

**Illinois State University Institutional Review Board
Research with Human Subjects
Protocol Submission Form**

IRB Number _____ (Number to be completed by REC)
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Federal regulations and Illinois State University policy require that all research involving humans as subjects be reviewed and approved by the University Institutional Review Board (IRB) prior to conducting the research. **As of January 1, 2011, the IRB will not review any protocol submitted without documentation of mandatory CITI training.** For information on training requirements, human subjects research policies, forms, and templates, please visit the Research Ethics & Compliance (REC) website at: rsp.illinoisstate.edu/research/.

Please complete and forward this form and all supporting documents to your Department/Unit IRB representative. Handwritten applications will not be accepted. If you have any questions, please contact your Departmental/Unit IRB representative or the Research Ethics & Compliance Office at 438-2529 or via email at rec@IllinoisState.edu.

I. General Information

A. Protocol Title

What students learn from participation in a SoTL research project team

B. Purpose of Project

Student Research (check one): Class project (Course #) Dissertation Thesis Batch protocol (Course #)

Faculty/Staff Research (indicate funding source):

Non-funded University funds Corporate sponsor Foundation

Externally funded: To be submitted Submitted In Review Award Pending Award Made

Name of Sponsor: _____ Agency Assigned Grant # _____ RSP # _____

Address: _____ Contact Person: _____

C. Investigator Information

Principal Investigator Information (PI must be an ISU faculty or staff member)

Principal Investigator		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff		
Dept	Mail Code	Telephone Number	E-mail Address	CITI Training Completion Code

Co-Principal Investigator Information

Co-Principal Investigator		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student		Participation Start Date
Dept	Mail Code	Telephone Number	E-mail Address	CITI Training Completion Code

Additional personnel should be listed on a separate sheet attached to the protocol. Include (at a minimum) name, role in the research, start date, and CITI Training Completion Code.

II. Principal Investigator Assurance

As Principal Investigator, I certify that to the best of my knowledge:

- The information provided for this project is correct
- I agree to conduct this research as described in the attached supporting documents and no other procedures will be used.
- I will not implement any changes to the protocol (procedures, personnel, etc.), including modifications requested by the funding agency, prior to receiving written approval from the IRB.
- I will comply with federal and University policies for conducting ethical research.
- I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol.
- Any unexpected or otherwise significant events in the course of this study will be promptly reported to the REC.
- I understand that any noncompliance associated with this protocol can result in disciplinary action under the IRB as well as the Academic Integrity policy of the University.

Principal Investigator Signature _____
Date

III. Protocol Description

A. GENERAL

The IRB is required to assess whether the proposed research design is scientifically sound and will not unnecessarily expose subjects to risk. Please provide a **BRIEF** description of the proposed research. State the goals and/or hypotheses of this study and how these goals relate to previous research in this area. The description must be made in **LAYPERSON'S TERMS**, as the IRB is made up of researchers, non-researchers, and community members with diverse backgrounds and expertise. *Any technical terms or terms of art must be explained.* If the research is being conducted in conjunction with classroom activities, be sure to clearly describe the normal classroom activities separately from the research component.

Over the past four years grants have been awarded by the Office of the Cross Chair to teams of faculty interested in studying a SoTL research problem related to student autonomy, civic engagement, and and other student learning topics. As a requirement for the grant, each team was to involve a student in meaningful ways with the research project. This research project seeks to explore what outcomes students took away from this experience as a member of a SoTL research team. Currently, 12 students who were research partners are still enrolled at Illinois State University and before they graduated we wanted to hear from them about their learning in order to assist other faculty who wanted to better involve students in a research process.

METHODOLOGY

1. **Subject Selection and Recruitment:** The IRB must assure that subjects have been selected equitably in terms of gender, race, and ethnicity; that benefits are distributed fairly among the community's populations; and that additional safeguards are in place to protect vulnerable populations.

a) Identify all participant groups in the study and indicate criteria for including or excluding individuals from participation, such as gender, race, socioeconomic level, age, etc.

