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## IRB Application Instructions

Thank you for your interest in conducting research at South Piedmont Community College. Instructions for submitting a project to the Institutional Review Board (IRB) are included in this document. Please contact us if you have any questions at [IRB@spcc.edu](mailto:IRB@spcc.edu).

### **IRB Documents**

All documents are available on our website at: [spcc.edu/institutional-review-board](http://spcc.edu/institutional-review-board)

Forms are posted in the Adobe PDF Fillable format. Please complete the required fields in each form and save a copy for your records. Submit documents to the SPCC IRB via email attachment.

1. For new research projects, complete the “IRB Application” and submit along with the other documents outlined in the application electronically to [IRB@spcc.edu](mailto:IRB@spcc.edu). The cover page with signatures may be sent via postal mail (if unable to send electronically) to Institutional Effectiveness, South Piedmont Community College, PO Box 5041, Monroe, NC 28111. A member of the IRB will contact you to let you know we have received your materials.
2. The IRB will review the submitted materials and provide a decision in writing. The project may be approved, approved pending modifications, deferred, or denied. If additional information is requested, the researcher must supply information to the IRB within two weeks. A project application may be resubmitted if it is not approved. The IRB reserves the right to suspend IRB approval due to unanticipated problems involving risk to subjects or serious or continuing noncompliance with IRB requirements and ethical guidelines. The IRB will provide all decisions in writing.
3. If modifications are needed to a previously approved project, the “IRB Application” should be resubmitted to outline the modifications needed. Changes may not be implemented until they are approved by the IRB.
4. If more time is needed to continue a project, the “IRB Renewal Application” should be submitted. All IRB approvals have an expiration date included. A renewal is required if an extension is needed.
5. In the case that an unanticipated event occurs that was not specified in the project approval, promptly report the event to the IRB using the “IRB Unexpected Event Report Form”. The event should be reported within one week of the researcher(s) becoming aware of the event.
6. Once your project is complete, submit the “IRB Closure Application”.
7. Researchers must use the “IRB Informed Consent Form” or if minors will be participating in research, the “IRB Informed Consent Parent-Minor Form”.

## **IRB Application Process**

It is the responsibility of the researcher to be familiar with the IRB Application Instructions (this document) and to submit applications for review as indicated. Application to the IRB must be made prior to soliciting subject participation or data collection.

Informed consent is an essential part of ethical human subject research. The requirement to obtain the informed consent of individuals before involving them in research is founded on the principle of respect for persons, one of the three ethical principles governing human subjects research described in the Belmont Report. “Respect for persons” requires that individuals are treated as autonomous agents, the rights and welfare of persons with diminished autonomy are appropriately protected, and potential research participants are given the opportunity to choose what shall or shall not happen to them. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate and an opportunity to discuss that information.

Informed consent is an ongoing process. Even in the absence of new information or changes to research procedures, periodic review or confirmation of a participant’s consent is often desirable, e.g., in studies that take place over a long period of time, particularly complex studies, or longitudinal studies involving progressive disorders or aging populations. Participants must be in a position to freely decide whether to withdraw or to continue participating in the research.

All applications must contain a copy of the informed consent document intended to be used (either the SPCC IRB Informed Consent Form or the SPCC IRB Parent-Minor Informed Consent Form updated with applicable project information). The IRB will provide informed consent guidelines (see Appendix B). Institutional Review Boards and investigators are responsible for ensuring that research subjects provide informed consent prior to participating in research, unless the requirement for informed consent is waived or altered by the IRB.

All investigators (Principal Investigators and Co-PIs) must have completed training on the protection of human subjects in the past two years. A written certification of completion must be provided from an approved training program in the protection of human research participants. Contact the SPCC IRB if you do not have access to a training program.

The IRB will review each application based on the IRB Project Review Checklist and ensure that all required elements have been met. The SPCC IRB does not make use of broad consent or use of data for secondary research projects.

## **Safeguards for Minors Involved in Studies**

All minors involved in a study will be required to submit a parental informed consent form before they can participate in a study. In the event of an online study, any student who is a minor will be required to have a hard copy parental informed consent form filled out and returned before they are given access to the study website. Security procedures should be initiated in order to prevent minors from participating without proper consent.

## APPENDIX A: Definitions

**Anonymous-** The individual that participated in the study cannot be identified in any way by anyone, including the investigator.

**Confidential-** The investigator can identify individuals who participated in the study, however, the investigator will not share the study information with anyone other than authorized individuals

**Coercion-** Persuasion (i.e. of an unwilling person) to do or agree to something by using obvious or implied force or threats.

**Diminished Autonomy-** A person who does not have the ability to make deliberate choices *and* fully act on those choices due to current circumstances, i.e. imprisonment, cognitive impairment, illness, or language barrier.

**Exculpatory Language-** Language that makes or appears to make a research participant waive their legal rights, or the general effect of freeing or appearing to free the researcher or an entity from malpractice, negligence, blame, fault or guilt.

