SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

Institutional Review Board

APPLICATION TO CONDUCT RESEARCH INVOLVING HUMAN SUBJECTS

Purpose of this form:

- University policy requires review of **ALL** research activities involving human subjects by the Institutional Review Board (IRB) **PRIOR** to the involvement of subjects.
- SIUC chooses to apply the federal regulations governing research with human subjects to all research conducted by SIUC-affiliated personnel involving human participants.
- This applies to all faculty, staff, and student research.

Compliance:

- **ONLY the IRB** can determine the review requirements for any particular research activity.
- Failure to obtain IRB review for human research activities violates federal and/or University policy and could result in a loss of grant funding, inability to present or publish, or rejection of research paper/thesis/dissertation by the Graduate School.
- **The IRB cannot review protocols for projects for which data collection has already begun.**

Review:

- Applications are given an initial review in the order they are received.
- The IRB will not review applications until all required documents are received and complete.
- Additional review time is required for applications categorized as Non-Exempt.
- Please contact the IRB at siuhsc@siu.edu with questions about your application status or assistance.

Submission Checklist:

I. Complete all applicable sections of this application

- ☐ Form A: Assurances and Approval, **AND**
- ☐ Form B1: Project Information, **AND**
- ☐ Form B2: Review Screening Questions, **AND**
- ☐ Form C: Category I (Exempt) Protocol, **OR**
- ☐ Form D: Category II/III (Non-Exempt) Protocol **OR**
- ☐ Form E: Existing Data Protocol

II. Attach all study materials, including but not limited to:

☐ Consent Forms ☐ Recruitment Letters ☐ Surveys ☐ Instruments

☐ Fliers/Social Media Posts/SONA Study Descriptions/MTurk HIT Descriptions

☐ Agency Permission Letter ☐ Translation Verification Letter

III. ☐ Save the complete application using the format: "**LastName MMDDYY IRB app"**

IV. ☐ If necessary, save supporting documents using the format: "**LastName MMDDYY IRB docs"**

V. ☐ Submit completed documents to: siuhsc@siu.edu

ROLES AND RESPONSIBILITIES

I. Principal Investigator (PI) – Faculty/Staff
1. Act as PI and accept responsibility for the research described.
2. Prepare and ensure all IRB application materials are complete and accurate, including completion of required training (CITI: *Social & Behavioral Research – Basic/Refresher*).
3. Obtain IRB review/approval prior to the initiation of any research activities involving human subjects.
4. Respond to all requests for revisions from the IRB in order to obtain application approval.
5. Ensure timely notification to the IRB of any proposed changes to an approved protocol and obtain proper approvals prior to their implementation.
6. Adhere to requirements of the IRB and Federal regulations for continuing review of approved research activities and report unanticipated problems or adverse events to the IRB.
II. Principal Investigator (PI) – Student
1. Act as PI and accept responsibility for the research described.
2. Prepare and ensure all IRB application materials are complete and accurate, including completion of required training (CITI: *Social & Behavioral Research – Basic/Refresher*).
3. Obtain IRB review/approval prior to the initiation of any research activities involving human subjects.
4. Respond to all requests for revisions from the IRB in order to obtain application approval.
5. Ensure timely notification to the IRB of any proposed changes to an approved protocol and obtain proper approvals prior to their implementation.
6. Adhere to requirements of the IRB and Federal regulations for continuing review of approved research activities and report unanticipated problems or adverse events to the IRB.
7. Meet with Co-PI regularly to report research progress.
III. Faculty Advisor/Sponsor (Co-PI)
1. Act as Co-PI and accept responsibility for the research described.
2. Actively mentor the PI in preparation of the IRB application materials, including proofreading prior to submission.
3. Accept responsibility for the planning and conduct of students' research activities. Assist in methodological development, assess scientific merit, and evaluate risks to subjects.
4. Maintain active communication with PI and IRB during the application approval process. Assist with meeting board requirements to obtain approval.
5. Oversee and ensure student researchers are trained and knowledgeable the ethical considerations outlined in Federal regulations, state and local law, and University policies relevant to human subjects research.
6. Supervise the student throughout the conduct of the research to ensure it is conducted according to an IRB approved protocol.
7. Meet with PI regularly to monitor research progress.
8. Complete required training (CITI: *Social & Behavioral Research – Basic/Refresher*).
9. When on sabbatical leave or vacation, arrange for an alternate faculty sponsor to assume responsibility during absence. Advise the Institutional Review Board by letter of such arrangements.

