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 Renewal or Modification of
Ongoing Research Involving Human Subjects

FORM B

Principal Investigator: Click here to enter text.

Project Title: Click here to enter text.

IRB#: Click here to enter text.

Date of initial approval: Click here to enter a date.

Date of this request: Click here to enter a date.

Research Project Site: Click here to enter text.

Number of Participants Enrolled Since Initial IRB Approval:

Total Subjects Required to Complete Project(s):

Risk Classification:

☐ More than minimal risk ☐ No more than minimal risk

Describe any significant preliminary findings.
Click here to enter text.

Describe any adverse events, including those were foreseeable and described in the initial application. Attach all adverse event reports to this Form, even if previously submitted to the IRB. If none, state "none".
Click here to enter text.

Describe any unanticipated problems involving (a) risks to subjects or others (such as the parents of minor subjects), (b) withdrawal of subjects from the project and/or (c) complaints about the project. If none, state "none".
Click here to enter text.

Summarize any recent literature findings or other relevant information that bears on the issue of risks or benefits associated with this research project. Click here to enter text.

Describe any proposed changes in the study design. If research includes a revised questionnaire or interview, highlight the questions that are being added or revised.

Click here to enter text.

Is the Informed Consent Form identical to that previously approved the IRB?

☐ Yes ☐ No

If no, please describe how the consent document has changed. Highlight the changes to the consent document in yellow and attach to this form.

Click here to describe changes to consent document.

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Signatures:

_____

Principal Investigator Date

_____

Faculty Advisor if PI is student Date

Approval for Renewal or Modification granted by:

_____

IRB Chairperson Date