Duke School of Nursing Scientific Culture and Accountability Plan

The Duke School of Nursing (DUSON) is committed to upholding the highest standards of scientific integrity, and to ensuring that all faculty and staff engaged in research reflect the values of scientific integrity.

The Duke School of Nursing’s Scientific Culture and Accountability Plan (SCAP) reflects the following principles:

1) We foster an environment where scientific integrity is the highest priority.
2) We emphasize high-quality, reproducible data and results.
3) We value constructive critiques of research.
4) We encourage open discussion of any concerns regarding research conduct or integrity.

In order to implement the Duke School of Nursing’s SCAP, the following levels of responsibility will be detailed at the level of the Individual Investigator, the Center for Nursing Research Clinical Research Unit (CRU), and the School.

1) Individual Investigator

Faculty members engaged in research should review the following expectations and develop processes in compliance with the practices outlined below. Faculty investigators are responsible for the following:

- Regularly review your study data with your research team.
- Ensure that all original electronic data are stored in a designated location on the DUSON server.
- Ensure that paper records are stored as required by Duke policies, and in keeping with the approved Research Data Storage Plan (if applicable).
- Develop a standard process for documenting research data. All data entries should be made contemporaneous to the work, and should document both the recorder’s initials and date of entry.
- Maintain all research data in compliance with applicable regulatory guidelines: Health Insurance Portability and Accountability Act (HIPAA), Duke Institutional Review Board (IRB), Good Clinical Practice (GCP), and Duke policies and procedures.
- Utilize institutional resources, such as REDCap databases or electronic research notebooks (LabArchives) for non-PHI data, and other centralized infrastructures that electronically track changes in data elements.
- Maintain all instrument-generated raw data, record the instrument on which the data were generated, and document the date and time of collection. Maintain documentation of the routine monitoring and calibration of all laboratory equipment (if applicable).
- Engage biostatistics expertise at the beginning of the research project on study design and data analysis.
- Promote honest discussion of results. Emphasize data quality and a zero tolerance policy for data falsification or fabrication.
• Ensure all members of your study team feel comfortable voicing concerns about data integrity, and are familiar with available reporting options (e.g., reporting to Associate Dean for Research Development and Regulatory Affairs or calling the Integrity Line: 1-800-826-8109).
• Assure compliance with all Duke laboratory safety and training requirements.
• Ensure that Data Use Agreements or Material Transfer Agreement are completed through the Duke Office of Corporate Research Collaborations whenever data or materials are transferred to or from Duke.
• Faculty members who leave DUSON must meet with the Regulatory Oversight and Compliance Core in the CRU to ensure appropriate storage of records and transfer of data, if applicable.

2) Center for Nursing Research CRU
The administrative structure of the Center for Nursing Research CRU ensures that all clinical research staff are trained properly and adhere to regulations and good clinical practice related to the conduct of research. The Center for Nursing Research CRU leadership is responsible for the following activities:
• Approve all human subjects research prior to review by the Institutional Review Board.
• Hold monthly meetings with all clinical research staff to discuss updates on regulatory and administrative policies and procedures.
• Work closely with the Center for Nursing Research statistical core to ensure that all researchers have access to statistical support.
• Coordinate with the Duke Office of Corporate Research Collaborations on all Data Use Agreements or Material Transfer Agreements when transferring data or materials to or from Duke.
• Require all faculty and staff engaged in research to complete required Responsible Conduct of Research trainings. Require all faculty and staff on IRB protocols to complete required CITI human subjects credentialing.
• Conduct internal quality assurance monitoring in compliance with Duke policies.

3) School of Nursing Leadership
The Dean of the School of Nursing, the Associate Dean for Research Development and Regulatory Affairs, and the Associate Dean for Research Development and Data Science, provide active oversight for departmental research activities. They are ultimately responsible for ensuring compliance with the policies and procedures of the Center for Nursing Research CRU. DUSON leadership ensures a culture of scientific integrity through the following activities:
• Familiarize and facilitate access for researchers to various divisional and school research support services, including research development, statistical and regulatory guidance.
• Incorporating updates on regulatory and administrative processes into meetings and communications with faculty.
• Providing structure to address research integrity concerns:
Concerns regarding research misconduct by any faculty, staff or student must be promptly reported to the Associate Dean for Research Development and Regulatory Affairs to investigate the concerns and take appropriate actions.

Concerns about research misconduct may also be reported anonymously to the Integrity Line: 1-800-826-8109.