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Institutional Review Board

The IRB procedures at Saint Xavier involve submitting a written proposal with the details of the project to the IRB. I have also done this previously and, like Jessica found the process to be fairly straightforward. I would really recommend that people have LOTS of lead time with their IRBs, because ours took much longer than we anticipated.

Also you want to make sure that anyone involved has their CITI Or NIH Certificate.

I have included the IRB check list and application form.

SXU-IRB Application Checklist

1. Does the project require any collaborators in outside institutions (other researchers, school teachers, principals?) If other collaborators are involved, has this project already been approved at the outside institutions? If so, please provide a signed letter from a gatekeeper(s) at this institution(s) at the time you submit your application materials.
2. Is general statement of the problem clearly stated? Do you provide research questions?
3. Do you provide a detailed description of the overall plan, procedures and methods?
4. Have you attached any questionnaires, interview protocols and/or testing instruments? If required copyright, please include permission letter from authors/publishers.
5. Have you attached a cover letter to participants with the formal consent and permission letter to parents?
6. Have you described a number, relevant characteristics and source of participants? Describe how the participants will be recruited. If relevant, specify institutional ethical procedures, at the site of data collection, to which application will be subjected (i.e., what are the research review procedures at the institution where the data will be obtained; or how will you account for some student inclusion and not others?)
7. Have you described how the anonymity of participants is protected and what is the procedure to access these data? What will be specifically culled from the data set? Provide a detailed description of all efforts to guard the confidentiality of participants (especially in the case of minors/ students in school settings) by keeping collected data in a secure place.
8. If relevant, specify any special participants populations (i.e., minors, prisons, or the mentally incompetent) involved in this project and describe the procedures for obtaining the appropriate consent. Participants may be considered 'special populations' when there is a question whether they are able to freely give consent to are coerced in giving consent.
9. Will the participant(s) be exposed to any psychological intervention such as deception, contrived social situations, manipulation of the participants' attitudes, opinions, or self-esteem, psychotherapeutic procedures, or other psychological influences? If so, describe procedures for follow-up and/or debriefing.

10. Have you descussed the status and qualifications of research assistants, if any?
11. If your project is funded, did you mention a source of funding for the project (if relevant, typically for faculty research)?
12. Have you indicated expected starting and ending dates for the project? Projects cannot begin without written approval of the IRB. DO NOT INCLUDE DATES ALREADY PAST!
13. Have you outlined potential benefit of this project to the individual participant, group of participants or society in general?
14. Have you discussed potential risks to participants and the measures taken to minimize such risks?
15. Make certain that all researchers are certified through CITI/NIH. Submit the Certificates at the time of application. Certification is required. No research proposal will be approved without proper documentation.

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Request for Ethical Review of Research on Human Subjects

Title of the Research Project:

Tracking Number:

Federal regulations and Saint Xavier 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 June 30, 2014, the IRB will not review any research project submitted without documentation of mandatory CITI training or NIH training for both investigators and faculty sponsors.** For information on training requirements, human subjects research policies, forms, and templates, please visit the Saint Xavier University IRB website. **Please refer to the SXU-IRB Application Checklist in completing your application.**
http://www.sxu.edu/academics/resources/irb/index.asp

Principal Investigator (Primary Contact)		**CITI Or NIH Certificate**
Name: School/Department/Office:	Phone: E-mail:	CITI code: NIH number:
Co-Investigator		
Name: School/Department/Office:	Phone: E-mail:	CITI code: NIH number:
Co-Investigator		
Name: School/Department/Office:	Phone: E-mail:	CITI code: NIH number:
Co-Investigator		
Name: School/Department/Office:	Phone: E-mail:	CITI code: NIH number:
Co-Investigator		
Name: School/Department/Office:	Phone: E-mail:	CITI code: NIH number:
Faculty-Sponsor (if applicable)		
Name: School/Department/Office:	Phone: E-mail:	CITI code: NIH number:

Phone numbers and e-mail addresses are **required** for all investigators and faculty sponsor.

