

DUKE SCHOOL OF NURSING SCIENTIFIC CULTURE AND ACCOUNTABILITY PLAN

The Duke University School of Nursing (DUSON) is committed to upholding the highest standards of scientific integrity and to ensuring that all faculty, staff and students engaged in research are aware of and following departmental and University policies and procedures put in place to reflect the values of scientific integrity.

Principles of 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.

Responsibility for Research Integrity

Scientific integrity is everyone's responsibility. Expectations are stratified below for individual investigators, the School of Nursing Clinical Research Unit (CRU), the Center for Nursing Research (CNR) and the School. These practices pertain to *Training and Education; Scientific Rigor and Reproducibility; Data Management, Storage and Provenance; and Communication*.

1) Individual Investigator

Investigators engaged in research and/or projects which require submission to the IRB (including exempt protocols) are responsible for the following:

- Fulfill Responsible Conduct of Research (RCR) and biomedical modules for Collaborative Institutional Training Initiative (CITI) training requirements. Student requirements may vary by academic level or program.
- Regularly review your research study data and management plans related to data storing and sharing with your research team (including your research mentor or advisor).
- Work with School of Nursing – Information Technology (SON-IT) to ensure that all original electronic data are stored in the designated approved, secure location on the DUSON server, or in the Protected Analytics Computing Environment (PACE) for data containing protected health information (PHI). Utilize the Honest Broker and Transfer Agent processes as applicable.
- Ensure that paper records are stored as required by Duke policies, and in keeping with the approved Research Data Storage Plan (if applicable) or Duke Research Data Lifecycle (DRDL).
- 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 other Duke policies and procedures, including required data entry into OnCore as applicable.
- Utilize institutional resources, such as REDCap databases or electronic research notebooks (e.g. 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.
- Regularly present research findings in open forums such as DUSON Research Interest Groups, Think tanks, Work-In-Progress groups, monthly Researcher Seminar Series, and around campus and the community.
- Provide results to research participants (return of results), as applicable, and develop a plan for this communication in advance.
- 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 the Vice Dean for Research and/or calling the Integrity Line: 1-800-826-8109).
- Assure compliance with all Duke Laboratory safety and training requirements.
- Promote credibility and transparency of the research by disclosing any financial or personal relationships through the Conflict-of-Interest process, and in your Other Support documents per agency requirements.
- Route Agreements such as Data Use and Material Transfer through the Duke Office of Research Contracts to ensure legal permission is in place for incoming or outgoing data use.
- Using MyResearchHome or other homepages, bookmark the Center for Nursing Research Hub for quick access to DUSON and University research policies and standard operating procedures.
- 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. Faculty members should refer to appropriate off-boarding checklists (available in the CNR Hub in Canvas)

2) School of Nursing CRU

The SON CRU is organized within the Center for Nursing Research and 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 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 Health Statistics and Data Science core to ensure that all researchers have access to statistical support.
- Coordinate with the Duke Office of Research Contracts 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 and/or projects which require submission to the IRB (including exempt projects) to complete the required Responsible Conduct of Research training courses.

- Provide oversight to ensure that investigators listed on IRB protocols have CITI human subjects credentialing.
- Conduct internal quality assurance monitoring and study audits in compliance with Duke policies.

3) School of Nursing Leadership

The Dean of the School of Nursing and the Vice Dean for Research (VDR) lead the School's research activities. They are ultimately responsible for promoting a culture of accountability and ensuring an environment that supports scientific integrity at the School of Nursing. The DUSON Research Quality Management Program (RQMP) team supports the Dean and VDR. It consists of a Research Quality Officer (RQO), a Lead Research Administrator (LRA), and various subject-matter expert delegates.

- Michael V. Relf, Dean
- Sharron Docherty, Vice Dean for Research

RQMP Team

- Staci Reynolds, Clinical Professor and CRU Director (RQO)
- Angie Keith, Vice Dean, Finance and Administration
- Jill Borland, Director, Research Administration (LRA)
- Carla Nichols, Director, Information Technology
- Caroline McEachern, Research Practice Manager
- Angel Barnes, Assistant Research Practice Manager
- Cam Sanders, Senior Clinical Research Coordinator

Culture of Research Integrity

Several resources are available to faculty, staff, and trainees in support of scientific culture and accountability.

- The CNR and Business Office provide services including pre- and post-award research administration, research development, health system data extraction, and statistical and regulatory guidance.
- All faculty conducting research are assigned a research mentor whose responsibilities include ensuring faculty have the training and resources to carry out the highest quality research.
- SON-IT provides services and access to secure data storage and can facilitate data storage management plans, as well as address data security concerns.
- The CNR sponsors Research Development workshops and provides a dedicated Canvas site for access to policies, procedures, templates, and services.
- Researchers can work with highly qualified Clinical Research Coordinators and Research Program Leaders under the direction of the Research Practice Manager and Assistant Research Practice Manager to ensure human subjects' compliance and best research practices.
- Faculty have access to resources for design such as (1) the Biomarker Lab and Biospecimen Repository directed by Julia Walker and (2) Health Innovation Lab directed by Ryan Shaw, a maker space and collaboration hub.
- In addition, Shila Nordone, Director of Scientific Development, is available to provide consultation and guidance to faculty related to methodological

and theoretical grant development.

DUSON implements its SCAP through a connected infrastructure of committees and strategic initiatives.

- Updates on regulatory and administrative processes come to faculty through the Faculty Governance Association and are distributed in various newsletters and blast announcements. The CNR Hub Canvas site serves as the repository for all policy, procedures, and changes related to regulatory and administrative issues.
- DUSON's Research Advisory Council meets quarterly and often reviews policies and procedures relevant to scientific integrity.
- The CNR will develop and deliver a bi-annual faculty research retreat for faculty and PhD students that discusses best practices for scientific integrity and responsible conduct of research.
- DUSON's RQMP committee meets as needed to review and deploy relevant information and concerns.

Addressing Research Integrity Concerns

DUSON seeks to foster a respectful and open environment for discussing research conduct and integrity. Members of the DUSON community are encouraged to raise any concerns.

Data integrity is not necessarily tied to scientific misconduct. Depending on the seriousness of concerns, individuals may reach out to the following (in order of escalation):

- Direct supervisor or mentor
- Division Chair
- CRU Director
- Vice Dean for Research
- Anonymous Duke Integrity Hotline (1-800-826-8109)
- Duke Office of Scientific Integrity (<https://dosi.duke.edu/>)

Scientific misconduct must be promptly reported to the Vice Dean for Research to investigate the concerns and take appropriate actions. For anonymous reporting, contact the Integrity Line: 1-800-826-8109.