

**APPLICATION FOR APPROVAL TO CONDUCT RESEARCH
INVOLVING HUMAN SUBJECTS**

**SOUTHERN ILLINOIS UNIVERSITY AT CARBONDALE
HUMAN SUBJECTS COMMITTEE**

University policy and federal policy (through the Department of Health and Human Services regulations for the Protection of Human Subjects Research) require review and approval of **ALL** research activities involving human subjects. This applies to all faculty and staff research as well as all student research, including research to satisfy the requirements of master's and doctoral degrees.

Approval of the Human Subjects Committee (HSC), which is the Institutional Review Board for Southern Illinois University at Carbondale, must be obtained **PRIOR** to the involvement of subjects, including pilot studies. Failure to have human subjects research reviewed and approved by the HSC is a violation of University and federal government policy and could result in a loss of grant funding or in a research paper/thesis or dissertation not being accepted by the Graduate School. **The HSC cannot review protocols for projects for which data collection has already begun.**

All proposals submitted will be given a preliminary review within two weeks of the submission date when University classes are in session, assuming that all necessary information is provided by the researcher. Additional reviews are required for Category II and Category III proposals.

Attached to this cover sheet are the following forms:

Form A:	Approval Page	Form C:	For Category I Review
Form B:	Screening Questions	Form D:	For Category II or III Review

SUBMISSION PROCEDURES

For **Category I** review, submit one original Form A and a total of three copies of Forms B and C.

For **Category II or III** review, submit one original Form A and a total of three copies of Forms B and D.

Also attach 3 copies of all materials relating to the research study (e.g., questionnaires, surveys, interview protocols, recruitment scripts, consent forms and/or cover letter). Copies of any published standardized tests are not required. If the HSC determines that a proposal falls under Category III review, the researcher will be notified of the additional number of copies that are needed.

For further assistance, contact the Human Subjects Committee Secretary at the address below. Application forms and information concerning University policy and other pertinent Federal policies and guidelines related to research involving human subjects are also available on the Internet at the address below.

SIUC Human Subjects Committee
Office of Research Development and Administration
Woody Hall C217
Southern Illinois University at Carbondale
Carbondale, IL 62901-4709
Ph. 618-453-4533 Fax 618-453-8038

www.siu.edu/worda/rates/human.html

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SIUC HSC FORM A

**REQUEST FOR APPROVAL TO CONDUCT RESEARCH ACTIVITIES
INVOLVING HUMAN SUBJECTS**

CERTIFICATION STATEMENT

By making this application, I certify that I have read and understand the University's policies and procedures governing research activities involving human subjects. I agree to comply with the letter and spirit of those policies. I acknowledge my obligation to:

1. Accept responsibility for the research described, including work by students under my direction.
2. Obtain written approval from the Human Subjects Committee of any changes from the originally approved protocol **BEFORE** implementing those changes.
3. Retain signed consent forms in a secure location separate from the data for at least **three** years after the completion of the research.
4. Immediately report any adverse effects of the study on the subjects to the Chairperson of the Human Subjects Committee, SIUC, Carbondale, Illinois - 618-453-4533 and to the Director of the Office of Research Development and Administration, SIUC - 618-453-4531.

Project Title:

Researcher(s) or Project Director(s)

Date

Please print or type name below signature.

Researcher's Advisor (required for all student projects)

Date

Please print or type name below signature.

The request submitted by the above-named researcher(s) was approved by the SIUC Human Subjects Committee.

This approval is valid for one year from the approval date. Researchers must request an extension to continue the research after that date. This approval form must be included in all Master's theses/research papers and Doctoral dissertations involving human subjects that are submitted to the Graduate School.

Chairperson, Southern Illinois University Human Subjects Committee

Date

FORM B-1

Please type all information or print neatly, using **black** ink.

STUDY IS PART OF: Thesis/Research Paper_____ Dissertation_____ Faculty Research_____
Undergraduate Project_____ Pilot Study _____ Other_____

Will this study be funded by a grant? Yes No If yes, indicate name of funding agency below.