FORM A
ASSURANCES

Project Title

☐ This is a STUDENT research project:

Principal Investigator:		School	
Faculty Advisor (Co-PI)		School	

As the Principal Investigator named above, by signing and submitting this application, I attest that I have reviewed the study and this application prior to submission. 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 and ensure that all key project personnel will act accordingly. I accept my responsibilities as PI as outlined above. I acknowledge that I am responsible for the research described herein, including work done by others under my direction. I agree to retain signed consent forms in a secure location separate from the data for at least three years after the completion of the research. I will obtain written approval from the IRB prior to initiation of any research activities, including modifications or deviations from previously approved protocols. I agree to immediately report any adverse effects of the study on subjects to the Chairperson of the Institutional Review Board, SIUC, Carbondale, Illinois (618) 453-4534, siuhsc@siu.edu.

Printed Name of Student or Faculty Researcher (PI)

Signature of Researcher (PI)

As the Faculty Advisor named above, by signing this application, I certify that the student is knowledgeable about the regulations and policies governing research with human subjects and that I have thoroughly reviewed the student's protocol for compliance with university policy. I accept the responsibilities as co-PI outlined above. I agree to be available to supervise the research described herein. When on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence. I will advise the Institutional Review Board by letter of such arrangements**.**

Printed Name of Faculty Advisor/Co-PI

Signature of Faculty Advisor/Co-PI

FORM B-1
PROJECT INFORMATION

STUDY IS PART OF: Other:

PROJECT TITLE

PRINCIPAL INVESTIGATOR **SCHOOL**

Campus (if applicable) or Street Address Phone Number

City State Zip E-mail Address

KEY PERSONNEL AND TRAINING (must include advisor)

[CITI: *Social & Behavioral Research*](#) – *Basic/Refresher* taken through the SIUC CITI affiliation is the **ONLY training that will be accepted.

** **Name**	**Role on Project**	**SIUC Affiliated (Yes/No)? (If no, please list affiliation)**	**CITI Training completion date**
	Principal Investigator		
	Faculty Advisor/Sponsor		

*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 Institutional Review Board.

FORM B-1
PROJECT INFORMATION

POTENTIAL CONFLICT OF INTEREST *Required*

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, describe the business entity and explain the relationship:

EXTERNAL FUNDING

Funding Source: ☐ Awarded ☐ Submitted
Effective Date: Expiration Date:
Exact application title:
University Account Number:

CONTROLLED SUBSTANCES

Does this project require procurement, administration, or laboratory testing of controlled substances?
☑ **No** ☐ **Yes:**
Name of the person who is or will be licensed to obtain controlled substances:
Illinois Controlled Substances License # (if still in process, type "pending"):
US Drug Enforcement Agency Registration # (if still in process, type "pending"):

PARTICIPANT INFORMATION

- Average time required (*both duration and frequency*) for an individual subject's participation.

- Number of 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.

SPECIAL REQUIREMENTS *see additional information for any "Yes" answers*

- Will any subject be audio or video recorded? ☐Yes ☐No
- Are you planning to solicit subjects by email? ☐Yes ☐No
- Will you access protected health information? ☐Yes ☐No
- Will non-English materials be used?** ☐Yes ☐No

If using foreign language materials, the IRB requires that you provide a verification of translation after final revisions are made in order to receive approval.

FORM B-2
SCREENING QUESTIONS

The following questions are designed to help you and the IRB determine the review level category of your project.

Question	Yes	No
1. Does this project involve minors (less than 18 years of age) as subjects, other than to study typical educational practices (e.g., instruction, classroom management) in an established educational setting?	☐	☐
2. Does this project involve prisoners or incarcerated persons as subjects?	☐	☐
3. Does this project involve persons with diminished mental capacity (e.g. intellectual, neurological, psychiatric, or related disability) as subjects?	☐	☐
4. Does this project involve persons in a residential program (e.g. hospital, developmental center, group home) as subjects?	☐	☐
5. Does this project involve clients of a human service program (e.g. counseling center or clinic) as subjects?	☐	☐
6. Does this project involve using deception (intentionally withholding from or giving false or misleading information to subjects)?	☐	☐
7. Does this project involve more than minimal risk (i.e. Will/Might/Can the research activities cause any degree of physical, emotional, and/or psychological discomfort that is greater than those ordinarily encountered in everyday life?)	☐	☐
8. Does this project involve existing information or biospecimens that are recorded in a manner that allows direct or indirect individual identification by the PI?	☐	☐

If you answered "NO" to ALL questions: Complete Form C or Form E (for existing data) for Category I (Exempt) review.