All 12 students who were part of a SoTL research team that are still enrolled at Illinois State will be invited to participate.

b) Total number of subjects: 12

If targeting males/females specifically, indicate the numbers of: Males _____ and/or Females _____. Provide an explanation of why this gender is being targeted:

If targeting a specific age range, indicate the range: From _____ to _____. Provide an explanation of why this age range is being targeted:

c) Federal regulations and guidance contain explicit requirements for conducting research with protected populations such as children, mentally disabled individuals, prisoners, pregnant women (where the condition of being pregnant is related to the research,) and persons unable to provide legal consent, such as the cognitively impaired. Please check all that apply and complete and attach the appropriate appendices to your protocol. This study will involve:

_____ Children **(Complete and attach Appendix B)**

_____ Prisoners **(Complete and attach Appendix C)**

_____ Pregnant Women, Human Fetuses, and Neonates **(Complete and attach Appendix D)**

_____ Cognitively Impaired Individuals **(Complete and Attach Appendix E)**

- d) Describe how potential participants will be identified and how access to contact information will be obtained. If you plan to obtain information not publicly available, such as non-directory information; any proprietary sources, i.e. listserv, organization roster, or school records; or other information covered under HIPAA or FERPA regulations, IRB approval of the project does not grant automatic access to this information. The individual with authority over the information has the sole responsibility for determining whether to grant access. Please include documentation of permission to use this information or describe how permission will be obtained.

Participants were located on the ISU website along with their ilstu.edu email address which is public information.

- e) Describe how participants will be recruited, including how will they be contacted and by whom. Attach copies of all recruitment documentation, (i.e. e-mail letters, flyers, telephone scripts, etc.).

All participants will be contacted via their ilstu.edu email account and invited to a focus group discussion to share their experiences with the SoTL research project. **See the email attached for specific wording.**

2. Informed Consent/Permission/Assent: Informed consent is the process by which the subjects are provided detailed information as to the purpose of the research, the risks and benefits to them as participants, what will be expected of them, and then given the opportunity to agree to participate or not. Consent documents and scripts must be written in a language and at a level the subjects will understand. The researcher is also responsible for minimizing coercion and undue influence. **Coercion** occurs when there is an overt or implicit threat of harm presented in order to obtain participation, such as when a subject will lose access to certain services if they decline participation, when a student will experience reprisal or disapproval from an instructor, or when an employee will experience reprisal or disapproval from a supervisor. **Undue influence** can occur when there is an offer of an excessive or inappropriate reward to secure participation, such as a large cash payment or other gift.

- a) *Required Elements of Informed Consent:* The required elements of informed consent are listed in **Appendix A**, which must be completed and can be found at the end of this document. Examples of informed consent and parent permission and guidance in drafting them can be found on the REC website. Please also refer to *45 CFR 46.116* for further information on requirements for informed consent and documentation, and the waiver or modification thereof.
- b) *Informed Consent Procedures:*
 - i. **Consent** may be obtained only from persons legally competent to give it. For research involving minors, **parental permission** as well as **minor assent** may be required. For research involving cognitively impaired individuals, consent must be given by a Legally Authorized Representative. Refer to the REC website for guidance on this issue. From whom will consent/assent/permission be obtained for this study?

Each participant will be provided an explanation of the research and offered the opportunity to ask questions. At the focus group meeting students will be given an informed consent document and asked to sign if they agree to participate.

- ii. Describe what procedures will be used (and in what order) to secure informed consent/assent. Include whether there will be written or verbal presentation, and whether signatures will be required. If written consent, permission, or assent forms are being used, attach exact copies. If presented verbally, attach a copy of the presentation script.

Students will provide written consent before they participate in a focus group. **See the attachment for a copy of the informed consent document.**

- iii. Describe who will obtain informed consent and how coercion and undue influence will be minimized.

The principal investigator will conduct the focus group. If more than one group is needed the Cross Chair in SoTL will conduct the other focus group. Whoever conducts the focus group will obtain informed consent form the student participants.

3. **Compensation:** Compensation (e.g. payment, gifts, extra credit) for participation is allowable if it is not excessive or inappropriate. Compensation is not a benefit of participation.

Will compensation be offered? XX_Yes _____No. If yes, complete the following:

- a) Indicate the type and amount.

Students will be offered lunch in exchange for participation in the focus group interview.

- b) Describe how compensation will be disbursed, including how it will be handled for participants who withdraw from the study.

Anyone who attends the focus group will be able to eat. Students who do not attend the focus group meeting will not receive lunch.

- c) Identify the funding source for the compensation (e.g. personal, grant, departmental).

The Cross Chair for SoTL will purchase lunch with her budget.

