APPLICATION FOR APPROVAL TO CONDUCT RESEARCH INVOLVING HUMAN SUBJECTS

SOUTHERN ILLINOIS UNIVERSITY CARBONDALE HUMAN SUBJECTS COMMITTEE

University and federal policy (e.g., 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, staff, and student research, including that 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 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 if all necessary information is provided by the researcher. Additional reviews are required for Category II (expedited) and Category III (fully convened IRB) proposals.

Attached to this cover sheet are the following forms:

Form A:	Approval Page	Form C:	For Category I (exempt) Review
Form B:	Screening Questions	Form D:	For Category II or III (non exempt) 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). Please include copies of tests that you plan to use that ask sensitive questions of a personal nature, such as illegal behavior, sexual behavior, illness, disease, and disability. These questions typically would be found on personality, attitude, behavior and health inventory and similar tests. Tests that generally do not involve sensitive questions, such as cognitive, vocational, career, speech and language, and educational tests do not have to be submitted. 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. All Category II and III research also require that key personnel complete appropriate training prior to application approval. These are persons who obtain consent, collect data or have access to the data.

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 Sponsored Projects Administration
Woody Hall C214
Southern Illinois University Carbondale
Carbondale, IL 62901-4709
Ph. 618-453-4533 Fax 618-453-8038
http://ospa.siu.edu/compliance/human-subjects

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 Sponsored Projects Administration, SIUC.
   Phone 618-453-4531. E-mail: **siuhsc@siu.edu**

Project Title
Core Alcohol & Drug Survey

RESEARCH ADVISOR'S ASSURANCE: My signature on this application certifies that the student is knowledgeable about the regulations and policies governing research with human subjects. I am aware of my obligations stated on Form A and will be available to supervise the research. When on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence. I will advise the Human Subjects Committee by letter of such arrangements**.**

Researcher(s) or Project Director(s) Chad Briggs, M.A., Laura Rowald, Ph.D., Ed Pimentel, M.S. Date: 11/6/15
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 review date. Unless the protocol is approved as Category I (exempt), 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/Dissertaton ☐ Student Project ☐ Faculty Research ☐ Other ☒ SIU Student Health Center & Core Institute Project

Undergraduate Project that does not fit the exemptions for course-related projects. See the Guide for Researchers 7.3 for more information ☐ (If project is a student learning experience, the HSC does not review it.)

IS THIS STUDY GRANT FUNDED? ☒ No ☐ Yes

If yes, funding source _____

Grant Proposal or BP #

Include the narrative section from the proposal that describes the human subjects research. Mark ☐ No ☐ Yes if this section is attached to this application.

PROJECT TITLE Core Alcohol & Drug Survey

PRINCIPAL INVESTIGATOR

Last	First	Department
Briggs	Chad	Student Health Center

Street	Phone Number
374 E Grand Ave	618-453-4204

City	State	Zip	E-mail Address
Carbondale	IL	62901-6740	briggs@siu.edu

*
All Key Personnel and training completion record if required.

Name	Role on Project	Training completion date and tutorial (CITI or NIH)	
Jane Doe	PI	6/22/2011	NIH
Laura Rowald	Co-PI		
Ed Pimentel	Co-PI		

*Key personnel are any individuals considered engaged in research. Examples include obtaining consent, obtaining or recording private behavior, analyzing identifiable data, etc. Any changes in personnel during the project require written notification to the Human Subjects Office.

Are any of the above listed personnel not affiliated with SIUC as either paid staff or student?
☐ Yes ☒ No If yes, please list these personnel above and their non-affiliation under "Role on Project" column.

POTENTIAL CONFLICT OF INTEREST: Do any investigators or key personnel in this research now have, or expect to have during the term of the project, any financial interest in a business entity that could reasonably be expected to bias the activities described in this application, or that could create a perception of bias on the part of the investigators? NO ☒ YES ☐ If yes, please describe the business entity and explain the relationship in an attached statement.

Estimate the following:

<Average time required for an individual subject's participation. 15-20 minutes (min/hrs per days/weeks)

<Number of subjects to be involved in the study. 1,000

<Approximate date when research subjects will be contacted. October 2013

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

<Approximate ending date for involvement of research subjects. December 2013

Will any subject be audio or videotaped?	☐Yes ☒No
(If yes, see page 9 for special requirements.) **Are you planning to solicit subjects for participation by email? (If yes, see page 9 for special requirements.)**	☒Yes ☐No
Will you access subjects' protected health information? (If yes, see page 9 for special requirements.)	☐Yes ☒No
Will a Certificate of Confidentiality be used?	☐Yes ☒No
Will a Data Safety Monitoring Board be used?	☐Yes ☒No
Will non-English be used in either the consent or data collection process? **(If yes, include both language versions. Include a letter which verifies the accurate translation from an unbiased individual with expertise in the native language.)**	☐Yes ☒No
If you are a graduate student, has your faculty committee approved your project's methodology? (If no, please do not submit your application until they have approved it.)	☐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 typical educational practices (e.g., instruction, classroom management)? ☐Yes ☒No

