

Scholarly Culture and Accountability Plan

Duke University is committed to maintaining the highest quality and integrity of all its scientific enterprises. Because of this commitment, the School of Medicine is required to have mechanisms to guarantee the responsible management and critical review of scientific data. This is analogous to the School's obligation to ensure lab safety, proper clinical study procedures, and the appropriate use of animals in research.

The School of Medicine has created the Duke Office of Scientific Integrity (DOSI) to support individual departments in adopting and implementing policies and procedures related to best practices for scientific accountability and integrity.

Purpose

Under the School of Medicine (SOM), departments are responsible for maintaining implemented policies and procedures that promote scientific accountability and integrity. The Department of Family Medicine and Community Health (FMCH) is committed to a scholarly environment that fosters rigorous, innovative, ethical, and impactful research across a broad range of disciplines, spanning clinical, community, and population health programs.

Under the School of Medicine (SOM), individual departments are responsible for maintaining implemented policies and procedures that promote scientific accountability and integrity. The FMCH Clinical Research Unit (FMCH-CRU) supports the department's research enterprise by promoting scientific rigor and integrity, regulatory compliance, and responsible stewardship of research resources, including research data and records.

The purpose of the FMCH-CRU Scholarly (Science) Culture and Accountability Plan (SCAP) is to establish a code of conduct that documents the standards and practices within FMCH that foster scientific integrity through innovation, discovery, open communication, and supportive mentorship and training. The SCAP describes how FMCH-CRU promotes transparent practices, constructive scientific discussion, and routine critical review of methods, data, and conclusions. It also clarifies accountability across roles so responsibilities for data integrity and appropriate oversight of primary data are explicit, and questions about research quality can be raised and addressed promptly and fairly as part of normal scientific work.

How this SCAP is Used

This SCAP is intended to be read, discussed, and applied in day-to-day research work. It summarizes unit-level expectations that apply across FMCH research activities and describes the practices used to support data integrity, appropriate oversight, and timely escalation of concerns. Study-specific procedures (e.g., IRB submission steps and data security requirements) are implemented through FMCH-CRU processes and Duke-required systems and policies.

Implemented Practices to Support a Culture of Integrity and Accountability

Communication, forum, and meetings

- Conduct monthly research committee meetings for FMCH faculty and staff engaged in research. These meetings are a combination of scientific presentations by departmental researchers and a forum to disseminate and discuss updates on regulatory and administrative processes.
- Hold Thursday brown bag sessions, which include all full-time researchers and clinical faculty interested in research as a vehicle for announcing and discussing important issues relevant to this work, in conjunction with scientific presentations.
- Provide and distribute a monthly electronic newsletter with CRU, Duke Office of Clinical Research, and Duke School of Medicine news and updates to research faculty and staff.
- Individual research groups have regularly scheduled meetings to discuss study progress and review data.
- Journal clubs, research seminars, and retreats are held to encourage discussion of work conducted within the department and recent journal articles.
- The Vice Chair for Research meets regularly with individual faculty to discuss their research, including any scientific or ethical concerns.
- The CRU Research Practice Manager (RPM) conducts monthly meetings for research staff to provide education and updates on research standards and to provide a forum where research staff can raise questions or concerns.

Education and Training

- Provide onboarding for all new research faculty and staff.
- Ensure that faculty and scientific staff engaged in research are in compliance with required research training.

Quality oversight (CQMP and quality assurance)

- The CRU CQMP reviewer will conduct ongoing quality assurance reviews of current research studies. Studies are selected according to the Duke School of Medicine Clinical Quality Management Plans (CQMP) policy.

Clinical and Data Quality Management Plan

- The CRU team has developed a checklist to ensure that Data Use Agreements or Material Transfer Agreements are completed through the Duke Office of Corporate

Research Collaborations whenever incoming or outgoing PIs have data or materials transferred to or from Duke.

- The CRU team conducts a review of data storage or disposal within the department, focusing on ensuring the Research Data Security Plans are up-to-date and that sensitive information is stored or destroyed appropriately.

