

ETHICS & THE IRB REVIEW PROCESS: A GUIDE FOR SoTL RESEARCHERS AT UC

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Ethical issues are not simply occasions for caution but windows into our aspirations and values as educators (Hutchings, 2003, p. 28).

Introduction

Because the Scholarship of Teaching and Learning (SoTL) involves systematic investigation into teaching practices and student learning, the focus of SoTL investigations is often the actions, beliefs, or knowledge of our fellow human beings. With the involvement of these “human subjects”—our students, our colleagues, and ourselves—comes a responsibility to act ethically as we carry out our work. As Hutchings (2003) suggests, reflection on the ethical implications of SoTL not only prevents foreseeable harm to those who make our work possible, but also creates an opportunity to examine our own aspirations and values as educators and researchers. One formal occasion for considering the ethical tradeoffs inherent in our work is while preparing documents for review by the Institutional Review Board (IRB), a federally-mandated board that reviews human subjects research across a variety of disciplines to ensure the protection of participants’ rights and welfare.

Before continuing this discussion, it is important to acknowledge that many SoTL researchers across institutions have experienced difficulty navigating the IRB review process. There are several reasons for this. First, most IRBs must review research that comes from a wide variety of disciplines and contexts. IRB boards were not designed with SoTL in mind and individual IRB board members have varying degrees of familiarity with SoTL. In addition, the IRB process can be confusing because broad federal guidelines must be interpreted locally. This can lead to a bewildering amount of variation in how SoTL is treated across institutional contexts and even by different members of the same IRB. For example, many institutions have grappled with the question of whether SoTL should be treated as “human subjects research” or “quality assurance projects,” classifications that are dealt with differently by federal regulations. There is no clear answer to this question, and institutions have interpreted the regulations differently. Finally, SoTL researchers themselves come from diverse academic disciplines and research traditions. Thus, an experienced researcher in a discipline such as archeology may find herself grappling with issues of the ethical treatment of human subjects for the first time when she initiates a SoTL investigation. Moreover, even researchers who are well versed in navigating the IRB process as part of their disciplinary work may find themselves in unfamiliar territory when submitting a SoTL investigation for review. Knowing how to minimize risks and maximize benefits for participants in a clinical trial of medicine does not necessarily prepare a researcher to assess the risks and benefits (including psychological) for students who participate in a SoTL investigation.

In spite of these obvious challenges, participation in the IRB process can be an opportunity for SoTL researchers to clarify their research plans and reflect on the ethical implications of their work as they relate to their values and aspirations as educators and researchers. For this reason, in the next section of this document, we present a brief discussion of ethics in SoTL. It is our hope that the questions posed in this section will help spur critical reflection and debate that goes beyond the requirements of the IRB process. We then move on to present practical advice related to navigating the IRB process at UC. We close with a list of additional resources that may be useful in considering the ethical implications of SoTL research and completing the IRB review process.

Ethics in the Scholarship of Teaching and Learning

In general, the ethical considerations IRB members weigh are derived from three principles:

- *Respect for Persons*, including their right to freely choose whether or not they participate in research (e.g., “informed consent”);
- *Beneficence*, or maximizing benefit and minimizing risk; and
- *Justice*, or ensuring that the appropriate population bears the burden and reaps the benefit from research participation.

In applying these ethical principles to the scholarship of teaching and learning, researchers often confront unfamiliar dilemmas without clear answers. In situations where we conduct research in our own classrooms, these issues can be complicated by our dual responsibilities as both teacher and researcher and by the power differential inherent in the relationship between teacher and student. For example, SoTL researchers might find themselves asking, “Under what circumstances must I ask students for their consent to use the work they completed as a normal part of my course? How might I design data collection so that it contributes as much as possible to student learning? What is the most ethical way of presenting flawed student work to an audience beyond my classroom?”

In *Table 1*, we provide a list of questions for reflection and discussion (Hutchings, 2002, 2003). While this list can be useful for individual researchers considering the ethical implications of their work during the planning stages of SoTL, we believe that it is especially useful as a starting point for discussion among researchers with diverse viewpoints. Because this list may seem overwhelming, we recommend selecting a small number of questions as a launching point for discussion, rather than attempting to cover the entire list at one time. Of course, it is possible to revisit this list, posing new questions at different stages in the research process.