   If so, will the research be conducted in an established educational setting? ☐Yes ☐No

2. Does this research consist solely of giving published/standardized tests, survey or interview procedures, or observation of public behavior? ☒Yes ☐No

3. Will the subjects be anonymous? (i.e., if the investigator receives names of participants on consent forms, involves interviews, or can link a number with a name, one can only guarantee confidentiality.) ☐Yes ☒No

4. If information about subjects is disclosed, including personal characteristics and other information gathered during research, can you ensure that they will not be at risk for damage to their financial standing, employability, or reputation? ☒Yes ☐No

5. Does this research involve the collection or study of existing data, documents, records, pathological or diagnostic specimens where :

   a. their sources are publicly available? ☐Yes ☒No

   b. the data cannot be linked to identifiable subjects? ☐Yes ☒No

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6. Does this study involve deception (i.e., withholding from or giving false or misleading information to subjects)? ☐Yes ☒No

7. Will procedures cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, threaten the dignity, or otherwise potentially harm subjects? ☐Yes ☒No

8. Will subjects be interviewed for an oral history or in a focus group setting? ☐Yes ☒No

9. Are subjects from any of the categories listed below?

   a. Minors (less than 18 years of age) ☐Yes ☒No
   b. Prisoners or persons who are under criminal sanctions ☐Yes ☒No
   c. Persons with diminished mental capacity (e.g., mental retardation, neurological, psychiatric, or related disability) ☐Yes ☒No
   d. Persons in a residential program (e.g., hospital, developmental center, group home, etc.) ☐Yes ☒No
   e. Clients of a human service program (e.g., counseling center, clinic, etc.) ☐Yes ☒No

If you answered "yes" to any of the questions 1 through 5 and "no" to all the questions 6 through 8, complete Form C for Category I review.

If you answered "yes" to any of the questions 6 through 9, complete Form D for Category II or III review.

FORM C — CATEGORY I EXEMPT REVIEW

The following questions pertain to potential risks to subjects.

1. State the purpose of the study.

The Core Alcohol and Drug Survey will quantify and document college students' attitudes, perceptions and behaviors regarding alcohol and other drug use (AOD), as well as measure the self-reported consequences of AOD use. This information will be used to evaluate the effectiveness of current prevention and intervention activities, and to improve such programs for students on the SIU campus. Composite data will be assessed to determine the most effective way for the university to utilize resources for prevention and treatment. Additionally, the data will be included along with other participating Illinois two- and four-year college campuses in aggregated form to the Illinois Higher Education Center for Alcohol, Other Drug and Violence Prevention and the Illinois Department of Human Services to help in fund-seeking, program development, resource allocation and assessment.

2. Describe your potential subject pool.

A random sample of half of all Carbondale-area students, age 18 or older, enrolled at SIU for the fall semester will comprise the participant pool.

3. How will you recruit subjects?

Potential participants will be contacted via E-mail with an invitation and link to the web-survey. A total of four e-mail contacts will be made, each providing an opportunity for students to opt-out of future contacts.

4. Where is the location of the research? (e.g., Lawson 121, subject's home, via mail)

The survey is provided, housed and made secure by the Core Institute, which is part of the Student Health Center at SIU (http://core.siu.edu/).

5. 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

6. Is there is a pre-existing dual relationship between the researcher and subject (e.g., teacher-student, counselor-client)? ..... ☐Yes ☒No
Explain

If "yes," explain the nature of the relationship and how you will arrange to have a third party solicit subjects' participation in your study.

7. If research will be conducted with students in their classroom or clients in their human service delivery setting, will it require any activity that is not part of the normal class or service delivery? ..... ☒N/A ☐Yes ☐No
Explain

8. Will a consent form or a cover letter be provided to participants? ..... ☒Yes ☐No
Explain

9. If subjects are minors, will parental consent be obtained for participation? ..... ☒N/A ☐Yes ☐No
Explain

10. Will subjects be told that participation is voluntary and they are free to withdraw **at any time?** ☒Yes ☐No
Explain

11. Will subjects receive compensation for participating in the research (e.g., money, extra credit toward grades)? ..... ☒Yes ☐No
Explain

12. 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

13. Will the data be recorded in such a way that the individual subjects cannot be **linked to the data?** ..... ☐Yes ☒No
Explain

14. 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

15. (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 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. (Description may be on separate page, if necessary.)