If you answered "YES" to ANY question: Complete Form D for Category II/II (Non-exempt) review.

FORM C
CATEGORY I (EXEMPT) REVIEW

1. State the purpose of the study.

2. Describe your potential subject pool.

3. How will you obtain contact information for your potential subjects? *If from other than public sources, a permission letter to access contact information must be obtained*

4. How will you recruit subjects (e.g. email, verbal script, flyer, MTurk HIT description, SONA description, Social Media posts, etc.)
5. Where is the location of the research? (e.g., Lawson 121, subject's home, via mail, via Zoom, online survey) *If using an online survey, please indicate which platform will host your survey and include a link to the live survey for review.*
6. Is there a pre-existing dual 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 subject for participation:*

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 delivery?
☐N/A ☐Yes ☐No *If "Yes," explain:*

8. Will a consent form be provided to participants? ☐Yes ☐No *If "No," explain*:

9. Will subjects receive compensation for participating in the research (e.g., money, extra credit toward grades)? ☐Yes ☐No *If "Yes," explain:*

10. 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 *If "No," explain:*

11. Will the data be recorded in such a way that the individual subjects cannot be linked to the data?
☐Yes ☐No *If "No," describe methods to ensure confidentiality:*

FORM C
CATEGORY I (EXEMPT) REVIEW

12. At the completion of the study, will you destroy or delete any materials (e.g., code lists, audio/video recordings) that identify individual subjects? (Federal regulations require research records to be retained for at least 3 years after the completion of the research.) ☐Yes ☐No
If "Yes," indicate method and timeframe of destruction. If "No," explain why not.

13. Describe procedures IN DETAIL. Begin with the process of recruitment, then explain how consent will be collected from participants. Include exactly how you will interact with your subjects and what measurements will be taken. Provide copies of any materials that will be used during the research study (e.g., recruitment scripts, consent forms, questionnaires, interview protocols, surveys, etc.). Each participant **must** be provided with a consent form that explains the study. See page 15 for required elements of consent forms. (Description may be on separate page, if necessary.)

FORM D
CATEGORY II/III (NON-EXEMPT) REVIEW

Please provide the information requested 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 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**.

1. 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.

B. 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 Institutional Review Board prior to beginning your study.

III. LOCATION OF RESEARCH:

A. Exactly where will research be conducted (e.g., Lawson 121, subject's home, online, via Zoom, etc.)? *If using an online survey, please indicate which platform will host your survey and include a link to the live survey for review.*

B. 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? Describe.

IV. CONFIDENTIALITY: ***Federal regulations require research records to be retained for at least 3 years after the completion of the research.**

A. 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.)?

B. Will you keep a sheet that will match the random number with any identifying type of information? If so, the code listing and data must be kept in separate and secure locations. Where will the data be kept (indicate building and room if on campus or sepicify location)?

C. Will you destroy the code list upon completion of the study? If so, when?

D. Who will have access to the code list and the gathered data? Include this information in the 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 so, provide justification and include this information in the consent form. Attach all materials used in the follow-up.

VI. METHODOLOGY:

A. COMPENSATION

1. Describe any form of compensation provided to subjects (e.g., money, extra credit, etc.)

2. 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, present poster)

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

D. MEASUREMENTS/ PROCEDURES. Attach any questionnaires, measurement instruments, and interview protocols to be used.

1. Describe the procedures that the researcher will use with the subjects.

2. If you have more than one group in the study, how many subjects will be in each group?

3. Will any group receive less than standard practice?

4. 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. ELECTRICAL EQUIPMENT

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. AUDIO/VIDEO RECORDING

If the project involves recording, provide an explanation of the need for recording, the location where recording(s) will be stored, the specific intended uses of the recording(s), the person(s) who will have access to the recording(s), and when or if recording(s) will be deleted. **NOTE**: 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 record the research sessions. Subjects must be given the right to agree or to refuse to be quoted.

G. MORE THAN MINIMAL RISK

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: *See Basic Required Elements section and sample documents*

A. 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. **NOTE**: If your subject pool includes special populations who lack the capacity to give valid/legal consent, permission (consent) must be obtained from their legal guardians.

B. 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:

FORM D
CATEGORY II/III (NON-EXEMPT) REVIEW

A. 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.

B. If the subject's personal files (school, medical, etc.) will be read, where are the files kept and who will gather the information?

C. Has permission been obtained to gather this information?

D. 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. **NOTE**: 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.