Table 1. Ethical Questions for SoTL Researchers¹

<p>Purpose, Participation, and Consent</p> <ul style="list-style-type: none">• What is the question or problem you want to investigate, and why is it important enough to spend your own and others' time and energy on it?• Whose consent, permission, cooperation, involvement, or collaboration will be required for the conduct of your project? How can roles and permissions be negotiated and renegotiated over time?• What concerns might students have about your work and their participation in it? What choices do students have if they are uncomfortable?• Whose perspectives will be represented in the work? How can various perspectives be honored? What special concerns do you have about representing individuals or groups who have less power in the educational system?• What power relationships need to be taken into account in negotiating roles, permissions, and involvements by various participants in your work? Are there issues of gender, race, culture, and status difference that need to be taken into account?
<p>Methods</p> <ul style="list-style-type: none">• What methods will you use in your investigation? What type of data will you gather? Will this include data that goes beyond normal classroom activities and assessments? How much class time will additional data collection activities take?• How can your investigation be made educationally valuable for students? Might students be involved, for instance by gathering and analyzing data?• Will your data collection choices (e.g., video recording, use of personal writing, use of data from whole-class discussion) affect your ability to protect students' privacy?
<p>Results and the Presentation of Results to Various Audiences</p> <ul style="list-style-type: none">• What negative or embarrassing data can you anticipate emerging from your scholarship of teaching and learning, and who might be harmed as a consequence? How can you create a context for understanding "bad news"? How in particular, can examples of work by students who are novices, or who are struggling with new material be treated with respect?• Who will see the results and products of your work? What conclusions might be drawn by various audiences: About students? About teaching? About your department, discipline, or campus? About higher education? About you? How is your choice of medium (e.g., video recording) related to those concerns?• How can contributions to your work by various participants (including both colleagues and students) be acknowledged and/or cited, while maintaining appropriate confidentiality?

¹ This table presents a slight adaption of questions presented by Hutchings (2002, 2003).

Reflection and Development

- Whom can you talk to about the above questions? How can you create occasions for discussion and reflection about them with colleagues?
 - What are you learning from your project that can inform future practice related to ethical issues in the scholarship of teaching and learning?
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The brief preceding section provides an entry point for thinking about ethics and the scholarship of teaching and learning. For a more in-depth discussion, we recommend consulting *Ethics of Inquiry: Issues in the Scholarship of Teaching and Learning* (2002). In this volume, Pat Hutchings and researchers participating in a Carnegie Foundation for the Advancement of Teaching program to support SoTL present seven case studies describing real ethical dilemmas the researchers faced at different stages of their work from study design to the presentation of results. For example, English Professor James Seitz believed that it was crucial for SoTL researchers to reject the “standard narrative” where “at the beginning of the semester, students were struggling...then the teacher helped them to see the light...and now, as evidence of how far they progressed, the teacher offers a sample of student writing that displays notable accomplishment, thereby demonstrating the success of the teacher’s pedagogy” (Hutchings, 2002, p. 65). For this reason, he decided that his own scholarship must include student writing that would “highlight unresolved difficulties in teaching and learning rather than difficulties overcome,” in other words, writing selected because of its inadequacy (Hutchings, 2002, p. 65). This decision led Seitz to wonder about a number of ethical issues including how his work might be perceived by a public habituated to publications bemoaning the failure of today’s students and calling for a return to former educational practices. He also wondered about the ethics of informed consent and whether his students would have given him consent to use their writing if they had known how he would use it. In addition to Seitz’s reflection, this volume offers other excellent examples of the types of tradeoffs reflective SoTL researchers might face as well as a range of solutions they might consider.

Practical Advice for Navigating the IRB Process at UC

All UC researchers who conduct research with human subjects are required to (a.) complete an online training in human subjects research history and ethics ([CITI Training](#)) and (b.) submit appropriate documents for review and approval by the IRB before beginning research. UC currently uses an electronic Protocol Administration System (ePAS) to manage the submission of documents for IRB review. You can access ePAS using your UC credentials and the following link: https://epas.research.cchmc.org/ePAS_PRD. There are several resources specific to navigating ePAS provided in the Appendix of this document.

At the outset, it is important for SoTL researchers to understand that the definitions of some words used by IRB regulatory specialists may differ in significant ways from the definitions used within our disciplinary traditions as well as everyday word uses. Particularly important in this

respect are the federal definitions for what constitutes “research” and “human subjects.” Understanding how IRB specialists think about these terms is important because they are used to determine the type of documentation that must be submitted for IRB review.