A request will be made of the Office of Institutional Research for a randomly selected list of half of all students, age 18 or older, who are enrolled during the fall semester. The list of students will include their Dawg Tag numbers, e-mail addresses and demographic information (i.e., gender, age, race/ethnicity, year-in-school, first-generation student status). Once the list is obtained, a random ID number will be generated for each student. The random IDs, e-mail addresses and students' first names will then be separated from the rest of the students' records, and will be uploaded to the Core Institute's survey administration site, along with the text for the consent form and e-mail cover letters.

After these data have been uploaded, the Core Institute will then disseminate the cover letters (with an embedded survey link) via e-mail. A total of four e-mail survey invitations will be sent out (approximately 3 to 5 days apart) to the participant pool. Each invitation will be personalized (with "Dear [student's first name]), and will highlight the purpose of the survey along with the incentives for participating. An opportunity to opt-out of future e-mail contacts will also be included with each letter.

Students that access the survey via the embedded URL will be taken directly to the consent form. At the bottom of the consent form, the following text will appear: "If you agree to participate in the survey, please click on the 'Go to next question' button below to begin." At the conclusion of the survey, respondents will be able to designate a $1 contribution to one of the following charities: (1) Cardinal Glennon Memorial Children's Hospital; (2) Green Earth; (3) NAACP (National Association for the Advancement of Colored People); (4) SIU Student Food Bank; and, (5) St. Francis Community Animal Rescue. All of the survey data will be protected by a secure, encrypted server.

Once the survey has been closed, the survey responses, along with the original data that were uploaded (i.e., random ID numbers, e-mail addresses and first names) will be downloaded, and joined with the original data file provided by Institutional Research. Once the data have been merged, students' identifying information (names and Dawg Tag numbers) will again be separated from the rest of the data, and will be stored in a separate and secure location.

At the conclusion of each academic year, the Dawg Tag numbers of the participating students will be sent to Institutional Research along with a request for GPA and retention data. Once obtained, these data points will be merged with the participants' survey responses for analysis. After merging the new data, the Dawg Tag numbers will once again be separated and stored in a separate and secure location. These procedures ensure that only the principal investigators will have access to both the survey data and the academic success outcome data.

Institutional Research follows students' retention records for six years. To remain consistent with the overall reporting procedures for the university, we will gather academic outcome data for a period of six years. At the conclusion of this six-year period, the respondent's identifying information will be destroyed.

Use the space below to provide an explanation for any of the questions 5-14. Indicate the appropriate question number with the explanation. (Use separate pages, if necessary.)

11. As incentive for participating in the study, $1 will be donated to a charity of the participant's choice. Five charity options will be provided: (1) Cardinal Glennon Memorial Children's Hospital; (2) Green Earth; (3) NAACP (National Association for the Advancement of Colored People); (4) SIU Student Food Bank; and, (5) St. Francis Community Animal Rescue.

13. Student Dawgtag numbers will be obtained, along with their e-mail addresses and demographic information (gender, age, race/ethnicity, year-in-school, first-generation student status) prior to sending the survey. These data will then be linked to participants' survey responses so that demographic trends can be examined. In addition, GPA and retention data will be linked to the survey responses at the end of each academic year so that linkages between student survey responses and student success outcomes can be assessed.

14. Given that we are interested in assessing the linkages between participant survey responses to future academic outcomes, identifying information will not be destroyed immediately. Institutional Research follows students' retention records for six years. To remain consistent with the overall reporting procedures for the university, we will gather academic outcome data for a period of six years. At the conclusion of this six-year period, the respondent's identifying information will be destroyed.

FORM D

FOR CATEGORY II OR III NON EXEMPT 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 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. If subjects will not be identified from public sources, you should get signed approval from the designated authority to recruit subjects, conduct the study, or use existing data prior to conducting the research. Include 3 copies of any advertisement(s) to be used.

C. **RECRUITMENT:**

1. After subjects are identified, how will they be recruited (i.e., by mail, phone, classroom presentation, personal contacts, etc.)?
2. Who will recruit subjects (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.

D. **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. The letter must be sent to the Human Subjects Committee prior to beginning your study.

III. LOCATION OF RESEARCH: Exactly where will research be conducted (e.g., Lawson 121, subject's home, via mail, etc.)? 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 ?

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 be 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.

NOTE: You cannot guarantee confidentiality. Use a statement such as "We will take all reasonable steps to protect your identity. 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 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?)

