Institutional Review Board (IRB)

Procedure Manual

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Introduction

The Institutional Review Board (IORG0008731) at Sussex County Community College (hereafter referred to as "SCCC IRB") operates according to the Code of Federal Regulations (Title 45, Part 46) of the U.S. Department of Health and Human Services (HHS) and is guided by the Ethical Principles and Guidelines set forth in the Belmont Report (1979).

As per Title 45, Part 46 of the Code of Federal Regulations and for the purposes of the SCCC IRB, research is defined as "any systematic investigation designed to contribute to a body of generalized public knowledge". The use of human subjects refers to "data collection through interaction with individuals or the collection of identifiable private information about individuals." Activities that meet this definition of human subjects research should be submitted to the IRB for review following the procedures described in both this manual and on the Institutional Research, Planning, Assessment, and Distance Learning section of the SCCC website. The purpose of this review process is to determine whether the research design and activities will adequately protect the rights and welfare of the participants.

This manual has been created by the current members of the SCCC IRB. It is intended to be utilized by both internal and external members of the community who are interested in research involving human subjects at Sussex County Community College.

If, after reading this manual, there are ambiguities or questions concerning IRB processes and procedures at Sussex County Community College, please contact:

Cory Homer, IRB Chair

Vice President of Student Success and Institutional Effectiveness

973-300-2116

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Use of Human Subjects in Research Review Procedures
Sussex County Community College

1.0 PROCEDURES STATEMENT

The purpose of this procedure is to establish responsibility for reviewing the use of human subjects in research activities and recognize Sussex County Community College's right to comply with applicable federal regulations; safeguard the rights, well-being, and personal privacy of individuals; and protect the interests of Sussex County Community College.

2.0 DEFINITIONS

2.1 Research: A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45CFR46.102(d)).

2.2 Principal Investigator: The principal investigator is a SCCC staff, faculty, student, or an individual unaffiliated with SCCC that wishes to conduct research involving human subjects either at SCCC, or with SCCC employees and/or SCCC students.

2.3 Institutional Review Board (IRB): The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The SCCC IRB is approved by the United States Department of Health and Human Services (IORG0008731).

2.4 Research Proposal: A detailed explanation of the proposed research project's purpose and procedures included in the application for approval.

2.5 Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects: The federal policy regarding the use of human subjects in research released by the Department of Health and Human Services. The SCCC IRB will be guided by and operate in compliance with applicable sections of this policy and procedure, as well as the Belmont Report (1978).

2.6 Expedited Review: Expedited reviews are conducted by at least one experienced member of the SCCC IRB. In order to qualify for review via expedited procedures, the research must not be greater than minimal risk and fall into at least one of the expedited categories defined by the federal regulations.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that

risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.

2.7 Full Review: Research that is greater than minimal risk and/or does not qualify for exempt or expedited review will be reviewed at a Full Board IRB meeting.

2.8 Exempt Review: Exempt reviews are conducted by at least one experienced member of the SCCC IRB. In order to qualify for review via exempt procedures, the research must not be greater than minimal risk and must fall into at least one of the exempt categories defined by federal regulations.

2.9 Minimal risk: The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

3.0 RESPONSIBILITIES

3.1 Principal Investigator: Prior to conducting any scholarly research activities, the principal investigator must apply for approval to the SCCC IRB. The principal investigator must also notify the committee if any changes are made to the research design and if any subjects experience adverse effects as a result of their participation in the research project.

3.2 SCCC Institutional Review Board (IRB): The SCCC IRB will review all research proposals to determine whether the research design and activities adequately protect the rights and welfare of the subjects.

3.3 Office of Institutional Research, Planning, Assessment, and Distance Learning: The Office of Institutional Research, Planning, Assessment, and Distance Learning will compile and keep records of all research proposals submitted to the SCCC IRB. It will also be a resource for any questions the principal investigator may have before, during, or after the review process.

4.0 PROCEDURES

4.1 No research project involving human subjects shall be undertaken unless the SCCC IRB has reviewed and subsequently approved the project. This includes any scholarly research activities either at SCCC or off-campus with SCCC employees and/or SCCC students. Therefore, the principal investigator must apply to the SCCC IRB for approval prior to starting their research, even if the principal investigator's research project has been approved by another institution's or organization's Institutional Review Board. The application for approval (titled *Application for the Use of Human Subjects-SCCC)* can be obtained from the Institutional Research, Planning, Assessment, and Distance Learning section of the SCCC website or by contacting the Director of Institutional Research, Assessment, Planning, and
Distance Learning. The application can be submitted anytime.