4. **Research Location:** Where will the research take place? Please be as specific as possible. If research is confidential in nature, please explain how location will help preserve confidentiality.

The focus group will be conducted in the conference room at the Center for Teaching, Learning, and Technology which is a private room with doors that close.

C. PROCEDURE

1. Individuals collecting the data must be appropriately trained to handle foreseeable adverse events, such as a subject being injured or becoming emotionally distressed. They must also fully understand the research project, including confidentiality issues. Please describe who will be collecting the data and their relevant training.

The principal investigator and the Cross Chair are both faculty members skilled in conducting interviews and focus groups.

2. Describe what participants will be expected to do, and in what order.

Students will be asked a few questions about their learning experiences as a member of a SoTL research team. These questions are provided at the end of the document. A discussion should take place based on these questions, allowing all participants the opportunity to share their experiences and react to the experiences of others in the focus group. Most research teams had only one student member, so all the experiences that students share could be unique.

3. The use of psychological interventions, deception, or biomedical procedures, requires special review procedures, as each has particular risks. Please check all that apply:

_____ *Psychological Interventions:* e.g. contrived social situations, manipulation of the subjects' attitudes, opinions, or self-esteem. **(Complete and attach Appendix F)**

_____ *Deception*: e.g. false information is given to subjects, false impressions created, or information relating to the subjects' participation is withheld from them. **(Complete and attach Appendix G)**

_____ *Biomedical procedures*: e.g. the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision. **(Complete and attach Appendix H)**

4. **Audio recording, video recording, and recording still images, including digital recordings**, of participants can present special concerns, particularly regarding confidentiality. Projects involving these must make specific mention of them in the consent documents, including information about the storage of recorded material and how and when they will be destroyed. Please check all that apply below, and **complete and attach Appendix I if required**. This project will involve:

XX_ Audio recording _____ Video recording _____ Still images

In order to assist with understanding the students' experiences, the focus groups will be audio recorded.

D. INSTRUMENTS/APPARATUS

Describe any forms, surveys, or instruments you plan to use. (Copies of each must be attached to the protocol.) If online surveys will be used, please identify the system to be used and describe the system's confidentiality protections.

The interview protocol to be followed is provided at the end of the document.

E. DATA

Data security is critical to the protection of subjects' identities and private information. The IRB must evaluate whether the systems in place to protect the data are appropriate for the level of risk to the subjects.

1. Data can either be anonymous, confidential, or, if the subjects agree, neither anonymous nor confidential. Please note that even if names are not collected, it may be possible to identify subjects through IP addresses for web-based surveys, the collection of certain demographic information, etc. Please consider this when checking one of the following:

_____ Anonymous (subjects cannot be identified, either directly or through identifiers)

XX Confidential (subjects will be identified, but their identities will be protected from disclosure)

_____ Neither (subjects will be informed that their identities will be disclosed)

As the focus groups are face-to-face interactions, the interviewer(s) will know which student provided what information. In the transcribed interview documents no names will be associated with responses, so participants will remain anonymous to anyone else aside from the focus group facilitators.

2. Describe how and where will the data stored and kept secure. Please specify the building and room number, if applicable.

The data will be stored in the Cross Chair and/or principal investigator's university offices in a locked file cabinet.

3. Indicate who will have access to the data.

Only the principal investigator and the Cross Chair will have access to the raw data...recordings or written transcription documents. If an outside transcriptionist is used, that person will sign a confidentiality form.

4. Describe how the data will be used, both during and after the research. Indicate whether it will be disseminated through publication, presentation or other means, and in what form (e.g. identifiable raw data, aggregate results with no identifiers, etc.).

The data will be analyzed using qualitative methods looking for themes, common ideas, and unique experiences of the student researchers. The information collected will be used for presentations and workshops about involving students in research projects. In addition there may be publications (both internal and external to the campus) written based on this study.

5. Describe how and when the data will be disposed of.

The raw data on the audio recordings will be erased after it is transcribed. The transcription documents will be maintained until the presentations/workshops and publications are completed (about three years).

F. RISKS

Risks to the subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. *Physical risks* include anything potentially harmful to the body, including injury, illness, or death, while *psychological risks* can include reactions such as emotional distress or anxiety. *Social risks* include exposure to criminal or civil liability, or damage to the subjects' financial standing, employability, or reputation. Please note that all risks must be articulated in the consent form.

