North Carolina Central University
Application for IRB Approval of Human Subjects Research

Cover Sheet

Title of Study: Click here to enter text.

Name, Title and Degrees of Principal Investigator (PI): Click here to enter text.

Department, address, email and phone number of PI:
Click here to enter text.

If the PI's title is "Student", provide the name, phone number and email of the Faculty Advisor who bears ultimate responsibility for the research: Click here to enter text.

List all other project personnel who will have contact with subjects or identifiable data from subjects. Include an email address for each person who should receive electronic copies of IRB correspondence to the PI. Note: Documentation of training in research with human subjects is required of all personnel listed here. Click here to enter text.

Name of Funding Source or Sponsor. If none, state "none". Click here to enter text.

Proposed time span of research: From Click here to enter a date. To Click here to enter a date.

Does this research involve a vulnerable population that requires special protection by the IRB, such as pregnant women, prisoners, children, mentally or physically challenged, economically disadvantaged, or non-English speaking?

☐ No ☐ Yes

If yes, click here to describe.

PI's recommendation for IRB Review (select one):

☐ Full Board Review

☐ Expedited review for projects involving no more than minimal risk

☐ Determination of Exempt

Category for exemption: *(Include all that apply. Refer to 3.c. Exempt Criteria)*

INVESTIGATOR'S ASSURANCE: I will personally conduct or supervise this research study.

I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies. I will obtain IRB approval before making any changes or additions to this project. I will report all unanticipated problems or adverse events involving risk to human subjects to the IRB. I will follow the IRB approved consent process for all subjects. I will notify the IRB when this research study is completed or discontinued. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this application is accurate and complete.

_____ _____

Signature of Principal Investigator Date

FACULTY ADVISOR (if PI is a student): I accept ultimate responsibility for ensuring that this project complies with all regulatory, University, and fiscal requirements.

_____ _____

Signature of Faculty Advisor Date

DEPARTMENT CHAIR (not required if PI is a student): I certify that this research is appropriate for this Principle Investigator, that the investigators are qualified to conduct the research, and that there are adequate resources (including financial, support and facilities) available. I support this application, and hereby submit it for further review.

_____ _____

Signature of Department Chair Date
(or Chair's designee if Chair is PI or otherwise unable to review)

_____ _____

Print Name of Department Chair or designee Department

For IRB Use Only:
Protocol Number: _____
☐ ☐ ApprovedExempt under category ☐ ☐
_____Approval Withheld Withdrawn

_____

IRB Chairperson Date

North Carolina Central University
Application for IRB Approval of
Research Involving Human Subjects

FORM A

All questions on Form A must be answered. Do not alter wording or delete questions. Form A must "stand alone" and should provide complete answers. A response of "See Attached" is not permitted. A response of N/A is not permitted.

1. **Research Title**: Click here to enter text.

2. **Summary:** Provide a brief, non-technical description of the study, to be used in IRB documents as a description of the study (50 – 100 words). Click here to enter text.

3. **Participants:** Who will be your research participants and how will they be recruited? Describe who will do the recruiting and how subjects will be contacted. Recruitment materials must be submitted with this application.

Click here to enter text.

4. **Study Design:** Describe the research study design and procedures. Include a sequential description of what subjects will be asked to do; how data will be collected, and how the results will be analyzed.

Click here to enter text.

5. **Benefits to subjects and/or society:** Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained. If there is no direct benefit to the individual subject, it must be disclosed here and on the consent form.

Click here to enter text.

6. **Attendant Risks:** Describe risks and measures to minimize risks. Include risk of psychosocial harm (embarrassment, emotional distress, breach of confidentiality), economic harm (loss of employment, loss of professional standing, loss of standing within the community). Describe how the procedures used reflect respect for privacy, feelings, and dignity of subjects, avoid unwarranted invasion of privacy, and minimize risks as much as possible.

Click here to enter text.

7. **Confidentiality:** Describe the procedures to assure confidentiality in the use, storage, and disposal of the primary data. If electronic storage of data is used, describe safeguards to protect confidentiality.

Click here to enter text.

8. **Informed Consent:** Describe the *process* of obtaining informed consent from subjects. If children will be research subjects, describe the provisions for obtaining parental permission and assent of the child. Do not include the Consent Document here. Click here to enter text.

9. **Inducements for Participation:** Describe all inducements to participate, monetary or nonmonetary. If inducements are used, explain how the inducements are not coercive. Click here to enter text.

10. **Costs to research subjects:** Include travel, parking, child care, etc. If there are no costs to subjects other than their time to participate, indicate this. Click here to enter text.