Duke Aging Center
Duke University School of Medicine

Aging Center **S**cholarly **C**ulture and Accountability **P**lan (SCAP)

Guiding Principles

The primary goal of the Aging Center is to make significant research contributions to the study of aging and to educate future gerontologists and researchers in fields relevant to the study of aging. Research conducted by the >100 Duke Scientists and scholars from a multitude of disciplines includes multidisciplinary, biologic, clinical, and social and behavioral research. The resulting diversity in investigators and research activities necessitates the articulation and implementation of a plan to promote standards for research, including open, honest, and critical research-centered discussions among faculty, staff, trainees, and all others affiliated with Center research.

In alignment with the leadership of the Duke School of Medicine the Aging Center embraces these important 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 allow open discussion of any concerns regarding research conduct or integrity.

All faculty, trainees, and staff involved in research at any level are expected to adhere to the highest of ethical and professional standards. This includes maintaining an environment that fosters mutual respect and teamwork, honesty, accountability, and open inquiry. Principal Investigators are ultimately responsible for the quality of research produced by their teams, and the highest priority is placed upon the integrity of the science produced within the department.

Structural Organization

The Research Quality Team (RQT) is comprised of:

- Heather Whitson, MD, Research Quality Officer (RQO)
- Sara Patillo, MSHS, Assistant Research Quality Officer (aRQO)
- Heather Ellis, Lead Research Administrator (LRA)
- Sarah Peskoe, PhD, DMSP/SAP Officer
- Rebecca North, PhD, Assistant DMSP/SAP Officer

The RQO, aided by the Assistant RQO, has primary responsibility for addressing research integrity concerns, keeping research faculty and staff informed of relevant updates to institutional policies and procedures, assisting with Clinical Quality Management Plans (CQMP) and data management plans (DMP), and working with the Advancing Scientific Integrity, Services and Training (ASIST) Team to track research related training compliance.

Research administration is overseen by the LRA in conjunction with Research Administration Support Resource (RASR). The Aging Center Grants Team supports faculty members who are interested in submitting grant applications to federal, foundation, and institutions with the use of the Intent to Submit tool. Grant administrators and managers connect regularly with faculty and staff involved in funded research to address grant-related issues such as effort management, complying with both institutional and federal guidelines, and assistance with oversight responsibilities during the post award management and research project closeout process.

Questions related to Scientific Culture and/or Accountability, or anything related to scientific integrity may be directed to any member of this team at any time.

Promoting a Culture of Accountability

Education of faculty, staff, and trainees

1. All faculty and staff engaged in research in any way are required to participate in the relevant Responsible Conduct of Research (RCR) Program. For new faculty and staff, information related to institutional policies and procedures, as well as expectations related to scientific integrity and accountability are included in the on-boarding process. Unit-level training is conducted periodically and tailored as much as possible to each specific unit.
2. Changes to policies and procedures will be communicated to faculty and staff engaged in research regularly. This may occur at protocol or project meetings, or center-wide meetings depending on the material to be presented.
3. For Faculty and Staff pursuing grant funding, additional onboarding education and regular meetings with the grants team are conducted to ensure all parties are informed and accountable throughout the grant process.
4. Faculty and staff engaged in research are encouraged to participate in additional educational opportunities related to professional development and scientific integrity (e.g. offerings through the Duke University School of Medicine Office for Faculty Development or the Career Development Seminar Series offered by the Department of Medicine).

Scientific Rigor and Reproducibility

1. Communication

    a. Principal Investigators within the Aging Center are expected to be responsible for the integrity of their research and the conduct of those involved in their investigations. While trust among team members is important, a culture of honesty, accountability, and constructive criticism is also critical. PIs are expected to be role models of this behavior, and should support each other in this pursuit.

    b. Research-track trainees and junior faculty have formal mentoring teams, assigned through appointment letters and/or through sponsored projects (e.g., T32, career development awards). Each faculty meets regularly with their research mentors and at least annually with senior leadership to evaluate the quality and status of research accomplished to date. Formal mentoring plans incorporate all aspects of the conduct of research, including integrity and accountability.