In the following sections, we have created a set of steps to help SoTL researchers determine the scope of their SoTL investigation, the type of IRB review necessary, and the required documentation. However, we do so knowing that there are many gray areas that are open to interpretation. In addition to the more specific guidance offered below, we offer one general piece of advice. If you are ever in doubt, feel free to contact the UC IRB at 513.558.5259 or irb@ucmail.uc.edu. You are also welcome to use the following directory to find the contact information for the IRB support person dedicated to your department or research group: <http://researchcompliance.uc.edu/HRPP/IRB/IRBOverview/DeptDedication.aspx>.

Determining Scope, Part 1: Is your investigation “research”?

The first question to ask is whether your SoTL investigation meets the federal definition of “research.” Federal guidelines define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (DHHS Protection of Human Subjects, 2009). Quality SoTL investigations are, by definition, systematic investigations. However, it can be difficult to determine whether a particular investigation is “generalizable,” as defined by federal regulations. This is especially true if the investigation will focus on a very small number of classrooms. The intent to publish or present investigation findings are not definitive criteria for determining generalizability. In fact, there are no definitive criteria. Our best advice, in determining whether your SoTL investigation is “generalizable,” is to focus on your primary intent or goal in undertaking the work.

If the goal of your investigation is primarily to improve your own teaching or to benefit a particular group of students, it does not meet the federal guidelines for generalizable research. For example, imagine a situation in which a Biology Instructor has decided to try teaching her students about enzymes using a guided investigation process in which students use a model and dataset to work through a set of questions. The questions are designed to increase in complexity and the amount of higher order thinking required. She has noticed that her students have struggled to learn the targeted concepts in the past and wonders if the guided investigation process will prove more effective than her previous teaching practices. For this reason, she decides to collect and systematically analyze student work products and assessments to determine how to teach students about enzymes in the future. Because her primary intent is to improve her own teaching and benefit her particular students, this investigation would not be considered generalizable according to federal guidelines. Of course, her investigation remains a valuable source of information to improve her own teaching, and may also prove helpful to others.

In this situation, when a SoTL investigation does not meet the federal definition of human subjects research, the SoTL researcher completes an abbreviated process asking the IRB to confirm that the investigation does not require IRB oversight. Please note that this formal confirmation is required at UC and documentation of this process may be requested by conference organizers or journal editors. In order to receive confirmation that a SoTL investigation does not require IRB oversight, the researcher types information about the investigation into the smart form of the web-based [ePAS](#) system and requests a “Not Human Subjects Research Determination.” The researcher is not required to submit the detailed attachments required when submitting an investigation that does require IRB oversight². A “Not Human Subjects Research Determination” is generally completed within a few days to a week of submission and remains in effect indefinitely.

If, however, your intent is to collect and analyze data in such a way that your findings will be generalizable (e.g., data is collected from several sections of a course and meant to generalize to all students taking a course), or if you are conducting a small pilot investigation that you are intending to expand in the future in a way that meets the federal definition of research, your SoTL investigation likely meets the federal definition of research. In this case, you will need to determine if your research involves human subjects, as defined by federal guidelines.

Determining Scope, Part 2: Does your research involve “human subjects”?

If you believe your SoTL investigation falls within the federal definition of research, the next question to ask is whether this research involves “human subjects.” The federal definition for “human subjects” is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” (DHHS Protection of Human Subjects, 2009). If either of these conditions are true, the federal definition for use of human subjects has been met.

Most SoTL investigations meet the federal definition for human subjects because they involve interactions with students where the classroom environment is changed for research purposes or where identifiable private information is being collected. For example, imagine a situation where a group of Economics Instructors wants to investigate the impact of incorporating more cooperative learning activities into their large-enrollment introductory economics courses. They design a SoTL investigation where they will compare course sections taught incorporating cooperative learning to course sections taught in the usual manner. This investigation would meet the federal definition for human subjects because the researchers are intervening and changing classroom instruction for the purposes of research.

² If the IRB determines that a project submitted for a “Not Human Subjects Determination” does indeed meet the federal definition for human subjects research, the Principal Investigator will receive a notification that he/she should revise the submission to include all documentation required when standard human subjects research projects are submitted for IRB review.

Now imagine a second scenario where a group of physics instructors is interested in learning more about students' textbook use and study habits. They plan to distribute a survey to all students online. This survey will ask for students' ID numbers so that the information collected in the survey can be linked to students' grade and demographic information. Unlike the previous example, this SoTL investigation will not involve intervening in the students' classroom environments. However, it would involve collecting identifiable private information—the researchers can easily link the survey data to the individual students' identities by using their ID numbers. Therefore, it would still meet the federal definition of human subjects research.

