

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

**DATA SAFETY MONITORING GUIDELINES  
FOR HUMAN SUBJECTS RESEARCH**

In June 1998, the National Institutes of Health (NIH) issued a policy on data and safety monitoring (<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>) that requires oversight and monitoring of all intervention studies to ensure the safety of participants and the validity and integrity of the data. The policy further elaborates that monitoring should be commensurate with risks and with the size and complexity of the trials. While the NIH policy is specifically directed to clinical trials, a DSMB may be appropriate if the studies have multiple clinical sites, are blinded (masked), or employ particularly high-risk interventions or vulnerable populations. The UNCG School of Nursing includes data safety and monitoring as part of its commitment to assurance of human subjects protection in research. The guidelines also assist faculty, students and staff in the conduct of research.

Oversight within the SON does not replace or supersede the University Institutional Review Board (IRB) guidelines, the Food and Drug Administration (FDA) requirements, or special NIH /DHHS guidelines (e.g., NIH Guidelines for Research Involving Recombinant DNA Molecules.)

The Director of Research (DOR) in collaboration with the SON Research and Scholarship committee chair will coordinate data Safety and Monitoring activities. SON Research and Scholarship Committee members will conduct the reviews. In the event that SON committee members are not available due to conflict of interest, a designated faculty member from the SON or another academic unit on campus will be selected by the DOR to conduct the review. All persons conducting reviews must hold doctoral degrees and have written confirmation of OHRP/NIH Human Subjects Protection certification filed with the SON Research Office. The IRB representative or the DOR will provide an orientation, information and training session annually for reviewers.

At least 10% of active protocols will be reviewed annually; at least 50% of active funded projects will be reviewed. Studies that have been completed in the past three years are also subject to review. Protocols will be selected for review by the Director of Research. The DSM checklist will be used to review selected protocols.

Principal Investigators will be notified of the pending review in writing (paper or electronic) or by personal contact. Faculty sponsors (if PI is a student) will be notified and are responsible to notify the student, provide access to materials and ensure compliance with procedures. Investigators should be aware that prior notice is not required to conduct the reviews, but every effort will be made to avoid conflicts with investigator's required course and meeting schedules. Investigators are expected to cooperate fully and in a timely manner with the reviews.

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Investigators should plan for annual review of:

1. Signed consent forms, confidentiality forms, and data forms, and storage of those items according to the approved protocol.
2. Sampling plan, recruitment efforts, and subject accrual information.
3. Documentation of any adverse events, expected or unexpected.
4. Adherence to data collection procedures.
5. Review of data, databases, data points and analyses.
6. Personal contact with data sources (including agencies and individual subjects) by reviewers to verify compliance with procedures.

The checklist will be completed and a summary report be written by the review member and forwarded to the DOR. The DOR will discuss any deficiencies or concerns with the PI. A written summary of this discussion will be completed as part of the review report, as well as a written plan for removing or avoiding deficiencies. All reviews will be kept in a locked file in the SON Research Office.

Summary reports will be available to the SON UNCG IRB representative for review. Deficiencies will be reported to the UNCG IRB SON representative by the PI and the IRB representative to discuss plans of action. The DOR may provide reports to the IRB when the PI or IRB representative are not available in a timely manner or have not reported such to the IRB. The IRB may also request reports for any approved protocol.

The SON IRB representative or DOR may suspend any study until IRB notification has taken place and a plan for assurance of correction of deficiencies is approved. It is the responsibility of the PI, in consultation with the IRB and Office of Research Services, to notify a funding agency of deficiencies and the plan of action. The consultation and notification should be documented in writing and a copy filed with the DOR.

Review members will be required to maintain confidentiality for each protocol, associated data, subject contact and review findings. Reviewers must also avoid conflicts of interest with protocols and reviews.

If the PI has a concern that the review may cause or increase risks to human subjects, especially to confidentiality, the PI should notify the DOR or SON IRB representative prior to the initiation of the review. Assistance from the UNCG IRB and legal counsel will be sought to determine the most effective manner with which to conduct a review and remove or decrease any risk to subjects.