

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
(or Chair's designee if Chair is PI or otherwise unable to review)

Date

Print Name of Department Chair or designee

Department

For IRB Use Only:

Protocol Number: _____

Approved Exempt under category

Approval Withheld Withdrawn

IRB Chairperson

Date

North Carolina Central University
Notification of Status of Research Involving Human Subjects

FORM C

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.](#)

Research Project Site: [Click here to enter text.](#)

Current Status:

Completed

Discontinued

Ongoing

Date Completed or Discontinued: [Click here to enter a date.](#)

If discontinued, state reason(s): [Click here to enter text.](#)

Describe any unforeseen risks or unanticipated results from this research. If none, state “none”.
[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.](#)

Signature:

Principal Investigator

Date

Faculty Advisor if PI is a student: I accept ultimate responsibility for ensuring that the PI complies with the University’s conflict of interest policies and procedures.

Conflict of Interest Certification

The following questions apply to **all investigators and study staff** engaged in the design, or reporting of results of this project **and/or their immediate members**. For these purposes, “family” includes the individual’s spouse and dependent children. “Spouse” includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other’s welfare and shares financial obligations.

1. Currently or during the term of this research study, does any member of the Yes No research team or his/her family member have or expect to have:
 - (a) A personal interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study? Yes No
 - (b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process, or technology studied in this project? Yes No
 - (c) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor? Yes No
 - (d) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process, or technology studied in this project? Yes No
2. Has the University or has a University-related foundation received a cash or in- Yes No kind gift from the sponsor of this study for the use or benefit of any member of the research team?
3. Has the University or has a University-related foundation received a cash or in- Yes No kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, processor technology studied in this project?

If the answer to any of the questions above is *yes*, the PI will be contacted by the Director of Research Compliance for conflict management. List name(s) of all research team members for whom any answer to the questions above is *yes*:

Certification by Principle Investigator: By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of all members of my research team who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above. I understand that as Principle Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by University policy.

Signature of Principle Investigator

Date

Faculty Advisor if PI is a student: I accept ultimate responsibility for ensuring that the PI complies with the University’s conflict of interest policies and procedures.

Signature of Faculty Advisor

Date