

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

IRB Number _____
(Number to be completed by REC)

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). Any person (ISU faculty member, staff member, student, or other person) wanting to engage in human subject research at or through Illinois State University must receive written approval from the IRB before conducting research. For more information, templates, and forms please go to www.rsp.ilstu.edu

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, (REC) 438-2520, Campus Box 3330

I. General Information

A. Protocol Information	
Protocol Title:	
Purpose of Project (Please check only one box) <input type="checkbox"/> Dissertation <input type="checkbox"/> Thesis	
<input type="checkbox"/> Class project (Please give course number) _____	<input type="checkbox"/> Other
<input type="checkbox"/> Externally funded faculty/staff research (Complete Appendix B)	<input type="checkbox"/> Non-externally funded faculty/staff research

B. 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	Email Address
Co-Principal Investigator Information			
Co- Principal Investigator		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Grad. Student <input type="checkbox"/> Undergrad. Student	
Dept	Mail Code	Telephone Number	Email Address
Co-Principal Investigator Information			
Co- Principal Investigator		<input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Grad. Student <input type="checkbox"/> Undergrad. Student	
Dept	Mail Code	Telephone Number	Email Address

II. Principal Investigator Assurance

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

- The information provided for this project is correct
- No other procedures will be used in this protocol
- I agree to conduct this research as described in the attached supporting documents
- I will request and receive approval from the IRB for changes prior to implementing changes (including but not limited to changes in cooperating investigators or any changes in procedures).
- I will comply with IRB and ISU 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.
- In the case of student research, I assume responsibility for ensuring that any student will comply with University and Federal regulations regarding the use of human subjects in research.
- In the case of externally funded research, I will request a modification to my approved protocol if any relative changes to the project's scope of work are requested by the agency.

Principal Investigator Signature

Date

III. Protocol Description

- A. Provide a **BRIEF** description, in **LAYPERSON'S TERMS**, of the proposed research. State the goals and/or hypotheses of this study and how these goals relate to previous research in this area.

B. Methodology

a. Identify all participant groups in the study and indicate criteria for including or excluding individuals from participation.

b. How many participants will be included in the study?

Number: Male _____ Female _____ Total _____
(N/A _____ if not targeting males/females specifically)

Age range: _____ to _____

c. Justify use of any protected populations (e.g., children, mentally disabled individuals, prisoners, pregnant women). Complete whichever is appropriate, Appendix C-F, for that population.

d. How will you identify potential participants and get access to contact information? Please include documentation of permission to use any proprietary sources, i.e. listserv, organization roster, etc.

e. How will participants be recruited? Attach all recruitment documentation, (i.e. e-mail letters, flyers, telephone scripts, etc.) and indicate how they will be contacted and by whom.

f. Who will obtain informed consent/assent and what procedures will be used (and in what order) to secure informed consent/assent?

g. How will the risk of coercion be minimized?

- h. 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.

If consent, permission, and assent forms are being used, attach copies. If presented verbally, a copy of any presentation script must be submitted. **Examples of informed consent and parent permission can be found at http://www.rsp.ilstu.edu/research/human_subjects/index.shtml**

C. PROCEDURE

- a. Who will collect data?

- b. What are you asking the participants to do? In what order?

- c. Will you involve them in a psychological intervention, biomedical procedure, or deception? If so, complete relevant Appendix G, H, or J.

- d. If participants are receiving compensation for participation (e.g., payment, gifts, extra credit, etc.) indicate type and amount of compensation, how it will be disbursed, and identify the funding source.

- d. Will you record audio_____, video _____, or still images_____ of participants whether by film, tape, digital or other media? Please check and complete Appendix K.

D. INSTRUMENTS/APPARATUS

What forms, surveys, equipment, etc. will you use? (**Attach copies** of all forms, surveys and instruments to be used.) If online surveys will be used, please identify the system to be used and describe the system's confidentiality protections.

E. DATA

- a. How/where will the data be stored and kept secure? Please specify building and room number.

- b. Who will have access?

- c. How will the data be used (during and after the research)? Will it be disseminated through publication, presentation or other means?

- d. How and when will the data be disposed of?

F. RISKS

- a. What are the physical, psychological, or social (loss of reputation, privacy, or employability) risks?