NAME

Last

First

Middle Initial

Phone number

MAILING ADDRESS

Street

Apt/Unit #

City

State

Zip

E-mail Address

PROJECT

TITLE

ADVISOR 'S NAME (for student projects)

OR CO-RESEARCHER(S) NAME(S)

DEPARTMENT

PHONE

Estimate the following:

▶Average time required for an individual subject's participation. _____ (min/hrs per days/weeks)

▶Number of volunteers(subjects) to be involved in the study. _____

▶Approximate date when research subjects will be contacted. _____

(must be after anticipated approval date; allow at least two weeks following submission of application)

▶Approximate ending date for involvement of research subjects. _____

Will any subject be audio or videotaped? Yes No

FORM B-2

SCREENING QUESTIONS

The following questions are designed to help you and the HSC determine the review level category of your project. Please circle the appropriate answer to all questions.

- | | | | |
|----|--|-----|----|
| 1. | Is this research designed to study normal educational practices <u>and</u> is this research being conducted in an established educational setting? | YES | NO |
| 2. | Does this research consist solely of giving published/standardized tests (Cognitive, diagnostic, aptitude, achievement, attitudes, personality, etc.)? | YES | NO |
| 3. | Does this research involve the collection or study of existing data, documents, records, pathological or diagnostic specimens where : | | |
| | a. the sources are publicly available | YES | NO |
| | b. the existing data are recorded in such a manner that the subject will remain anonymous? | YES | NO |
| 4. | Does the research: | | |
| | a. allow subjects to remain anonymous? | YES | NO |
| | b. ensure that subjects' participation will not lead to criminal or civil liability or damage to their financial standing, employability, or reputation? | YES | NO |
| | c. involve respondents who are elected or appointed officials? | YES | NO |

If you answered “yes” to any of the questions 1 through 4, your research probably falls under Category I review. Complete the following questions.

- | | | | |
|----|--|-----|----|
| 5. | Does this study involve deception (i.e., giving false or misleading information to subjects or withholding information)? | YES | NO |
| 6. | Will the procedures cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, or threat to the dignity of subjects, or be otherwise potentially harmful to subjects? | YES | NO |
| 7. | If the project will <u>NOT</u> be conducted in an established educational setting, is it specifically designed to involve subjects listed below? | N/A | |
| | a. Minors (less than 18 years of age)? | YES | NO |
| | b. Prisoners? | YES | NO |
| | c. Mentally retarded persons? | YES | NO |
| | d. Mentally disabled persons (neurological, psychiatric, or related disability that may diminish mental capacity)? | YES | NO |
| | e. Persons in a residential program (e.g., hospital, developmental center, group home, etc.)? | YES | NO |
| | f. Clients of service units (e.g., counseling center, clinic, etc.)? | YES | NO |

If you answered “no” to all the questions 5 through 7, your research protocol falls under Category I review. Complete Form C.

If you answered “yes” to any of the questions 5 through 7, your research protocol falls under Category II or III review. Complete Form D.

FORM C — CATEGORY I REVIEW

The following questions pertain to potential risks to subjects. For responses that require an explanation, please use the reverse side of this page. Cite the question number and explain how you will minimize risk to the subjects.

1. What is the purpose of the study?

2. Describe your potential subject pool.

3. How will you recruit subjects?

4. If subjects will not be identified from public sources, will signed approval to recruit subjects, conduct the study, or use existing data be obtained from the designated authority prior to conducting the research? N/A YES NO
Explain

5. Is there a pre-existing professional relationship between the researcher and subject (e.g., teacher-student, counselor-client)? YES NO
If “yes” explain the nature of the relationship and how you will arrange to have a third party solicit their participation in your study.

6. If research will be conducted in a classroom or service delivery setting, will it require any activity that is not part of the normal class or service delivery? N/A YES NO
Explain

7. Will a consent form or a cover letter be provided to participants? YES NO
Explain

8. If subjects are minors, will parental consent be obtained for participation? N/A YES NO
Explain

9. Will subjects be told that participation is voluntary and they are free to withdraw at any time? YES NO
Explain

10. Will subjects receive compensation for participating in the research (e.g., money, extra credit toward grades) YES NO
Explain

11. If extra course credit will be given, will students who choose not to participate in the research have alternative opportunities to earn credit? N/A YES NO
Explain

12. Will the data be recorded in such a way that the individual subjects cannot be linked to the data? YES NO
Explain

13. At the completion of the study, will you destroy or erase any materials (e.g., data sheets, audio/video tapes) that identify individual subjects? N/A YES NO
Explain

FORM C continued

14.(Note: This question **MUST** be completed.) Describe procedures **IN DETAIL**. Include exactly what will be done with the subjects and what measurements will be taken. Provide **THREE (3)** copies of any material that will be used during the research study (e.g., recruitment scripts, consent forms, cover letters, questionnaires, interview protocols, surveys, etc). Each participant **must** be provided with a cover letter or consent form that explains the study. See page 8 for required elements of cover letters and consent forms.

