1. Purpose

Federal law and University regulation require that all research involving human subjects, conducted by NCCU researchers (faculty, staff or students) must be reviewed and approved by the NCCU Institutional Review Board (IRB) for the Use of Human Subjects in Research. This includes educational tests, survey procedures, interview procedures or observations of public behavior, as defined by the Department of Health and Human Services (DHHS) regulations. The Institutional Review Board (IRB) for the Protection of Human Subjects in Research has the authority to review, approve, or disapprove all research endeavors initiated, promoted, and supported by NCCU.

2. General Principles

All North Carolina Central University researchers (faculty, staff, and students) must adhere to strict ethical standards for the use of human subjects in their research. These standards are in place to protect the basic rights of their subjects. Any research that departs from the spirit of these standards violates University policy. Below are some guidelines that the IRB members consider during their reviews to maintain these standards.

2.1 All research procedures minimize the risks to subjects.

2.2 Any risk must be reasonable in relation to the potential benefits from the study.

2.3 Informed consent must be obtained from the subject before participation. This consent must be in writing unless exempted by the committee.

2.4 Subject must be provided with adequate detail regarding the study to make an informed decision regarding their participation. This information should be included on the consent form and should be written in lay language, so that the subjects can make an informed decision regarding
participation.

2.5 Subject's privacy must be maintained.

2.6 Subjects need to be made aware that they participate of their own choice and are free to withdraw from the study at any time

3. Review Categories

There are three categories (or types of review) for projects that are submitted to the IRB. These are as follows:

3.1 Exempt from further review.

3.2 Subject to expedited review.

3.3 Subject to full review.

Determination of the type of review will be made by the chair of the IRB upon consideration of the submitted materials. Expedited review will typically be conducted on those projects that involve no more than minimal risk.

4. Definitions

4.1 Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Proposed activities are not intended to develop or contribute to generalizable knowledge, it is not research. Generalizable knowledge includes information presented to a broader audience or published with the intent of drawing scientific conclusions or increasing the body of scientific knowledge.

4.2 Human Subject - Means a living individual, about whom an investigator (whether professional or student) conducting research obtains:

4.2.1 Data through intervention or interaction with the individual; or

4.2.2 Identifiable private information

4.2.3 Intervention includes both physical procedures, by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

4.4.4 Private information includes information about behavior that occurs in a context, in which an individual can reasonably expect that no observation or recording is taking place, and information, which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information), in order for obtaining the information to constitute research involving human subjects.

4.2.5 IRB Approval - the determination of the IRB that the research has been reviewed and may be conducted at NCCU within the constraints set forth by the IRB, and by other institutional and federal requirements.

4.3 Minimal Risk - means that 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.

5. Procedures

Described below is the process by which a principal investigator seeks approval from the NCCU IRB for the Use of Human Subjects in Research.

5.1 The IRB accepts applications on a rolling basis. The application forms are found in the Appendix to the IRB Manual as Microsoft Word 2007 documents. Applications may be submitted as a single hard copy or electronically. When the IRB receives an application, the IRB will notify the Principal Investigator (PI) by email within two business days that the application was received, and whether the application is complete or has missing parts.

5.2 Once an application is complete, it will be reviewed by the IRB. Completed applications received by the 5th of the month will be reviewed and a response issued by the end of the same month. The PI will receive written notification of the IRB’s decision to approve or disapprove the proposed research activity, or of modifications required to receive IRB approval. If a protocol is not approved, the PI will receive a statement detailing the reasons for the IRB’s decision, and the PI will have an opportunity to respond either in writing or in person.

6. Review

6.1 Annual Renewals of Approved Protocols

6.1.1 IRB approval is for a period of one year. If the research activities extend longer than one year, it is necessary to renew IRB approval.

6.1.2 To request a renewal of a previously approved protocol, complete and sign Form B and the Conflict of Interest Certification, found in the Appendix A of the IRB Manual. Submit Form B and the Financial Conflict of Interest Certification as hard copies to the IRB office, 309 Hubbard-Totton Bldg, North Carolina Central University, 1801 Fayetteville St, Durham, NC 27707, or electronically to IRB@nccu.edu no later than one (1) month prior to the expiration of the initial approval.

6.1.3 Failure to comply with the requirement to renew IRB approval annually will result in suspension of the research activities.

6.2 Modifications of Approved Protocols - All modifications to a previously approved protocol must be approved by the IRB prior to implementing the changes. To request a modification of a previously approved protocol, complete and sign Form B, found in Appendix A of the IRB Manual. Submit Form B as a hard copy to the IRB office or electronically to IRB@nccu.edu.

7. Status Reports of Approved Protocols

7.1 Ongoing protocols not subject to annual review - Although protocols that are approved as Exempt from the Federal Policy are not subject to the requirement for annual review, the PI must notify the IRB annually of the status of the research. This notification is accomplished by completing Form C, found in Appendix A of the IRB Manual. The IRB will send a reminder to the PI approximately one month prior to the anniversary of the initial approval.

7.2 Completed or discontinued protocols - When an approved project is completed or discontinued, the IRB must be notified using Form C, found in Appendix A of the IRB Manual. Submit Form C as a hard copy to the IRB office, 309 Hubbard-Totton Bldg, North Carolina Central University, 1801 Fayetteville St, Durham, NC 27707, or electronically to IRB@nccu.edu. The requirement to notify the IRB when a protocol is completed or discontinued applies to all protocols, including those that are approved as Exempt from the Federal Policy.
8. Retention of Documentation

A copy of all records relating to the research project (original submitted protocol, all signed consent forms, correspondence with the IRB, etc.) should be retained for at least three years after the completion of the research.