1. Describe foreseeable risks to the subject.

The risks to the participants are minimal as they are free to share as much or as little about their learning in the focus group meeting as they want. They may compare their experiences with research to other students and feel proud or disappointed that their experience was not the same as others.

2. Describe how these risks will be minimized.

Students will be informed that they can choose to respond (or not) to any questions asked. The questions to be asked are not really "risky" as they ask about experiences with a research study.

3. If these risks are greater than those encountered in everyday activities (more than "minimal risk,") additional explanation is required

Are these risks greater than minimal risk? _____ Yes XX No. If yes, complete the following:

- a) Explain how they are outweighed by the sum of the benefits to the individual subject and to the importance of the knowledge to be gained.
- b) Discuss the alternative ways of conducting this research and why the one chosen is superior.
- c) Explain fully how the **rights and welfare** of such subjects at risk will be protected (e.g., equipment closely monitored, psychological screening of prospective subjects, medical exam given prior to procedure).

G. BENEFITS

Benefits to the subjects must be weighed against foreseeable risks, and are to be distributed fairly among the community's population. Benefits may include anything health-related, psychosocial, or other direct value for individual subjects, or may yield generalizable knowledge that may further society's understanding of a disorder or condition. Compensation for participation is not a benefit.

1. Describe what you hope to learn from the study.

What students learned from participation on a research team. What students learned about other students learning as a result of their conducting a SoTL study. How other faculty could meaningfully involve students in SoTL research projects.

2. Who might find these results useful?

Anyone who wants to work with students on research projects would be very interested in this study.

3. Describe direct benefits to the participants, if any?

By having the opportunity to reflect on their learning, students may better understand their preferences when it comes to being involved in research or in learning new material. They may have ideas to share about working collaboratively with faculty on a research project. They may also be interested in sharing the results of the research they conducted with other students in a group setting.

4. Explain how the benefits justify the associated risks.

The risks to participants are minimal as are the benefits to them individually. If students are willing to share their experiences we will be happy to use that information in a way that will enhance research experiences of other students in the future.

IV. Checklist

Please complete this checklist to assure that all required components of your protocol have been included prior to submitting your protocol to your Departmental Representative. Incomplete protocols will be returned to the PI.

- X Informed consent procedures/documentation, or the request for modification or waiver thereof, have been clearly explained. Appendix A is attached.
- NO This project involves the following vulnerable populations:
- Minors. Appendix B is attached.
 - Prisoners. Appendix C is attached.
 - Pregnant women, (where the condition of pregnancy is related to the study), human fetuses or neonates. Appendix D is attached.
- NO Cognitively impaired individuals. Appendix E is attached.
- NO Psychological interventions will be employed, such as contrived social situations, manipulation of the subject's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences. Appendix F is attached.
- NO Elements of deception will be used. Appendix G is attached.
- NO Biomedical procedures will be used. Appendix H is attached.
- X Audio recording, video recording, or still images will be used. Appendix I is attached.

Appendix A: Elements of Informed Consent

Federal regulations specify the required elements of informed consent. The regulations also allow for waiver or alteration of these elements under specific circumstances. If no waiver or alteration of the elements of informed consent has been requested, the informed consent procedures described in the protocol and consent documents must contain all of the elements listed below. Please mark "Yes" to indicate they are included in both the protocol and the consent documents, unless you have requested to waive or alter a particular element.

- Yes 1. A statement that the study involves research
- Yes 2. An explanation of the purposes of the research
- Yes 3. The duration of the participant's participation
- Yes 4. A description of procedures to be followed
- Yes 5. A description of foreseeable risks or discomforts to the participant
- Yes 6. A description of any benefits to the participants or any others that may be expected from the research
- Yes 7. A statement describing the extent, if any, that confidentiality will be maintained
- Yes 8. An explanation as to whom to contact concerning questions about the research; this should include the Principal Investigator's name and contact information. In addition, for questions about research participants' rights and/or a research related injury or adverse effects, list the Research Ethics & Compliance Office name and contact information: (309) 438-2529 and/or rec@ilstu.edu.
- Yes 9. A statement that participation is voluntary
- Yes 10. A statement that refusal to participate involves no penalty or loss of benefits
- Yes 11. A statement that the subject may discontinue participation at any time without penalty or loss of benefits