

University of North Carolina at Greensboro

PROCEDURES FOR RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS

All research activities conducted by faculty or students in the University of North Carolina at Greensboro must comply with University policies on research, including the University Policy and Procedure for Ethics in Research (<http://www.uncg.edu/apl/POLICIES/va006.html>), the Policy on the Protection of Human Subjects in Research (<http://www.uncg.edu/apl/POLICIES/va002.html>), the Policy on the Protection of Animal Subjects in Research (<http://www.uncg.edu/apl/POLICIES/va001.html>), the Copyright and Use Policy (http://www.uncg.edu/apl/POLICIES/copyright_and_use.htm), the Patent and Copyright Policies (<http://www.uncg.edu/apl/POLICIES/va003.html>), and the Guidelines on Use of Indirect Cost Recovered (<http://shadow.uncg.edu/pvt/publications/personnel/1indirectcost.html>), and the Policy on Data Safety and Compliance Monitoring (<http://www.uncg.edu/rss/DSMPolicy.pdf>).

Procedures for the conduct of research follow.

I. RESEARCH BY STUDENTS

Students proposing research must have a faculty sponsor. The faculty sponsor is responsible for ensuring that the procedures for review and conduct of the study are followed appropriately. Faculty members who assign or supervise research conducted by students are responsible for the scientific integrity of the study, and for safeguarding the rights and welfare of subjects in the research.

II. GRANT PROPOSALS

All proposals for research funding initiated by University faculty and students must be approved by the Office of Research Compliance (ORC) and the Office of Contracts and Grants before submission to potential funding agencies. Proposals for research involving human participants must be approved by the Institutional Review Board (IRB). Proposals for research involving animal subjects must be approved by the Institutional Animal Care and Use Committee (IACUC). Proposals for research involving recombinant DNA or other biohazards must be approved by the Institutional Biosafety Committee (IBC).

III. RESEARCH INVOLVING HUMAN PARTICIPANTS

The Institutional Review Board (IRB) must review all plans for the use of human participants in research prior to the beginning of the research. The IRB must also review all revisions to research protocols before the changes are implemented. The IRB and Office of Research Compliance are responsible for monitoring and periodic review of ongoing research.

A. Procedures for obtaining IRB approval for **new** research involving human participants

1. The Principal Investigator (PI) completes the Application for the Use of Human Participants in Research and the Checklist, available at <http://www.uncg.edu/rss/irb.html> or from Office of Research Compliance. Since the application form is updated regularly, the current version should be used each time an application is made. Both the IRB Chair and the unit's IRB Representative are available for consultation in completing IRB applications.
2. PIs and Co-Investigators must also present evidence of current education in the protection of human research participants. Research assistants and data collectors who interact with subjects or collect data without supervision by an investigator must also fulfill the educational requirement. Research assistants and data collectors who work under supervision of an investigator are NOT required to fulfill the educational requirement. Investigators are encouraged to complete the Human Subjects Protection for Research Teams web-based program (<http://cem.nih.gov/intro.html>) and attach a copy of the certification of completion to application. Investigators must retain the original. Investigators who wish to use other evidence of training in the protection of human research participants, e.g., completion of the web-based program from Stanford University or the University of Virginia, or attendance at an Office of Human Research Protections (OHRP)-sponsored conference, should submit this evidence to the IRB Chair or the Director for Office of Research Compliance for review. If deemed comparable, it will be substituted for the evidence described above. Educational programs should be repeated at least every three years.
3. The PI submits two copies of the Application, Checklist, and evidence of education on protection of human subjects, to the unit's IRB Representative. The unit's IRB Representative will coordinate review by the UNCG IRB. The PI should retain one copy of all materials for his/her records. The IRB Representative may refer applications to the Director for Office of Research Compliance for clarification of methods or issues pertaining to scientific integrity.
4. Federal guidelines require that some types of studies be reviewed by the full IRB committee, but allow others to be reviewed by a subcommittee in an expedited process (<http://www.ohrp.osophs.dhhs.gov/polasur.htm>). If the application requires review by the full IRB committee, the PI will be invited to attend. It is **highly recommended** that the PI attend the review meeting. When applications by students are reviewed, both the faculty sponsors and students should attend.
5. The UNCG IRB will review studies that require either a full committee review or an expedited procedure in accordance with OHRP guidelines (see <http://ohrp.osophs.dhhs.gov/polasur.htm>). The IRB will either approve or disapprove the study. **No data collection, recruitment of subjects, or other research activities can be conducted until approval of the IRB is obtained.** The Office of Research Compliance will notify the faculty PI of the disposition of the application. For research proposed by students, the Office of Research Compliance notifies the faculty sponsor, not the student,