4.1a The application for approval addresses, but is not limited to, the following areas:

- Description of the research project and rationale
- Procedures
- Desired subjects
- How confidentiality will be maintained
- Debriefing process

4.2 Upon receipt of the application, the Chair of the SCCC IRB (hereafter referred to as "the Chair") will review the application to determine whether the research is exempt from the review process, qualifies for expedited review, or qualifies for full review. This determination cannot be made by the principal investigator.

4.3 In accordance with the Code of Federal Regulations regarding the Protection of Human Subjects, the following categories of research are **exempt** from the review process:

- Research in educational settings on instructional techniques, curricula, or classroom instructional techniques where there is no risk to subject's employability and confidentiality is protected.
- Research involving the use of educational tests, survey procedures, interview procedures, or observations of public behavior unless the subject can be identified and disclosure of the subject's responses would put the subject at risk of civil or criminal liability or damage the subject's financial standing and employability.
- Student academic assessments conducted by the college or course instructors.
- Research involving the use of existing data, documents, records, etc., if these sources are publicly available or if the information is recorded by the principal investigator in such a way that subjects cannot be identified directly or through identifiers linked to the subjects.
- Data gathered for the purposes of fundraising, market research for admissions recruiting, recruiting efforts for faculty or staff, and statistical data collected for the management of institutional affairs including surveys of students, prospective students, and alumni.
- Anonymous questionnaires in which disclosure of responses would not place participants at risk of criminal or civil liability or damage their financial standing, employability, or reputation and confidentiality is protected.

If a research project does not clearly fall into any of the above categories, the Chair can determine whether it is exempt.

4.4 If the research project involves no more than minimal risk, it may be reviewed and approved by the Chair using an **expedited review process**. In these situations, a summary of the research proposal will be provided to each of the committee members. As long as no concerns are posed by any of the committee members, the Chair will approve the research proposal. If disagreement arises, then the research proposal will be subject to full review (refer to the process outlined in section 4.5).

4.4a Research proposals that could qualify for expedited review include:

- Minor changes in previously authorized research
- Research involving survey or interview procedures that meet all of the following conditions:
    - Responses are recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects
    - The subject's responses, if they become known outside of the research, would not place the subject at risk of civil or criminal liability or be damaging to the subject's financial standing or employability
    - The research does not deal with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or alcohol use, and is not likely to cause the subject undue stress, fatigue, or any other psychological reactions
    - The research proposal makes adequate provision for obtaining the informed consent and voluntary participation of subjects

4.5 When the Chair deems that a research project has moderate or substantial risks or costs to the subjects, it must be submitted to full review for approval. In these situations, the SCCC IRB will meet to thoroughly discuss the research proposal. During this meeting, the SCCC IRB will determine whether to approve, conditionally approve, or disapprove the research proposal.

4.5a A research proposal is considered **approved** when a majority of the membership votes that the research proposal meets the SCCC Criteria for IRB Approval.

4.5b A research proposal is considered **conditionally approved** when a majority of the membership votes that the principal investigator must address the concerns of the SCCCIRB in order to receive approval. After a principal investigator addresses the SCCCIRB concerns, they may apply for an expedited review.

- If a principal investigator does not respond to the SCCCIRB concerns within 90 days, the research proposal will be closed and considered disapproved.

4.5c A research proposal is considered **disapproved** when a majority of the membership votes that the risks of the research proposal are too great for the participants and outweigh the benefits of the proposed research.

4.6 In the event that a conflict of interest arises with a member of the SCCC IRB related to a research proposal (e.g., the committee member is the principal investigator of the research proposal), that member will be excluded from participating in the review of that proposal.

4.7 The principal investigator will receive a letter detailing the SCCC IRB's decision; this should occur within thirty working days of the initial application submission date.

4.7a If the research proposal is approved, then the letter will contain the following information:

- A statement of approval
- The time period of approval (typically one year from the date of approval)
- Situations when the principal investigator should contact the committee (e.g., subjects experience adverse effects from participation)
- A contact person for questions/concerns

4.7b If the research proposal is disapproved, then the letter will contain the following information:

- A statement of disapproval
- A detailed explanation of why the research proposal was disapproved
- A contact person for questions/concerns

4.8 For approved research proposals, the principal investigator has the following responsibilities:

- Contact the SCCC IRB if changes are made to the original research design.
- Contact the SCCC IRB if any subjects experience adverse effects from participation.
- If the principal investigator would like to extend the study period beyond the initial period granted by the committee, the principal investigator must submit a new application for approval prior to the end of the initial approval period.