Research might meet the federal definition for human subjects even if the link to individuals' identities is less straightforward. For example, if a psychology instructor collects students' descriptive journal entries in a small enrollment course for research purposes, students may be individually identifiable and therefore it may meet the federal definition for human subjects.

If your SoTL investigation meets the federal definitions for both “research” and “human subjects,” you will need to submit a “Standard Research Project” for review by the IRB. Details for how to complete this process at UC are found in the following section.

Submitting a “Standard Research Project” for Review

As we previously noted, prior to the release of your IRB approval, all members of the research team must complete an online training in human subjects research history and ethics ([CITI Training](#)). After the training has been completed, you can move forward with submitting a standard research project for review. In order to do so, you will type information about the investigation into the smart form of the web-based [ePAS](#) system and include a full “protocol” document and other attachments for review by the IRB. [Protocol templates](#) can be found on the IRB website. This template prompts researchers to fill in detailed information about their study including participant recruitment, risks and benefits for participants, and procedures for data collection and analysis. Next, you (the Principal Investigator) must attach a Curriculum Vita. In addition, you may also be asked to include an informed consent document. [Informed consent templates](#) are also found on the IRB website. Each person on the research team is also required to complete and sign a [conflict of interest disclosure](#). Finally, depending on the nature of your SoTL investigation, you may be required to submit other documents, such as interview protocols, survey instruments, or recruitment letters, for review. On average, the review and approval process takes 6-8 weeks.

Understanding the Three Research Categories

When a standard research project is submitted for review, IRB specialists first determine its Research Category: Exempt, Expedited, or Full Board. The Research Category a project falls into is determined primarily by the amount of risk posed to study participants. The vast majority of SoTL investigations pose no more than minimal risk (i.e., risk ordinarily encountered in daily life) to study participants and therefore qualify for the Exempt or Expedited categories. Although there are three possible Research Categories, there are only two processes for review,

Expedited and Full Board. Studies that fall into both the Exempt and Expedited Research Categories are reviewed using the Expedited Review Process (*Table 2*).

Table 2. Matrix Mapping the Three Research Categories to the Two Review Processes

Research Category	Review Process
Exempt Expedited	Expedited Review Process (determination made by one or more selected IRB members)
Full Board	Full Board Review Process (Reviewed at a convened meeting of the IRB)

At UC, the same requirements for documentation apply to projects falling into all three Research Categories. No matter which Research Category you anticipate, you should submit a standard research project with attachments (e.g., protocol, CV, informed consent, conflict of interest disclosure). In the following sections, we provide more detail about the three Research Categories.

[Understanding What “Exempt” Means](#)

Many SoTL investigations fit within the Exempt Research Category as defined by Title 45 Code of Federal Regulations (CFR) Section 46.101(b) (DHHS Protection of Human Subjects, 2009). However, the term “exempt” can be misleading. It does not mean that the research is exempt from initial review by the IRB. All researchers who are working with human subjects must submit their projects for review. What this categorization means is that, after the IRB member reviews a study and approves it as Exempt, it is exempt from continued review and monitoring by the IRB. In order to be designated Exempt, a study must pose no more than minimal risk to participants and fall under one of six federally defined categories. The majority of SoTL research falls within categories one and two, which relate to normal educational practices and anonymous tests, surveys, interviews, or observations. For your reference, in *Table 3*, we list each of the six categories.

Table 3. The Six Federally Defined Categories for Exempt Research

45 CFR 46.101(b) Categories of Exempt Human Subjects Research ³
<p>Category 1. Normal Educational Practices and Settings 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.</p>

³ The following research is never exempt: (i) research involving prisoners, (ii) survey research involving minors, or (iii) observation of a minor’s public behavior unless the investigator does not participate in the activities being observed.

Category 2. Anonymous Educational Tests, Surveys, Interviews, or Observations

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 subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

Category 3. Identifiable Subjects in Special Circumstances

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) the federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4. Collection or Study of Existing Data

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.

Category 5. Public Benefit or Service Program

Research and demonstration projects that 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; (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Category 6. Taste and Food Evaluation and Acceptance Studies

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 for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: This category is unlikely to apply to SoTL.