B. What do you **INTEND** to do with the data collected (e.g., publish data, present paper)

C. Describe what **SUBJECTS** will be asked to do.

D. Describe all **MEASUREMENTS/ PROCEDURES**. Attach 3 copies of any questionnaires, measurement instruments, and interview protocols to be used. Describe the procedures that the researcher will use with the subjects. If you have more than one group in the study, how many subjects will be in each group? Will any group receive less than standard practice? 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.

You should include a sentence at the end of the consent form that reminds subjects that their signatures give the researcher permission to audio/video tape the research sessions. If you want to quote subjects in your report, include a sentence at the end of the consent form requesting permission to attribute quotes to them. Subjects must be given the right to agree or to refuse to be quoted.

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.

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 for guardians. 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 these data and include a letter from an authorized individual stating that you have permission to access these 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.

XIV. 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–that 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, or phone script.

1. A statement explaining 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. **NOTE:** If you assign a number, it must **not** be the Social Security number.

    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 "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 information.**

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 Sponsored Projects Administration, Southern Illinois University, Carbondale, IL 62901-4709. Phone (618) 453-4533. E-mail siuhsc@siu.edu"

SEE FORMATTING SUGGESTION BELOW:

- Place the HSC statement at the very bottom of the cover letter/consent form.
- You may use a smaller font than used in the rest of the document.
- Do not combine this statement with researcher or advisor contact information.

More Required Elements next page

Required Elements continued

9. **If children will 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 subjects will be audio/videotaped**:

    a. Include a statement describing the recording procedures.

    b. Indicate how confidentiality will be maintained and what will happen to the tapes upon completion of the study.

    c. Include a statement similar to: "I agree to participate in this activity and know that my responses will be recorded on audio/video tape." If you want to quote subjects in your report, include a sentence at the end of the consent form requesting permission to attribute quotes to them. Subjects must be given the right to agree or to refuse to be quoted. For example: "I agree ___I disagree___that Dr. XXX may quote me in her paper."

    d. Each subject must sign the consent form, indicating approval for the taping.

    e. If taping is planned in a group setting, the consent of all members of the group must be obtained for taping to take place.

    f. Describe how the tapes will be stored, who will be allowed to hear/view the tapes, and when the tapes will be erased.

    g. If the tapes will **not** be erased:
    - Get the subjects' written permission to keep the tapes.
    - State where the tapes will be kept.
    - State who will hear/view the tapes.
    - State how the tapes will be used in the future (e.g., future research, valuable historical data).

11. **If an e-mail solicitation of subjects will be used**, add the following information:
    a. The "from line" should be the researcher's name.
    b. The "subject line" should be "Research Request".
    c. The message should state at the outset where the e-mail addresses were obtained.
    d. Include **either** a statement saying there will be no future e-mails **or** an opt-out message that permits addressees to have their names removed from any future mailings.
    e. **If** you plan future e-mails, add the statement, "If you do not respond to this survey or return the opt-out message, you will be contacted again with this request X times during the next X weeks."
    f. The HSC's e-mail address (siuhsc@siu.edu) after our phone number in the last sentence of the HSC approval statement.
    g. Use a blind copy format so that the list of recipients will not appear in the header.

12. **If research involves using focus groups** the following language should be included in the consent form:

"All reports based on this research and written by the researcher will maintain the confidentiality of individuals in the group. Only group data will be reported and no names will be used. Since a focus group involves a group process, all members of the group will be privy to the discussions that occur during the session; therefore, absolute confidentiality on the part of the participants, themselves, may be difficult to ensure."

13. If you plan to access subjects' **private health information,** recent federal law has changed the procedures for releasing health records. Our website ospa.siu.edu/human/ has information about the Health Insurance Portability and Accountability Act (HIPAA). However, you should contact the agency that has the health records and ask them what procedures they require before they will release subjects' private health information.

The following elements may also be required for research that falls under the Category II or III review criteria.

1. 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."

2. A statement of any **foreseeable risks or discomforts** to the subject or a statement that the risks are minimal.

3. A **description of any benefits** to the subject or to others which may reasonably be expected from participation in the research.

4. For projects that 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. The researchers do not have funds specifically dedicated to compensate you for any adverse effects that you may experience by participating in this research. Nevertheless, you retain all your legal rights to seek compensation in the event of injury or other adverse event. If you are a registered student at SIUC, you are eligible to receive medical treatment at SIUC Student Health Center. If you are not a registered student at the university, immediate medical treatment is available at usual and customary fees at Memorial Hospital of Carbondale.***** 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."

      *****(Note that the name of the hospital or other health care facility should be appropriate to the location where the study will be conducted.)

   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.