Use the space below to provide an explanation for any of the questions 4-13. Indicate the appropriate question number with the explanation.

FORM D

FOR CATEGORY II OR III REVIEW

Please provide (on additional pages) the information requested below. Refer to the same Roman numerals and capitalized key words as used in the outline below. Your responses should be concise and, insofar as possible, be in non-technical language. Items that do not apply to your research should be designated “N/A” for “Not Applicable.” Do not submit more than five (5) additional pages, excluding attachments. Do not send copies of a prospectus.

- I. **PURPOSE:** Describe the general purpose of the study.
- II. **INFORMATION ABOUT POTENTIAL SUBJECTS:**
- A. Describe your **POTENTIAL SUBJECT POOL.**
- B. **IDENTIFICATION:** Describe specifically how potential subjects’ names will be obtained (e.g., from what membership lists, class lists, telephone books, etc.) and how you will have access to these lists. Include three (3) copies of any advertisement(s) to be used.
- C. **EXPECTED GROUP(S)** (control, experimental, etc.): Describe the groups that will be used and the anticipated number of subjects in each.
- D. **RECRUITMENT:**
1. How will subjects be recruited once they are identified (by mail, phone, classroom presentation, personal contacts, etc.?)
 2. Who will recruit them (researcher, third party, clinic secretary, etc.)?
 3. If you are associated with the subjects (e.g., your students, employees, clients, patients), explain the nature of the association and how you will arrange to have a third party solicit their participation in your study.
- E. **INCLUSION CRITERIA:** Outline what determines your choice of subjects, justifying the involvement of any special populations. If the project will involve another institution or business, you must obtain letters of permission or cooperation—on the institution’s letterhead—to use their facilities and interact with personnel there.
- III. **LOCATION OF RESEARCH:** Exactly where will research be conducted (e.g., Lawson 121, subject’s home, via mail, etc.)?
- IV. **CONFIDENTIALITY:** How will data be recorded to ensure anonymity/confidentiality of subjects (e.g., substituting numbers for names, keeping data in locked files, not identifying individuals in reports, etc.)?
NOTE: If you assign a number, it must not include the Social Security number.
- A. Will you keep a sheet that will match the random number with any identifying type of information? If you will, the code listing and data must be kept in separate and secure locations.
- B. Will you destroy the code list upon completion of the study?
- C. Who will have access to the code list and the gathered data? Include this information in the cover letter/consent form.

FORM D continued

NOTE: You cannot guarantee confidentiality. Use a statement such as “We will take all reasonable steps to protect your identify” or “The confidentiality of the records will be maintained within legal limits.” Do not confuse confidentiality with anonymity. Anonymity applies only when subjects’ identities cannot be known.

V. **FOLLOW-UP:** Is a subject follow-up anticipated? If it is, state for what reason and include this information in the cover letter/consent form. Attach three (3) copies of all materials used in the follow-up.

VI. **METHODOLOGY:**

A. Describe any form of **COMPENSATION** to subjects (e.g., money, grade, extra credit, etc. If extra credit or grade is given to subjects who participate in the project, what alternative opportunity for extra credit or grade is provided to students who choose not to participate?) **Please note:** For multi-phase projects, compensation should not be contingent upon completion of the whole project. Rather, some compensation should be given for each phase of the project. This information must be included in the consent form.

B. What do you **INTEND** to do with the data collected (e.g., publish data, present paper, erase audio or video tapes of subjects after completion of data analyses and publication, etc.)?

C. Describe the **ROLE OF SUBJECTS**, including what they will be asked to do, the amount of time the subject will be involved in the study (in minutes/hours per days/per week), etc.