[Understanding What "Expedited" Means](#)

SoTL research that does not fall into the Exempt Research Category often fits into the Expedited Research Category as defined by Title 45 CFR Section 46.110 (DHHS Protection of Human

Subjects, 2009). Federal regulations define nine categories of Expedited Research. However, many of these categories are specific to medical research and unlikely to apply to SoTL. In *Table 4*, we list the three categories most likely to be relevant to SoTL researchers.

Table 4. The Federally Defined Categories for Expedited Research Most Relevant to SoTL

63 Federal Registrar 60364-60367

Category 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.)
Note: In the case of SoTL, this might apply to materials originally collected for educational purposes only (e.g., grades, student assignments, lesson plans).

Category 6
 Collection of data from voice, video, digital or image recordings made for research purposes.

Category 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), i.e., if anonymous. This listing refers only to research that is not exempt.)

Category 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.

Again the language can be misleading. The term “expedited” does not mean that the review will necessarily take less time than usual. The process can still take some time to complete. This is especially true if the IRB reviewer requires more information from the researcher than is initially provided or suggests revisions.

Understanding What “Full Board Review” Means

It is unlikely that SoTL research will need to undergo full board review. This type of review is conducted when studies do not fit the exempt or expedited criteria. For example, studies in need of full board review might pose more than minimal risk to participants, involve prisoners, or have the potential for participant coercion.

Conclusion

Our goals for this document are twofold. First, we hope that it provides a jumping off point for SoTL researchers to engage with one another in conversations about how to behave ethically and responsibly toward those who make our work possible. Second, we hope that it provides an initial roadmap for those new to the IRB review process at UC. However, we recognize that no one document can answer all of the questions most relevant to a given SoTL investigation. Thus we hope that you will contact UC IRB at 513.558.5259 or irb@ucmail.uc.edu with any remaining questions about your specific situation. You are also welcome to use the following directory to find the contact information for the IRB support person dedicated to your department or research group:

<http://researchcompliance.uc.edu/HRPP/IRB/IRBOverview/DeptDedication.aspx>.

References

DHHS Protection of Human Subjects, 45 CFR Code of Federal Regulations §§ 46.101b-102 (2009).

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Linder, K.E., Elek, E.D., & Calderon, L. (2014). SoTL and the institutional review board: Considerations before navigating the application process for classroom research in higher education. *Journal of the Scholarship of Teaching and Learning*, 14, 1-14. Doi: <http://dx.doi.org/10.14434/josotl.v14i2.4217>

Appendix: Additional Resources by Topic

Ethical Considerations, the IRB, and SoTL

Martin, R.C. (2013). Navigating the IRB: The ethics of SoTL. *New Directions for Teaching and Learning Special Issue: Doing the Scholarship of Teaching and Learning: Measuring Systemic Changes to Teaching and Improvements in Learning*, 2013(136), 59-71.

doi: 10.1002/tl.20076 Retrieved from

<http://onlinelibrary.wiley.com/doi/10.1002/tl.20076/abstract>

Pritchard, I.A. (2002). Travelers and trolls: Practitioner research and institutional review boards.

Educational Researcher, 31(3), 3-13. Retrieved from

<http://www.jstor.org/stable/3594477>

Shulman, J.H. (1990). Now you see them, now you don't: Anonymity versus visibility in case studies of teachers. *Educational Researcher*, 19(6), 11-15. Retrieved from

<http://www.jstor.org/stable/1177137>

Visible Knowledge Project. (2009, January 14). Institutional review board (IRB) & scholarship of teaching and learning. [Web log post]. Retrieved from

<https://blogs.commonsgorgetown.edu/vkp/2009/01/14/institutional-review-board/>

Werder, C. & Otis, M.M. (Eds.). (2010). *Engaging student voices in the study of teaching and learning*. Sterling, VA: Stylus.

Using the ePAS System for IRB Review

Guide to the IRB Review Process: Step-by-step Help in Navigating ePAS and IRB Review.

[Currently available in draft form. To obtain a copy, contact Claudia Norman at 513.558.5784 or claudia.norman@uc.edu.]

Submitting Your Research Study to UC's IRB Using ePAS: A Demonstration and Troubleshooting

Guide. Training overview video retrieved from

<http://researchcompliance.uc.edu/HRPP/IRB/ePAS.aspx>

Troubleshooting for ePAS. Troubleshooting guide retrieved from

<http://researchcompliance.uc.edu/HRPP/IRB/ePAS.aspx>