B. 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. ATTACHMENTS (check all that apply)

☐ **COPIES OF EXACTLY WHAT THE SUBJECTS WILL BE TOLD/READ PRIOR TO INVOLVEMENT IN THE STUDY (i.e., verbal script, handout, etc.).**

☐ **CONSENT FORM**. If project involves minors, attach parental consent form.

☐ **SEPARATE CHILDREN'S ASSENT FORM** – if project involves minors.

☐ **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.

FORM D
CATEGORY II/III (NON-EXEMPT) REVIEW

Extra Space to Elaborate on Previous Responses

FORM E
EXISTING DATA REVIEW

Question	**Yes**	**No**
1. Will information or biospecimens be obtained by intervention or interaction with a human subject? ** If yes, you must complete Form C.*	☐	☐
2. Will this project involve existing information or biospecimens from prisoners?	☐	☐
3. Will this project involve existing information or biospecimens from school records?	☐	☐
4. Will this project involve existing information or biospecimens from medical records? ** If you plan to access private medical information, you must comply with the Health Insurance Portability and Accountability Act (HIPAA). You should contact the medical facility where the records are kept and ask about special requirements for accessing their medical records.*	☐	☐
5. Will information or biospecimens contain any information that could directly identify individual subjects? ** If yes, you must complete Form C.*	☐	☐
6. Will information or biospecimens be obtained from a publicly available source? (e.g., access is available without need for a password or agreement, from the Census Bureau, or public court records)	☐	☐
7. Will any information or biospecimens be obtained from a source that is not publicly available? (e.g., are there agreements, credentials required to access the data?) ** If yes, a letter granting you permission to use the information or biospecimens must be attached.*	☐	☐
8. Will this project involve the physical handling of previously collected human tissue and/or body fluids? ** If yes, approval must be obtained from the Institutional Biosafety Committee and attached*	☐	☐

9. Provide a brief description of the proposed study. Include the purpose of the study, the problem to be investigated, the source of the data, and the information about subjects that you plan to get from the data. (e.g., age, sex, test scores, number of arrests, number of children)

BASIC REQUIRED ELEMENTS
OF CONSENT DOCUMENTS

❖ 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.

1. Always begin with an **introduction** by name, school, and SIU affiliation.
2. Indicate that the study involves research and an explanation of the **purpose of the research** in terms the potential subjects can readily understand.
3. Include a description of the **procedures to be followed** and **how long participation in the study will take**.
4. Include a statement concerning the **voluntary** nature of the study.
5. Indicate that **not participating or withdrawing** will bear no penalty.
    - Additionally, this may include a statement that there will be no effect on class standing, grades, services/care, etc.

6. Include instructions for how a participant may withdraw from the study and what will happen to any information submitted prior to withdrawal.

7. Include 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.

    - If your project will be **anonymous**, please clearly state this.
    - The confidentiality statement should incorporate all of the following items that apply to your project:
        i. 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 a code is utilized, it must **not** be identifiable in any way.
        ii. 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.
        iii. State who will have access to the code list and the gathered data.
        iv. 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?)
        v. Include a statement such as "We will take all reasonable steps to protect your identity."

8. Clearly state that survey or interview **questions may be skipped** if the participant so chooses.

BASIC REQUIRED ELEMENTS
OF CONSENT DOCUMENTS

9. Indicate the **minimum age** for participation. For adults, this is 18 years of age in most states. However, if your participants might reside in Alabama or Nebraska, the minimum age will need to be 19 years of age.

10. Include a statement of any **foreseeable risks or discomforts** to the subject or a statement that the risks are minimal. If physical risk is possible, see Item 20 below.

11. Include a statement of any **benefits** to the subject or to others which may reasonably be expected from participation in the research. Compensation may NOT be considered a benefit.

12. Include information about **compensation**, if any is offered. Indicate what the compensation will be and if it will be for all participants or if there will be a drawing. (Do not use the word "raffle.") If a drawing is used, indicate an estimated number of participants that will be included in the drawing.

13. Include a statement of **whom to contact** for answers to questions about the research. **Students must include the name, title, email address, and telephone number of the faculty member who is supervising the project, as well as their own information.** (Students are not required to list their phone number.)

14. Include the Institutional Review Board **approval statement**:

"This project has been reviewed and approved by the SIUC Institutional Review Board. Questions concerning your rights as a participant in this research may be addressed to the Institutional Review Board Chair, Office of Research Compliance, Southern Illinois University, Carbondale, IL 62901-4709. Phone (618) 453-4534. E-mail siuhsc@siu.edu"

- Place the IRB approval statement at the very bottom of the 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.