of the disposition. It is the faculty sponsor's responsibility to notify the student of disposition of the application.

6. IRB approval is valid for no more than a 1 year time period. Before the end of one year, the ORC will send the PI (or faculty sponsor, for student research) a renewal application. The renewal application must be completed and approved by the IRB before the expiration date for research activities to continue. The IRB will review applications for renewal in accordance with OHRP guidelines (see <http://ohrp.osophs.dhhs.gov/polasur.htm>). A study may be renewed up to five times, after which a new application must be submitted. If the research is completed, the PI (or faculty sponsor, for student research) must indicate this on the renewal application and return it to ORC.

B. Procedures for obtaining IRB approval for a **change** to an already approved study involving human participants

1. When a PI wishes to make a change to an already approved study, s/he completes the Application for Modification to an Approved IRB Protocol (<http://www.uncg.edu/rss/irb.htm>), and gives it to the unit's IRB Representative. The PI should retain one copy of all materials for his/her records. The unit's IRB Representative will coordinate review of the proposed change in accordance with OHRP guidelines (see <http://ohrp.osophs.dhhs.gov/polasur.htm>). **The change cannot be implemented until approved by the IRB.**

2. The IRB Chair will notify the PI (or faculty sponsors, in the case of student research) and the Office of Research Compliance of the disposition of the Application for Modification.

C. Procedures for Conducting a Study Involving Human Participants

1. Before beginning a study, all students, faculty, staff and consultants who will have access to data should sign a *UNCG Research Confidentiality Agreement* (below). If new workers are added to the study after its inception, they must sign the Confidentiality Agreement before being allowed access to data.

2. Confidentiality Agreements, research records and signed consent forms from human research participants must be retained in a secure location for at least three years after completion of the study. **Faculty sponsors should retain records from research conducted by students.** The Confidentiality Agreements, records and consent forms must be available for review by the IRB or the Office of Research Compliance for data safety and compliance monitoring.

3. The Office of Research Compliance will periodically conduct safety and compliance monitoring to ensure adherence to approved study procedures and consent procedures, security of data, protection of subject confidentiality, and provision of appropriate

protections to participants. See *UNCG Data Safety and Compliance Monitoring Guidelines* (<http://www.uncg.edu/rss/DSMPolicy.pdf>).

4. The PI should notify the IRB Chair immediately if any injury or harm to participants occurs during a study, or if any unexpected circumstances arise. In the case of harm resulting from unanticipated risks, the PI must discontinue all data collection until the IRB has reviewed the incident.

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RESEARCH CONFIDENTIALITY AGREEMENT
FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

I name of person have agreed to assist with type role in project for the research project entitled type title of project as on IRB approval form IRB # _____.

I agree not to discuss or disclose any of the content or personal information contained within the data, tapes, transcriptions or other research records with anyone other than the Principal Investigator, type in name the Co-Investigator, type in name or in the context of the research team. I agree to maintain confidentiality at all times and to abide by the UNCG Policy and Procedure for Ethics in Research and the UNCG Policy on the Protection of Human Subjects in Research.

Date: _____

Signature

Principal Investigator

To be completed by all members of the research team with access to personal data on human research participants.

File a copy with the PI and a copy with the Office of Research Compliance Compliance.