**Human Subject-** A living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes information or biospecimens, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

**Informed Consent-** The knowing, legally effective consent of any individual or the individual's legally authorized representative; such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

**Institutional Review Board (IRB)-** An independent administrative body established to protect the rights and welfare of human research subjects. It consists of at least five members from varied disciplinary backgrounds who are qualified to review research.

**Legally Authorized Representative-** An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**Minimal Risk-** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Minor-** A person who has not attained the legal age for consent (below the age of 18) to treatments or procedures involved in the research.

**Research-** Systematic investigation designed to develop or contribute to generalizable knowledge.

**Risk-** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study.

**Vulnerable Subjects-** Human subjects who are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Vulnerable subjects must be afforded special safeguards in a study to protect their rights and welfare.

**Undue Influence-** Excessive or inappropriate reward or other incentive by which a person is induced to act other than by his/her own free will or without adequate consideration of the consequences.

## APPENDIX B: Informed Consent

### 1. Attributes of the Consent Process

To meet the federal requirements for informed consent, the consent process must have all of the following:

- An investigator (or approved designee) will obtain the informed consent of the potential subject or the subject's legally authorized representative, unless the IRB has altered the requirement for consent.
- The circumstances of the consent process will provide the subject or legally authorized representative sufficient opportunity to consider whether to participate.
- The circumstances of the consent process will minimize the possibility of coercion or undue influence.
- The information being communicated during the consent process will be free of exculpatory language through which the subject or legally authorized representative is made to waive or appear to waive any of the subject's legal rights or to release (or appear to release) the investigator, sponsor, or the college (or its agents) from liability for negligence.
- The information provided during the consent discussion must be presented in language understandable to the subject or the subject's legally authorized representative. The consent discussion should not include complex, technical, or highly specialized language or medical jargon that would not be understandable to potential participants.

### 2. Elements of Informed Consent

#### A. Required Elements:

The information provided during the consent process must be consistent with federal requirements. Unless informed consent is waived or altered by the IRB (see "Waiver or Alteration of Informed Consent" below), the consent process must include the following basic elements:

- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- A statement that the study involves research, explanation of the purposes of the research, expected duration of participation, description of the procedures to be followed, and identification of any procedures that are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others that may reasonably be expected from the research.
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- Explanation of whom to contact for answers to pertinent questions about the research and the subject's rights and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- For research involving greater than minimal risk, an explanation about whether:
  - Medical treatments are available if injury occurs and, if so, what they consist of or where further information can be obtained.
  - Compensation is available if injury occurs and, if so, an explanation as to what it consists of or where further information can be obtained.

## **B. Additional Elements**

One or more of the following elements will also be provided to potential participants during the consent process, when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- A statement about whether the subject will share in compensation if biospecimens are used for commercial profit.
- Notice about whether the subject will receive clinically-relevant results, including individual research results.
- A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided.
- Approximate number of subjects involved in the study.
- Additional information beyond the basic and additional elements of consent (above) may also be required when the IRB determines that this information would meaningfully add to the protection of research participants.

## **4. Waiver or Alteration of Informed Consent**

In the limited circumstances described below, the IRB can approve a consent process that does not include, or alters, some or all of the elements of informed consent.

### **A. Research on Public Benefit or Service Programs**

The IRB can waive or alter the requirements for informed consent for non-exempt research examining state or local public benefit or service programs or certain features of those programs if all of the following criteria are met:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs
- The research could not practicably be carried out without the waiver or alteration
- The research is not FDA-regulated.

Note: Similar research conducted under federal authority or research conducted by (or subject to the approval of) a private entity would not qualify for this waiver.

**B. Minimal Risk Research**

The IRB can waive or alter the requirements for informed consent for non-exempt research that meets all of the following criteria:

- The research involves no more than minimal risk to subjects.
- The waiver or alteration will not adversely affect the rights and welfare of subjects.
- The research could not practicably be carried out without the waiver or alteration.
- Whenever appropriate, subjects will be provided with additional pertinent information after participation.
- The research is not FDA-regulated.
- If the research involves identifiable private information or identifiable biospecimens, the research could not practically be carried out without using such information in an identifiable format.

**C. Research Designed to Study Conditions in Minors**

The IRB can ~~or~~ alter the requirements for parental or guardian permission for certain non-exempt research involving minors.

**D. Planned Emergency Research**

The IRB can approve a waiver of the requirements for informed consent for non-exempt research in life-threatening situations in which it is not possible to obtain informed consent from subjects or their legally authorized representatives.

## **APPENDIX C: Links to Additional Resources**

### **Belmont Report**

[www.hhs.gov/ohrp/regulations-and-policy/belmont-report](http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report)

### **45 CFR 46**

[www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46)

### **Common Rule Regulations**

[www.hhs.gov/ohrp/regulations-and-policy/regulations](http://www.hhs.gov/ohrp/regulations-and-policy/regulations)

### **Family Educational Rights and Privacy Act (FERPA)**

[www2.ed.gov/policy/gen/guid/fpco/ferpa](http://www2.ed.gov/policy/gen/guid/fpco/ferpa)

### **Health Insurance Portability and Accountability Act (HIPAA)**

[www.hhs.gov/hipaa](http://www.hhs.gov/hipaa)