SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

Institutional Review Board

Supplemental Consent Form Statements

Certain research projects may require specific statements within the informed consent that are not included in the regular consent templates. If you are unsure whether your proposed research requires one of these statements, the IRB coordinator is available for consultation; contact the SIUC IRB at siuhsc@siu.edu or 618-453-4533.

Study Component	Suggested Consent Language
Studies Involving Children (Minor Participants)	As an agent of Southern Illinois University, you may be 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 in the Confidentiality section of your consent: 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).
Studies Involving Disabled or Elderly Adults	Use the following statement if the nature of your professional certifications/credentials make you legally obligated to report suspected abuse of disabled or elderly adults: 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.
Focus Groups	While we ask all participants to respect the privacy and confidentiality of others in the focus group, we cannot guarantee that others will not share information discussed in the focus group. We encourage you to share only what you are comfortable discussing in a group setting and to not provide the names or other confidential information of individuals who are not part of the study. The research team will not disclose your identity in any reports or publications.

Study Component	Suggested Consent Language
Physical Activity/Risk	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 Human Subjects Committee, who will review the matter with you. Phone (618) 453-4534.
Studies with blood draws	Include a statement indicating the amount of blood to be withdrawn, number of times, and potential complications, including possible bruising, inflammation, and infection at the site of the puncture. Incorporate the name of the individual (or place) conducting the blood draw and their qualifications.
Protected Health Information	Research that accesses protected health information requires either a HIPAA release or a waiver of HIPAA authorization. For additional information, contact the SIUC IRB at siuhsc@siu.edu or 618-453-4533 for examples of these items.
Whole Genome Analysis	We may use the [type of biospecimen] collected for this study for whole genome sequencing which involves mapping all of your DNA for [what purpose].
Clinically Relevant Results	If a research study is likely to produce clinically relevant results during the course of the research, participants must be informed (A) if results will be returned to the subjects and (B) under what conditions. Example research that may produce clinically relevant results includes imaging and lab tests. Contact the IRB office for assistance in determining if your project should or should not share clinically relevant results and how to present this on your consent form.