4.9 For approved research proposals, the SCCC IRB any systematic investigation designed to contribute to a body of generalized public knowledge". has the following responsibilities:

- Review any changes the principal investigator makes to the original research design. For minor changes, this can be accomplished through an expedited review. For more substantial changes, a full review should be conducted.
- Determine whether a research project in which subjects experience adverse effects should be terminated.

Sussex County Community College

Criteria for IRB Approval

Derived from Title 45 of the Code of Federal Regulations, the SCCC IRB shall determine that all of the following requirements are satisfied in order to approve the research study.

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Potential Risks in Research Involving Human Subjects

1. Recalling traumatic or distressing events is normally a distressing activity, causing some level of suffering for your participants. The relatively short-term suffering involved within the specific time frame of your study may be followed, for some participants, by an extended period of flashbacks, nightmares, reactivation of fears, or unhappy rumination. Asking individuals to participate in research activating such memories should never be undertaken lightly.

   Examples of such events might be those of being a victim of torture, rape, or other crime; suffering sexual or other harassment; recalling embarrassing moments; providing information about one's illnesses; providing information about a family member's illness or death; describing the hassles of living in poverty; describing conflicts with one's partner or spouse, etc.

   When engaging in such research, it is good practice to provide the research participants with a list of community resources that can be helpful should counseling needs related to the above occur. Such resources should be those available at no or little cost to the individual, since it would be undesirable to have participants spend large amounts in counseling fees as a result of dealing with memories triggered by participation in someone's research. Some research projects (such as those by counseling, social work, or clinical psychology agencies) respond to this need by building free access to their own counseling staff into the research project.

2. Be aware of potential risks to people suffering allergies, phobias, or environmental sensitivities. Examples might be such things as the peanuts often included in candies; mold and dust of a research space; flickering lights triggering epileptic seizures; public speaking or group testing for people with agoraphobia; small laboratory cubicles for people with claustrophobia. Identify any pertinent aspects on the consent statement, and clearly request individuals who have a sensitivity to these stimuli to exclude themselves from participating in the research.

3. Boredom, mental fatigue, embarrassment at poor performance, or frustration are minor but common risks. If present, they should be identified on the consent statement.

4. Researchers should avoid impairing the subjects' relationships with others (e.g., asking a dating couple to discuss their conflicts; or asking employees about their dissatisfactions with their supervisors and making such information available to their employer).

5. Exercise-induced or repetition-exacerbated physical harm, such as carpal tunnel syndrome, stress fractures, asthma attacks, heart attacks may be risks for certain kinds of research.

6. Invasion of privacy asking about income, health habits, use of illegal substances, etc. may cause unnecessary discomfort to subjects. Refrain from such questions or provide a clear rationale to the IRB about their appropriateness for the proposed research.

Application for the Use of Human Subjects

Sussex County Community College

Part A: Applicant Information

Title of Study:		
Principal Investigator:		
Address:		
Phone:	Email:	Department:
*Co-Investigator:		
Address:		
Phone:	Email:	Department:

*If there is more than one co-investigator, include their contact information on a separate sheet to include with the proposal.

Part B: Research Study

Abbreviated Study Description:

Abbreviated Study Rationale:

What Research Questions will this Study Address:

Abbreviated Study Procedure:

Length of Study:
(Approximate duration for each participant)

Location of Research:
(Specific)

Subject Information:

Proposed number of Subjects: Gender of Subjects: Age of Subjects:

Potentially Vulnerable Populations: (Check All that Apply)

☐ Children ☐ Pregnant Women ☐ Cognitively Impaired ☐ Prisoners ☐ Institutionalized

☐ Faculty's Own Students ☐ Veterans ☐ Other. Please describe:

Procedure for Selecting Participants:
How/Where Information will be Stored:
Who will have access to the Data during the Study:
How Long will Information be Held:
How will Information be Destroyed:
What Known Risks to Participants are Involved:
What Known Benefits to the Participants are Involved:
Please provide a Detailed List of all Instruments used in the Study (Include copies of surveys, tests, etc.):

Provide a Comprehensive Description of the Informed Consent Process (Include copy of Consent Form):
Is Anonymity Guaranteed in the Study and how will Confidentiality be Maintained?
Describe the Procedures which will be followed if a Participant Withdraws:

What services are offered for the Participant if they experience harm during the Research?
How will Participants be Debriefed? (Include copy of Debriefing Form)

The attached research involves the use of human subjects. I understand the college's policy concerning research involving human subjects and I agree:

1. To obtain voluntary and informed consent of all subjects who participate in this research.
2. To report immediately to the Office of Institutional Research of any unanticipated effects on subjects which become apparent during the course of, or as a result of, the experimentation and the actions taken.
3. To obtain prior approval before amending or altering the scope of the project or implementing changes in the approved consent document.
4. To protect the confidentiality of research subjects and the data collected when the approved level of research requires it.
5. All surveys must be scheduled through the Office of Institutional Research. This process is necessary to ensure the consideration of staff, faculty, students, and community members to avoid duplication of effort.