- b. How will the risks be minimized?

- c. Will the data be anonymous _____ or confidential _____? (Please check one)

G. BENEFITS

a. What do you hope to learn?

b. Who might find these results useful?

c. How will the participants directly benefit? If they will not, please state that. Compensation is not a benefit.

d. Explain how the benefits justify the associated risks.

IV. Checklist

This checklist must be completed and attached to all protocols or Department Representatives will return them to the PI. Please note that for any items checked “yes” you must attach the designated, completed appendices and relevant forms and instruments.

- Yes No Informed consent procedures/ documentation have been clearly explained. (**All** protocols must have a completed **Appendix A.**)
- Yes No Is your research being funded? (If yes, complete **Appendix B.**)
- Yes No Are you recruiting and enrolling subjects 0-7 years old? (If yes, complete and attach **Appendix C.**)
- Yes No Are you recruiting and enrolling subjects 8-17 years old? (If yes, complete and attach **Appendix C.**)
- Yes No Are you recruiting and enrolling prisoners as subjects? (If yes, complete and attach **Appendix D.**)
- Yes No Are you recruiting and enrolling pregnant women as subjects? (If yes, complete and attach **Appendix E.**)
- Yes No Are you recruiting and enrolling mentally incapacitated individuals as subjects? (If yes, complete and attach **Appendix F.**)
- Yes No Will the subjects of this study be exposed to the possibility of harm, including physiological, psychological, or social (e.g., loss of reputation, privacy, or employability). (If yes, complete and attach **Appendix G.**)
- Yes No Will the subjects of this study be exposed to any psychological interventions such as contrived social situations, manipulation of the subject's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences. (If yes, complete and attach **Appendix H.**)
- Yes No Will this study involve any elements of deception? (If yes, complete and attach **Appendix I.**)
- Yes No Will the proposed research involve any 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). (If yes, complete and attach **Appendix J.**)
- Yes No Will all or some of the subject(s) of the proposed research be audio or videotaped or recorded in any other manner? (If yes, complete and attach **Appendix K.**)
- Yes No Will this proposed research involve any elements of technology? (i.e. web-based subject recruitment, email recruitment, web survey, etc.)

Appendix A: Elements of Informed Consent

Please ensure that all of these elements are included in the protocol and consent documents before checking "Yes". The informed consent procedures and documents outlined in this protocol must contain all of the following:

- | | | |
|------------------------------|-----|--|
| <input type="checkbox"/> Yes | 1. | A statement that the study involves research |
| <input type="checkbox"/> Yes | 2. | An explanation of the purposes of the research |
| <input type="checkbox"/> Yes | 3. | The duration of the participant's participation |
| <input type="checkbox"/> Yes | 4. | A description of procedures to be followed |
| <input type="checkbox"/> Yes | 5. | A description of foreseeable risks or discomforts to the participant |
| <input type="checkbox"/> Yes | 6. | A description of any benefits to the participants or any others that may be expected from the research |
| <input type="checkbox"/> Yes | 7. | A statement describing the extent, if any, that confidentiality will be maintained |
| <input type="checkbox"/> Yes | 8. | An explanation as to whom to contact concerning questions about the research, research participants' rights, and/or a research related injury or adverse effect. This should include the Principal Investigator's name and contact information as well as the Research Ethics & Compliance Office name and number: (309) 438-2520. |
| <input type="checkbox"/> Yes | 9. | A statement that participation is voluntary |
| <input type="checkbox"/> Yes | 10. | A statement that refusal to participate involves no penalty or loss of benefits |
| <input type="checkbox"/> Yes | 11. | A statement that the subject may discontinue participation at any time without penalty or loss of benefits |

Do the consent procedures and documents outlined in the protocol contain the following?

- | | | |
|---|----|--|
| <input type="checkbox"/> Yes <input type="checkbox"/> N/A | 1. | Identification of any experimental procedures |
| <input type="checkbox"/> Yes <input type="checkbox"/> N/A | 2. | A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject |
| <input type="checkbox"/> Yes <input type="checkbox"/> N/A | 3. | An explanation about any compensation or medical treatments that may be available if injury occurs, what they may be, and where to get further information |