2. Research Methods and Study Design

    a. A grant application committee consisting of three knowledgeable faculty members is currently available to review all DoD or NIH grant applications. Aging Center/Geriatrics mock study sections are convened approximately three times a year. A timeline for submission of grant materials under the auspices of this program is made available and investigators are encouraged to make use of the resource.

    b. Regular meetings are held at which investigators at all levels present and discuss projects currently in progress. The aim of these meeting is to garner critical feedback that addresses the progress of ongoing research, analytical plans and methods, as well as development of new forward-looking research ideas.

c. Research study design should ensure reproducibility. This includes establishing and adhering to Data Management and Sharing Plans beginning January 2023 per NIH mandate (see below) and creating a repository of methods protocols to be documented in the electronic lab notebook records and made available to all lab members, as described below. In appropriate study designs, randomization and masking of samples are essential to reduce selection bias and subsequent biases. Sample sizes are to be determined by power analysis. These measures allow reliable statistical testing and are critical, particularly to the interpretation of preclinical proof-of-concept studies. It is recommended that a second researcher or team in the lab be tasked to replicate pivotal experiments. As per NIH mandate, validation of resources such as mouse strains, cell lines, chemicals, and other reagents is essential and should be documented to ensure reproducibility.

3. Data Management, Storage, Provenance

a. All study teams are expected to create a Data Management and Sharing Plan (DMSP) describing how they will collect, process, manage, store, and potentially share data. These DMSPs should be reviewed and updated annually and submitted to the Aging Center DMSP/SAP Officer for review and archiving. This plan should address issues of roles & responsibilities of team members, training, research methods and data flow, data storage, organizational workflow, and data sharing. It is also understood that all team members are assigned duties based on their expertise and ability, and all understand their responsibilities as good data stewards.

b. A DMSP should be created for each clinical trial/study conducted within the department, along with a Statistical Analysis Plan. These should be made available for review as a 'locked' document upon request.

c. Assistance with preparing a DMSP is available from the Aging Center DMSP/SAP Officer, Duke/Medical Center Libraries, and the Duke Office of Scientific Integrity team for Advancing Scientific Integrity, Services, and Training.

d. All research data collected by research personnel or other authorized individuals from electronic sources, patients or other IRB-approved collection methods are stored in secure locations. Data transfers between PIs and team statisticians are securely conducted via REDCap or Duke Box. For activities deemed exempt by the IRB, data is either stored in Duke's Protected Analytics Computing Environment (PACE) or in designated, secure storage on Aging Center servers only accessible by departmental statisticians and IT personnel. Access to identifiable or limited data is strictly restricted to the study team members and managed by the Duke Institutional Review Board Office.

e. All data analyses conducted by the Aging Center's Data Science and Statistics Lab will be organized and thoroughly documented according to the lab's Standard Operating Procedures (SOPs) for electronic file structure (2022) and statistical programming (to be developed). This organized structure will facilitate any future requests of the analysis dataset for independent or other external post-hoc analyses of submitted and/or published results. Any edits to the analysis dataset after manuscript submission/publication will be thoroughly documented in the statistical programs with dates of edits clearly noted.

Voicing Concerns

a. Members of the Research Quality Team, especially the RQO and aRQO are available at any time to discuss any and all concerns from members of the research community. Raising a concern about research integrity is not equivalent to accusing someone of misconduct; only by raising and routinely responding to concerns related to

scientific integrity and establishing processes and a culture that encourage and supports ethical behavior can the highest standards of conduct become, in fact, standard.

b. Because all Aging Center faculty are required to have a faculty appointment in a Department, the Aging Center represents a complementary and alternative venue that our faculty may use for reporting concerns.
c. Other resources in the School of Medicine and the University are available for reference, assistance, and/or reporting of events, concerns or conflicts.

Research Integrity	Duke Office of Scientific Integrity: https://dosi.duke.edu	
	Anonymous Duke Integrity Hot Line: 1-800-826-8109. You do not need to leave a name and calls will not be traced. Or call Duke's Misconduct Review Officer: 919-668-5115	
Financial Conflicts of Interest	https://dosi.duke.edu/conflict-interest	
Human Subjects	DUHS	DUHS Institutional Review Board: https://irb.duhs.duke.edu/contact-us
	Campus Schools	Campus Institutional Review Board: https://campusirb.duke.edu/campus-institutional-review-board
Animal Subjects	Duke Animal Care and Use Program: https://sites.duke.edu/oawa/	
Workplace Environment	Occupational and Environmental Safety Office: https://www.safety.duke.edu/	
	Office for Institutional Equity: https://oie.duke.edu/	
Ombudspersons	University trainees	Undergraduate, Graduate, and Professional Students: Ada Gregory, 919-660-2444 or ada.gregory@duke.edu
	School of Medicine trainees	Student and Postdoctoral: Jean Spaulding, 919-668-3326 or ombudsman@mc.duke.edu
	Campus Faculty	Thomas B. Metzloff, 919-613-7055 or Metzloff@law.duke.edu
	School of Medicine Faculty	Laura Svetkey, 919-681-6386 or laura.svetkey@duke.edu