not submit this project.
 - (2) YES: you must submit your project to the IRB.
- 8) Is **one** of the purposes of your project to assess the reliability and/or validity of a measure, such as a questionnaire, attitude scale, and/or inventory?
 - a) NO: proceed to question 9.
 - b) YES: answer the following question
 - i) Do you intend or hope to publicize the results through publication, presentation (including posters), posting on a website, and/or generally disseminating a “white paper.”
 - (1) YES: you must submit your project to the IRB.
 - (2) NO: the project is for personal use only; you need not submit this project.
- 9) Is **one** of the purposes of your project to test procedures, logistics, or other aspects of the research protocol prior to implementing a fully developed protocol; that is, is this a pilot project?
 - a) NO: If you’ve reached this point in the decision tree and you have not been directed to submit your project to the IRB, then your project does not meet the guidelines regarding “generalized knowledge” and you do not need to submit it to the IRB.
 - b) YES: answer the following question:
 - i) Could any aspect of the project pose physical, psychological, emotional, or legal risks to participants that are greater than they would experience in everyday life?
 - (1) YES: you should submit the project to the IRB.
 - (2) NO: project is a minimal-risk pilot study and does not need to be submitted. However, the actual project should be subjected to these questions after you have finalized the protocol.