Location(s) where research will be conducted:

Location Name/ Address:	Location Name/ Address:	Location Name/ Address:	Location Name/ Address:	Location Name/ Address:

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Funding Source:	**Yes**___	**No**___
Will funding source create a conflict of interest?	**Yes**___	**No**___
Do researchers anticipate any conflict of interest?	**Yes**___	**No**___

If yes, please explain _____

_____

Anticipated Dates of Study:	From: / /	To: / /	
Anticipated Number of Human Research Subjects:	Students:	Parents:	Teachers:
Other (describe):			

If requesting a blanket IRB exemption/approval for all student research projects in a course, please provide:

Course/Section No.: Course Title: Term:

1. Will this study include MINORS as research subjects?	☐Yes	☐No
2. Will this study involve **DECEPTION** of human subjects?	☐Yes	☐No
3. Will subjects be **PAID**?	☐Yes	☐No
4. Will this study involve materials that may be **HAZARDOUS** to human subjects?	☐Yes	☐No
5. Will this be a **DRUG STUDY**?	☐Yes	☐No
6. Will this study include **PRISONERS** as research subjects?	☐Yes	☐No
7. Will this study include subjects who have a **COGNITIVE IMPAIRMENT** that interferes with the ability to provide informed consent?	☐Yes	☐No
8. Will this study include **PREGNANT WOMEN** as research subjects?	☐Yes	☐No
9. Will this study include **HUMAN TISSUES** as the subjects of research?	☐Yes	☐No

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Research Protocol

Please provide the following information:

a. Describe a setting for research (school, classroom, clinic, hospital, etc.)
b. Indicate anticipated dates of the study From: To:
c. Provide a detailed description of research participants (number, age (adults, minors over 12, minors under 12), vulnerable populations (see questions above), and describe how participants were selected or recruited
d. Discuss procedures for subject protection • How permissions from the site are used? • What are methods for attaining informed consent of subjects? • What are methods for protection of anonymity or confidentiality of subjects? • What are methods for protection from harm?
e. Describe data collection procedures (when administered, how administered, who administers)
f. Describe possible benefits and risks to subjects
g. If the study is experimental, describe interventions

Please check any of the following criteria that apply to the above mentioned research:

☐	1. Research will be conducted in established or commonly accepted educational settings, involving normal education practices, such as: (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of, or comparison among, instructional techniques, curricula, or classroom management methods. (Please list the courses in which the research will be conducted):
☐	2. Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement).
☐	3. Research employs survey procedures or interviews.
☐	4. Research is limited to observations of public behavior of adult subjects.
☐	5. Research is limited to observations of public behavior with children as subjects in which the investigator does not participate in the activities being observed.
☐	6. Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens which are publicly available.
☐	7. All information is recorded in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects

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Consent Letters/Forms

Please attach a copy of all informed consent letters/forms (e.g., adults, students, minors, school administrator's consent). In addition, a signed paper copy of the school or institution administrator's letter is required. This may be submitted separately either in person, via faculty advisor, or via U.S. Postal Service.

If any research materials, including consents or explanation of the study written for participants in a language other than English, please include these materials along with original and translated materials in this proposal.

Data Collection Instruments
Please attach copies of all data collection instruments. A citation for copyrighted instruments is sufficient.

<table>
<tr><td colspan="2">I certify that the above information is correct
(<u>all</u> investigators must sign):</td><td colspan="2">I have read and approved of the protocol:</td></tr>
<tr><td>Principal Investigator (sign and print)</td><td>Date</td><td>Faculty Sponsor (if appropriate - sign)</td><td>Date</td></tr>
<tr><td rowspan="2">Co-Investigator (sign)</td><td rowspan="2">Date</td><td colspan="2" rowspan="2">IRB USE ONLY:
Approve exemption: ☐
Recommend full review: ☐</td></tr>
<tr></tr>
<tr><td>Co-Investigator (sign)</td><td>Date</td><td colspan="2">Reviewer signature Date</td></tr>
<tr><td>Co-Investigator (sign)</td><td>Date</td><td colspan="2" rowspan="2"></td></tr>
<tr><td>Co-Investigator (sign)</td><td>Date</td></tr>
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</table>

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