D. Describe all **MEASUREMENTS/ PROCEDURES**. Attach three (3) copies of any questionnaires, measurement instruments, and interview protocols to be used. Describe exactly what will happen to study participants, including why you are conducting the study. Will the test results be disseminated to the subjects (and/or their parents or guardians)? If so, explain the qualifications of the person(s) interpreting the results.

E. Describe any type of **ELECTRICAL EQUIPMENT** that will be connected to the subjects. Attach a signed and dated letter from the individual who checked the equipment for electrical safety. The letter must include the person’s name and qualifications and the types and results of the safety checks performed.

F. If the project involves **AUDIO/VIDEO TAPING**, provide an explanation of the need for taping, the location where tape(s) will be stored, the specific intended uses of the tape(s), the person(s) who will have access to the tape(s), and when or if tape(s) will be erased.

If audio/video taping is an essential component of the study, the information should be in the consent form, and a **SEPARATE** permission line for the subject to sign should be included that indicates permission to audio/video tape. The same procedures should be followed if you are requesting permission to quote the individual in your final report.

G. If the project involves procedures that are considered to be **MORE THAN MINIMAL RISK** (e.g., obtaining blood samples, information on sensitive issues such as illegal drug use, treatment involving drugs, psychological manipulation, more than moderate exercise, etc.), describe these procedures in detail, including the qualifications/certification of the person(s) who are administering/assisting with the data collection.

FORM D continued

- VII. **Consent:** Describe how consent will be obtained (i.e., how, where, and when the study will be explained to the subjects) and how subjects will indicate their consent. If your subject pool includes special populations who lack the capacity to give valid/legal consent, a substitute consent form should be provided. A copy of the consent form or, in the case of a mailed survey, a cover letter explaining the project, must be offered to each subject. If you are requesting a waiver of the written/signed consent, describe the alternative method you plan to use to obtain consent.
- VIII. **EXISTING DATA:** If you are using existing/secondary data, describe how you have obtained permission to access this data and include a letter from an authorized individual stating that you have permission to access this data. If the subject's personal files (school, medical, etc.) will be read, where are the files kept and who will gather the information? Has permission been obtained to gather this information? Do the subjects (and/or their parents or guardians) know that these files will be read? If not, explain.
- IX. **RISK ASSESSMENT:**
- A. Describe any **RISKS TO THE SUBJECT** that might arise from participation in the study. Subjects should be protected against injury and invasion of their privacy, and their dignity should be preserved. Risks fall under the following categories: physical, psychological, social, economic, legal, and other. Please assess the risks involved in this research.
 - B. When visual or auditory stimuli, chemical substances, or other measures might affect the health of subjects, a **STATEMENT FROM A PERSON QUALIFIED TO EVALUATE RISKS FOR SUCH CONDITIONS** will be required by the Human Subjects Committee.
 - C. Describe **STEPS** you will take **TO MINIMIZE RISK**, as well as **PROTECT SUBJECTS' RIGHTS, WELFARE, AND PRIVACY**, including how subjects will be informed of the risks to which they will be subjected.
- X. **ATTACH A COPY OF EXACTLY WHAT THE SUBJECTS WILL BE TOLD/READ PRIOR TO INVOLVEMENT IN THE STUDY (i.e., verbal script, handout, etc.).**
- XI. **ATTACH CONSENT FORM.** If project involves minors, attach parental consent form.
- XII. **ATTACH COVER LETTER** to be sent to prospective subjects – if needed for subject recruitment.
- XIII. **ATTACH SEPARATE CHILDREN'S ASSENT FORM** – if project involves minors.
- IX. **ATTACH DEBRIEFING STATEMENT** – if project involves deception. Also describe the nature of the deception, why it is necessary, and how subjects will be debriefed. Include any feedback—educational or otherwise—which subjects will receive.

**BASIC REQUIRED ELEMENTS OF THE COVER LETTER
AND/OR CONSENT FORMS**

/

To facilitate review of your application, be sure to include all the following elements in your cover letter/consent form/instructions to the subjects/phone script.