15. If subjects will be **audio/videorecorded**:

- Indicate clearly what you will do if a participant refuses recording.
- State that participants should not use the names of nonparticipants to protect their privacy.
- Include a statement describing the recording procedures.
- Indicate how confidentiality will be maintained and what will happen to the recordings upon completion of the study.
- Include a statement similar to:

"I agree____I disagree____ to participate in this activity and know that my responses will be audio/video recorded."

- 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 directly quote me using a pseudonym in their paper."
- If recording is planned in a group setting, the **consent of <u>all</u> members of the group** must be obtained for recording to take place.
- Describe how the recordings will be stored, who will be allowed to hear/view the recordings, and when the recordings will be deleted.
- If the recordings will **<u>not</u>** be deleted, get the subjects' written permission to keep the recordings.
  i. State where the recordings will be kept.
  ii. State who will hear/view the recordings.
  iii. State how the recordings will be used in the future (e.g., future research, valuable historical data).

16. 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."

17. If you plan to access subjects' **private health information,**

- Contact the agency that has the health records and ask them what procedures they require before they will release subjects' private health information.
- Describe what medical information you intend to obtain and how it will be used toward the study objectives.

BASIC REQUIRED ELEMENTS
OF CONSENT DOCUMENTS

- In addition to consent to participate in research, you may need to include an authorization to use private health information (with a separate signature line):

  "By signing this form, you are authorizing the use and disclosure of your health information collected in connection with participation in this research study. Your information will only be used in accordance with the provisions of this consent form and applicable law.
  Representatives of the following groups are authorized to use and/or disclose your health information in connection with this research study: The principal investigator, _____, the SIU Institutional Review Board, {list every other class of persons or organization affiliated with the study, for example: the research team, the study coordinators, the dissertation committee, etc. who might need to use and/or disclose the subject's information in connection with this study.}
  The main reason to share this information is to ensure that the research meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.
  This Authorization to use your medical information for this project does not have an expiration date."

18. 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."

19. If using an **online survey**, include a statement of consent like, "By clicking NEXT below, I affirm that I am 18/19 years of age or older and voluntarily consent to participate in this study."

20. For projects that may involve **physical risk** to the subject, include:

- The following paragraph, <u>verbatim</u>:
  "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 compensating 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 Services. If you are not a registered student at the university, immediate medical treatment is available at usual and customary fees at {insert closest hospital to study site}. 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 Institutional Review Board, who will review the matter with you. Phone (618) 453-4534. Email siuhsc@siu.edu "

- A statement that a medical questionnaire must be completed, that subjects may be excluded from participation based on their responses and inclusion/exclusion criteria, and how the medical questionnaire will be stored/destroyed.
- 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.

21. For studies that involve **children**:

    As an agent of Southern Illinois University, you are mandated to report suspected child abuse. If your study design is such that you could become aware of or suspect a child is being abused, you must include the following language:

    "Under Illinois law, an exception to confidentiality is incidents of child abuse or neglect. If, in the course of my research, I develop reasonable cause to believe such an incident has occurred, I am required to contact the Illinois Department of Children and Family Services (DCFS)."

22. For studies that include **disabled or elderly adults**:

    The nature of your professional training or certifications/credentials may make you legally obligated to report suspected abuse of disabled or elderly adults. If you determine you are a mandated reporter, include the following statement in the guardian consent:

    "Under Illinois law, an exception to confidentiality is incidents of abuse or neglect. If, in the course of my research, I develop reasonable cause to believe such an incident has occurred, I am required to contact the Illinois Department on Aging."

BASIC REQUIRED ELEMENTS
OF RECRUITMENT DOCUMENTS

1. Always begin with an **introduction** by name, school, and SIU affiliation.

2. Describe the **purpose** of the study.

3. Describe the **activity** you propose and the estimated **time commitment**.

4. Indicate that the study is **voluntary**.

5. Indicate that **not participating or withdrawing** will bear no penalty. (Additionally, this may include a statement that there will be no effect on class standing, grades, services/care, etc.)

6. 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 pertaining to this study.

> 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."

7. Indicate the **minimum age** for participation. For adults, this is 18 years of age in most states. However, if your participants might reside in Alabama or Nebraska, this age will need to be 19 years of age.

8. Indicate any **other minimum qualifications** for participation.

9. Include a statement of **whom to contact** for answers to questions about the research. Students must include the name, title, email address and telephone number of the faculty member who is supervising the project, as well as their own information (student telephone numbers are not required).

10. Include instructions for **how the participant should respond** if interested in the study. If the study includes an online survey, include the link to the survey.

11. The IRB statement is not required for recruitment, but may be used if the investigator prefers.