Scientific and Operational Support (Services and Resources)

- Faculty have access to PhD-level epidemiological statistical support by the FMCH CRU to assist with study design and statistical analysis for grant applications and publications.
- All new research protocols submitted to the IRB are reviewed by a senior faculty member and the CRU director to ensure they are scientifically feasible and investigators have appropriate expertise.
- FMCH provides pre- and post-study assistance to FMCH faculty who are predominantly clinical and/or educators to ensure research and scholarship are completed with the necessary rigor, ethics, and regulatory compliance.
- Research protocols involving primary care clinical practices are reviewed by the Primary Care Research Advisory Board for feasibility and scientific rigor. Members of this board include the FMCH CRU director, other FMCH research faculty, and primary care clinicians.
- A document describing guidelines for conducting research in clinical practices or community settings has been developed and disseminated to departmental faculty. This document focuses on the need for collaborative efforts between the researcher and stakeholders in the clinical or community organization, beginning with the planning of the research and continuing through the implementation of the project and dissemination of results.

Voicing Concerns and Reporting Channels

The FMCH-CRU promotes a professional environment where questions and concerns about research quality and data integrity can be raised without hesitation and addressed promptly and fairly. Concerns may be raised through more than one channel to avoid conflicts of interest, including unit leadership and independent Duke reporting pathways.

- Faculty and staff are reminded regularly of the School of Medicine Integrity Line, which allows for anonymous reporting of issues and concerns. Flyers and brochures from the Integrity Office are posted at faculty and staff workstations.
- The FMCH Escalation plan is readily available on the FMCH CRU webpage and is communicated via newsletter to all members of the CRU.

Useful Duke Resources for Discussing Concerns		
Research Integrity	Duke Office of Scientific Integrity: https://research.duke.edu/dos	
	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://myresearchpath.duke.edu/topics/conflict-interest	
Human Subjects	DUHS	DUHS Institutional Review Board: https://irb.duhs.duke.edu/contact-us
	Campus Schools	Campus Institutional Review Board: https://research.duke.edu/campusirb/
Animal Subjects	Duke Animal Care and Use Program: https://myresearchpath.duke.edu/topics/conduct-research-animals	
Workplace Environment	Occupational and Environmental Safety Office: https://www.safety.duke.edu	
	Office for Institutional Equity: https://oie.duke.edu/	
Ombudspersons https://ombuds.duke.edu/contacts/	University trainees	Undergraduate, Graduate, and Professional Students: Keegan Cary, 919-503-0917 or ombuds@duke.edu
	School of Medicine Trainees and Medical Students	Student and Postdoctoral: Jean Spaulding, 919-668-3326 or ombudsman@mc.duke.edu
	All Faculty and Staff	Jessica Kuchta-Miller, 919-864-1032 or Jessica.kuchtamiller@duke.edu

Evidence for the Collection of Signed SOPs for Wet Lab Research

Not applicable. Currently, there is no ongoing wet lab research within the department.

Applicability and Attestation

This SCAP applies to all FMCH research personnel (faculty, staff, trainees, and postdoctoral scholars) and is made readily accessible on the FMCH website and on the shared drive, which faculty and staff have access to.

Attestation to the FMCH-CRU SCAP is completed through Qualtrics in accordance with the School of Medicine DOSI requirements, including:

- Attestation within 90 days of hire.
- Re-attestation at a minimum every three years, with earlier re-attestation when substantive updates are made.

Maintenance and Reinforcement Practices

The FMCH-CRU SCAP is updated according to DOSI policy to ensure that research faculty and supporting scientific staff are aware of institutional policies and procedures and complete the required attestation.

In addition, FMCH-CRU reinforces awareness and use of the SCAP by making sure:

- The SCAP is reviewed and updated annually by the FMCH-CRU (if applicable)
- The SCAP is reviewed by faculty and staff engaged in research activities upon onboarding.
- The SCAP is reviewed during annual year-end performance evaluations or check-ins with faculty and staff engaged in research activities upon onboarding.
- The SCAP is made available on a shared drive that faculty and staff have access to.
- When substantive updates are made, the updates are communicated to faculty and staff engaged in research activities, and re-attestation is required.