- _____ 1. A statement regarding your affiliation with Southern Illinois University at Carbondale.
- _____ 2. A statement that the study involves research and an explanation of the purpose of the research in terms the potential subjects can readily understand.
- _____ 3. A description of the procedures to be followed and approximately how long participation in the study will take.
- _____ 4. A brief statement of the criteria for subject selection.
- _____ 5. A statement concerning the voluntary nature of the study or a statement such as, "Completion and return of this survey indicates voluntary consent to participate in this study."
- _____ 6. A statement describing the extent, if any, to which confidentiality of records that identify the subject will be maintained and the precise means of maintaining confidentiality. The confidentiality statement should incorporate all of the following items that apply to your project:
 - _____ a. If a coding system will be used, you need to describe it and explain the purpose for keeping the list of subjects' names.
 - _____ b. If you will keep a sheet that matches the random number with any identifying information, state that the code listing and the data will be kept in separate and secure locations.
 - _____ c. State who will have access to the code list and the gathered data.
 - _____ d. State what will happen to the code list upon completion of the study (i.e., whether it will be destroyed. If not, how will it be kept secure?)
 - _____ e. Include a statement such as "The confidentiality of the records will be maintained within legal limits" or "We will take all reasonable steps to protect your identity."
- _____ 7. A statement of whom to contact for answers to questions about the research. **Students must include the name, title, address, and telephone number of the faculty member who is supervising the project, as well as their own.**
- _____ 8. **The Human Subjects Committee approval statement:** "This project has been reviewed and approved by the SIUC Human Subjects Committee. Questions concerning your rights as a participant in this research may be addressed to the Committee Chairperson, Office of Research Development and Administration, Southern Illinois University, Carbondale, IL 62901-4709. Phone (618) 453-4533."

REQUIRED ELEMENTS continued

IF YOUR RESEARCH INCLUDES CHILDREN OR AUDIO/VIDEO TAPING, REFER TO #9 AND #10 BELOW.

- _____ 9. **If children are to participate in the research**, provide both a consent form for the parent to read and sign and an appropriately phrased assent form for the child.
- _____ 10. **If participants are to be audio/videotaped**, include a statement describing the recording procedures.
& Indicate how confidentiality will be maintained and what will happen to the tapes upon completion of the study. **&** Also include a statement similar to: "I agree to participate in this activity and know that my responses will be recorded on audio/video tape." **&** Each participant must sign the consent form, indicating their approval for the audio/videotaping. **&** If taping is planned in a group setting, the consent of all members of the group must be obtained for taping to take place.

THE FOLLOWING ADDITIONAL ELEMENTS MAY BE REQUIRED FOR RESEARCH WHICH FALLS UNDER THE **CATEGORY II OR III** REVIEW CRITERIA. TO DETERMINE IF YOUR PROPOSAL SHOULD INCLUDE ANY OF THESE ELEMENTS, COMPLETE FORM B OF THE APPLICATION.

- _____ 11. All Category II and III research require that the subject sign the consent form, and all consent forms should include a statement similar to: "I have read the material above, and any questions I asked have been answered to my satisfaction. I understand a copy of this form will be made available to me for the relevant information and phone numbers. I realize that I may withdraw without prejudice at any time."
- _____ 12. A statement of any foreseeable risks or discomforts to the subject or a statement that the risks are minimal.
- _____ 13. A description of any benefits to the subject or to others which may reasonably be expected from participation in the research.
- _____ 14. For projects which may involve physical risk to the subject, include:
- _____ a. The following paragraph, verbatim: "The Department of Health and Human Services requires that you be advised as to the availability of medical treatment if a physical injury should result from research procedures. No special medical arrangements have been made regarding your participation in this project. If you are a registered student at SIUC, you are eligible to receive medical treatment at University Health Service. If you are not a registered student at the university, immediate medical treatment is available at usual and customary fees at Carbondale Memorial Hospital. In the event you believe you have suffered any injury as a result of participating in the research program, please contact the Chairperson of the Human Subjects Committee, who will review the matter with you." Phone (618) 453-4533."
- _____ b. A statement that a medical questionnaire must be completed and that subjects may be excluded from participation based on their responses.
- _____ c. If blood is to be withdrawn, include a statement indicating the amount of blood to be withdrawn and potential complications, including possible bruising, inflammation, and infection at the site of the puncture. Name the individual who will withdraw the blood, state his/her qualifications, and assure subjects that care will be taken to avoid any complications.