

**University of North Carolina at Greensboro
School of Nursing**

GUIDELINES FOR RESEARCH ACTIVITIES

All research activities conducted by faculty or students in the School of Nursing must comply with University policies on research, including the University Policy and Procedure for Ethics in Research (<http://provost.uncg.edu/publications/personnel/ethics.html>), the Policy on the Protection of Human Subjects in Research (<http://provost.uncg.edu/publications/personnel/1humans.html>), the Policy on the Protection of Animal Subjects in Research (<http://provost.uncg.edu/publications/personnel/pdf/animals.pdf>), the Policy on Data Safety and Compliance Monitoring (<http://www.uncg.edu/rsh/orc/DSMPolicy.pdf>), 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://provost.uncg.edu/publications/personnel/pdf/indirectcost.pdf>). The School of Nursing also has additional procedures that are specific to faculty and students in the School.

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 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 School of Nursing faculty and students must be approved by the School of Nursing Director of Research before submission to potential funding agencies. The Director of Research will assist the Principal Investigator (PI) in coordinating processing of the proposal by the Office of Research Services.

III. RESEARCH USING SCHOOL OF NURSING FACULTY OR STUDENTS AS SUBJECTS

It is preferable that all proposed research involving use of School of Nursing students, staff or faculty as subjects, whether initiated within the School or external to the School, is reviewed by the School of Nursing Director of Research, in consultation with the Research and Scholarship Committee and the chairs of any courses involved, to determine whether the proposed activities are consistent with the goals and mission of the School, and whether they place inappropriate burdens on faculty, staff or students.

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IV. RESEARCH INVOLVING HUMAN PARTICIPANTS

The UNCG 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.

A. Procedures for obtaining IRB approval for **new** research are as follows:

1. The Principal Investigator (PI) completes the Application for the Use of Human Participants in Research and the Checklist. Note: since the Application form is updated regularly, PIs should obtain a current form from the web site (<http://www.uncg.edu/rsh/orc/humanres.html>), or from Office of Research Compliance (204 Foust), each time an application is made. Both the School of Nursing Director of Research and the School of Nursing IRB Representative are available for consultation in completing the applications.

2. If funding is **not** sought for the study, the PI submits 2 copies of the Application and Checklist to the School of Nursing IRB Representative. The School of Nursing IRB Representative will coordinate review by the UNCG IRB. (See <http://www.uncg.edu/rsh/orc/IRBProceduresHumanSubjects.pdf> for more details on IRB procedures.) The PI should retain one copy for his/her records. The IRB Representative may refer applications to the Director of Research for clarification of methods or issues pertaining to scientific integrity.

If funding **will be** sought for the research, the PI submits a copy of the Application and Checklist to the School of Nursing Director of Research. The Director will coordinate review of the application by the Research and Scholarship Committee. Once the Research and Scholarship Committee has approved the Application, the Director will notify the PI, who then submits 2 copies of the Application and Checklist to the School of Nursing IRB Representative. The School of Nursing IRB Representative will coordinate review by the UNCG IRB. (See <http://www.uncg.edu/rsh/orc/IRBProceduresHumanSubjects.pdf> for more details on IRB procedures.)

3. 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. 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, so s/he can answer any questions the IRB has about the application. When applications by students are reviewed, faculty sponsors should also attend.

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4. The UNCG IRB will either approve or disapprove the study. **No data collection, recruitment or subjects, or other research activities can be conducted until approval of the IRB is obtained.** The IRB will notify faculty PI of the disposition of the application. For research proposed by students, the IRB notifies the faculty sponsor (rather than the student) of the disposition. It is the faculty sponsor's responsibility to notify the student of disposition of the application.

5. The PI provides a copy of the disposition notification to the UNCG IRB representative. When funding is sought, a copy should also be provided to the Director of Research. The PI should retain a copy of the disposition notification for his/her records.

6. IRB approval is valid for no more than a 1 year time period. Near the end of the year, the ORS will send the PI (or faculty sponsor, for student research) a renewal application. The renewal application must be completed and approved before the expiration date for research activities to continue. A study may be renewed up to 5 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 ORS.

B. Procedures for obtaining IRB approval for a **change** to an already approved study:

1. When a PI wishes to make a change to an already approved study, s/he completes an Application for Modification of an Approved IRB Protocol (available from the IRB web site <http://www.uncg.edu/rsh/orc/humanres.html>) and submits it to the School of Nursing IRB Representative. (See <http://www.uncg.edu/rsh/orc/IRBProceduresHumanSubjects.pdf> for more details on procedures.) If the study is funded, a copy should also be provided to the Director of Research. **The change cannot be implemented until approved by the IRB.**

2. The IRB will notify PI (or faculty sponsors, in the case of student research) of the disposition of the Application for Modification. The PI should provide a copy of the disposition notification to the UNCG IRB representative. For funded studies, a copy should also be provided to the Director of Research. The PI should retain a copy of the disposition notification for his/her records.

C. Procedures for Conducting a Study

1. Before beginning a study, all students, faculty, staff and consultants who will have access to data should sign a *School of Nursing Research Confidentiality Form*. If new workers are added to the study after inception, they must sign Confidentiality Forms before being allowed access to data. Each person involved in the studies must also complete the NIH/DHHS Office of Human Research Protection certification and provide a copy of the certification to the Principal Investigator and SON Research Office to be kept on file consistent with the approved protocol storage of materials. Certification and confidentiality forms for persons involved in NIH or other federal funded projects will be retained at least three years.

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2. Confidentiality forms, research records and signed consent forms from human subjects must be retained in a secure location for at least 3 years after completion of the study.

Faculty sponsors should retain records from research conducted by students. The records and consent forms must be available for review by the IRB or the Research and Scholarship Committee for data safety monitoring. If you need help securing your records after completion of a study, contact the Director of Research, who can assist with storage.

3. The Research and Scholarship Committee 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 subjects. The IRB may also conduct safety and compliance monitoring. *See the School of Nursing Data Safety Monitoring Guidelines*

4. The PI should notify the School of Nursing IRB Representative immediately if any injury or harm to subjects 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.

V. RESEARCH INVOLVING ANIMAL SUBJECTS

The Institutional Animal Care and Use Committee (IACUC) must review all plans for the use of animals in research prior to the beginning of the research. The IACUC must also review all revisions to research protocols before the changes are implemented.

Procedures for obtaining IACUC review for research are as follows:

1. The PI completes the Application for Research Animal Use, available from the site (<http://www.uncg.edu/rsh/orc/animalres.html>), or from Office of Research Compliance.

2. If funding is **not** sought for the study, the PI submits 2 copies of the Application to the School of Nursing IRB Representative. The School of Nursing IRB Representative will coordinate review by the UNCG IACUC. Retain one copy for your records. (See <http://www.uncg.edu/rsh/orc/animalres.html> for more details about procedures.)

If funding **will be** sought for the research, the PI submits a copy of the Application to the School of Nursing Director of Research. The Director will coordinate review of the application by the Research and Scholarship Committee. Once the Research and Scholarship Committee has approved the Application, the Director will notify the PI, who then submits 2 copies of the Application and Checklist to the School of Nursing IRB Representative. The School of Nursing IRB Representative will coordinate review by the UNCG IACUC. (See <http://www.uncg.edu/rsh/orc/animalres.html> for more details about procedures.)

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3. Follow other procedures as outlined above for human subjects. The IACUC, rather than the IRB, will provide oversight of studies involving animals. The roles of the Director of Research and the Research and Scholarship Committee will be the same as outlined above.

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