Signature of Principal Investigator:_____ Date:_____

Signature of Faculty Sponsor:_____ Date:_____
(If applicable)

For Office Use

☐ Expedited Review ☐ Full Review ☐ Exempt Review Date _____

☐ Reviewed ☐ Approved ☐ Rejected ☐ Returned for Revision

☐ Returned for Additional Information _____

_____

_____

Signatures:

_____, Committee Chair Date: _____

_____ Date: _____

_____ Date: _____

_____ Date:_____

Informed Consent Template

Sussex County Community College

Project Title: _____

Principal Investigator: _____

(Include Name, Title, Contact Information, and Department/Organization)

Co-Investigator: _____

(Include Name, Title, Contact Information, and Department/Organization)

Faculty Sponsor: _____

(Include Name, Title, Contact Information, and Department)

Invitation to Participate

We/I invite you to be part of a research study about [Topic and Purpose].

Description of Involvement

If you agree to be part of the research study, you will be asked to [Details].

Benefits of Participation

You may directly benefit from participating in this study because [Details].

OR

Although you may not directly benefit from participating in this study, others may benefit because [Details].

Risks and Discomforts of Participation

There may be some risk or discomfort involved from participation in this research
[List and describe *specific* risks and discomforts associated with the study]

OR

The researchers do not believe there are any risks or discomforts from participation in this research.

Available Resources

If you do experience any harm or discomfort by participating in this research, these resources are available for your use: [List available resources for participants]

Confidentiality

We/I plan to publish the research of this study. We/I will not include any information that would identify you. Your privacy will be protected and your research records will be confidential. We/I will store all data [Why, How, Duration, Access, Time reference for data destruction, and How data will be destroyed]. **Be sure to indicate if anonymity will not be guaranteed.**

Voluntary Participation

Participating in this study is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time without penalty. You do not have to answer a question you do not want to answer. Refusal to participate in the study will have no effect on any future services you may be entitled to from the college. If you decide to withdraw before the study is completed, [details about withdraw process].

Contact Information

If you have any questions or comments about this research, you may contact [PI name and contact information].

If you have questions about your right as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the:

Office of Institutional Research
Building B, Room B20
One College Hill Road
Newton, NJ 07860
Phone: 973-300-2116
Email: chomer@sussex.edu

Consent

I have read what this study is about and understood the risks and benefits. I have had adequate time to think about his and had the opportunity to ask questions and my questions have been answered.

I agree to participate in the research project, understanding the risks and contributions of my participation, that my participation is voluntary, and that I end my participation at any time.

_____ _____

Signature of participant Date

Researcher's Signature

I have explained this study to the best of my ability. I have invited questions and have given answers. I believe that the participant fully understands what is involved in participating in the study, any potential risks involved in the study, and that he/she has freely chosen to participate in the study.

_____ _____

Signature of Principal Investigator Date

Debriefing Form Template

Sussex County Community College

Thank you for participating in our research.

Purpose of the Study

If no deception was involved, concisely remind the participant of the purpose of your study. If deception was used, please explain the deception by:

- Reminding the participant of the reason originally given;
- Clearly stating that the original reason is not the real object of the study;
- Explaining what the study is actually designed to test;
- Explaining why deception was needed;
- Explaining why the study is beneficial;
- Providing an opportunity for the participant to withdraw his/her data from the study

Contact Information

Provide a statement which allows the participant an opportunity to ask any questions of you regarding the study. Please be sure to include:

- Contact information for the researcher(s) and the faculty sponsor if applicable
  - Name
  - Address
  - Phone Number
  - Email Address

Concerns

Please include this statement under this section:

If you have any concerns about this study or your rights as a participant in this research, you are encouraged to contact:

Cory Homer, SCCC IRB Chair
(973) 300-2116
chomer@sussex.edu

You may request to have your information or any part of your responses withdrawn from the study. You may do so at this time or at a later date by contacting the researcher. If you do so, there is no penalty.