Department of Population Health Sciences
Duke University School of Medicine

# DPHS Science Culture and Accountability Plan

Created: August 30, 2018
Updated: October 11, 2024

Duke University is committed to maintaining the highest quality and integrity of all its scientific enterprise. Because of this commitment, the School of Medicine (SOM) is required to have mechanisms to guarantee the responsible management and critical review of scientific data. The SOM has created the Advancing Scientific Integrity, Services and Training (ASIST) office to support individual departments in adopting and implementing policies and procedures related to best practices for scientific accountability and integrity. The Department of Population Health Sciences (DPHS) is committed to ensuring that departmental policies and procedures are in place to maintain the highest level of professional conduct—to promote a culture in which scientific results are critically reviewed, accountability for data integrity is clearly delineated, concerns can be brought forth without hesitation, and that there are mechanisms by which these concerns can be addressed fairly and expeditiously.

## I. Integrity in Research

When DPHS was founded, *integrity* was listed as the first of our key values that guide the work of the Department. Historically, this word has two important meanings:

- First is the notion of integrity as trustworthiness or moral uprightness; thus, we think of the integrity of the *scientist*. In DPHS, our faculty, staff, and students act in a way that earns the trust of their colleagues and the public.
- Second is the idea of integrity as referring to something that is structurally sound, cohesive, and robust; thus, we think of the integrity of the *science*. In DPHS, the integrity of our science is created through rigorous methods, transparent and reproducible datasets, and carefully drawn inferences.

DPHS structures, policies, and practices relevant to protecting and promoting both senses of *integrity* are described in this Science Culture and Accountability Plan (SCAP).

## II. Responsibility for Research Integrity within DPHS

### *Organization and Composition of DPHS*

The DPHS Leadership Team consists of the following members:

- Kevin Weinfurt, PhD, Professor and Interim Chair

- Hayden B. Bosworth, PhD, Professor and Vice Chair of Research
- Karen Steinhauser, PhD, Professor and Vice Chair for Faculty Affairs and Development
- Courtney Van Houtven, PhD, Professor and Chair of Appointments, Promotions, and Tenure (APT)
- Bryce Reeve, PhD, Professor and Director of the Center for Health Measurement
- Lauren Brinkley Rubenstein, PhD, Associate Professor and Vice Chair of Diversity, Equity, and Inclusion
- Asheley Skinner, PhD, Professor and Vice Chair of Education
- Suresh Balu, DPHS Strategy and Innovation Liaison, Associate Dean for Innovation and Partnership, School of Medicine
- Michael Fern, PhD, Chief Administrative Officer

DPHS is home to approximately 50 primary faculty, 50 secondary faculty, and 95 staff. DPHS houses faculty with doctoral training in epidemiology, public health, health services research and policy, implementation science, and related disciplines. Clinical faculty may have secondary appointments in the department.

At present, the Department is home to several research-related centers and labs:

The *Center for Health Measurement* employs multi-disciplinary research teams that conduct innovative patient-centered outcomes research bringing the voices of patients and caregivers more directly into care planning, treatment decisions, and health policy. Qualitative and quantitative methods include in-depth interviews, cognitive pretesting, psychometrics, latent variable modeling, and quantitative preference elicitation methods.

The *PopHealth DataShare,* a designated School of Medicine service center, maintains an extensive collection of research-ready, secure health care data including Medicare claims data repositories with nationally representative and geographic samples, disease-specific cohorts, Medicare linked to clinical data registries and EHR data, North Carolina Medicaid claims data, and the IBM Marketscan database. Access is provided through multiple data use agreements and our long-standing collaboration with the Center for Medicare and Medicaid Services (CMS) and the Research Data Assistance Center (ResDAC). PopHealth DataShare also provides access to tools and resources, education, regulatory support, analytics, and project management services.

The *Bioethics and Stakeholder Engagement (BASE) Lab* conducts empirical research to inform the planning, conduct, interpretation, and reporting of Duke University's clinical trials. The BASE Lab scientists partner with clinical investigators and key research stakeholders to 1) identify areas critical to the successful implementation of

clinical trials that can be strengthened with data from key research stakeholder groups, and 2) gather vital data through social science research with patients, research participants, communities, and other key stakeholders to use in decision making.

*QualCore* is a qualitative methods group consisting of doctorate-level and masters-level social scientists and research assistants in DHPS. Members provide scientific direction, methodological guidance, and interviewing and analysis expertise in qualitative research to faculty in the School of Medicine, to the Center for Health Measurement in DHS, and the Clinical Trials Transformation Initiative.

The *Implementation Science Research Collaborative (INTERACT) Core* is comprised of a team of multidisciplinary health services researchers, population health scientists, and research staff who use implementation designs and outcomes to create and adapt implementation research studies in order to improve the adoption and sustainment of evidence-based interventions, programs, and practices—then scale them locally, state-wide, and nationally.

The *Bellwether Collaborative for Health Justice* is an interdisciplinary research team with a shared goal of shining a light on how exposure to the criminal legal system drives multi-level inequity and is an integral component of structural racism. Our work draws on the expertise of people with lived expertise and multi-disciplinary academic and policy partners to inform innovative research that aims to eliminate health disparities and provide evidence of carceral harms that underscore the need for policy change and alternatives to punishment-oriented solutions.

The *Research to Eliminate Global Cancer Disparities (REGAL)* team aims to understand and address the underlying causes of cancer health disparities in the US and globally. They evaluate the relative and joint contributions of social determinants of health (e.g. healthcare access, socio-economic status, systemic racism) and molecular mechanisms that drive cancer mortality. Leveraging robust data from primary and secondary sources, high-quality biospecimen and molecular assay data, they utilize a *cell to society* framework to identify key factors that can be modified to eliminate racial disparities in cancer. The REGAL team includes junior faculty, post-docs, biostatisticians, project coordinators and grad students.

***Responsibility for Ensuring an Environment that Supports Integrity***

The DPHS Vice Chair for Research is responsible for ensuring that the environment within each entity supports the principles of research integrity. A research administrative coordinator supports the Vice Chair of Research & research activities,

including programmatic efforts to facilitate research within the Department, meeting institutional requirements such as the Research Quality Management Program, the Clinical Quality Management Program, and communications with both DPHS faculty and staff regarding research quality and integrity.

Primary responsibility for developing, maintaining, and updating this SCAP is also held by the Vice Chair for Research. Questions about or proposed changes to the SCAP are encouraged and can be directed to the current Vice Chair, Dr. Bosworth at hayden.bosworth@duke.edu.

## III. Promoting a Culture of Accountability within DPHS

### A. Education of DPHS Faculty, Students, and Staff

Several resources are available to faculty, staff, and trainees to help support an environment of scientific integrity.

- Education and training opportunities related to research integrity should be detailed annually in each staff member's performance evaluation and planning (PEP) and each trainee/faculty member's independent development program (IDP).
- Junior faculty will each have a mentor assigned to them, whose responsibilities include ensuring that the junior faculty member has the resources and training they need to conduct high quality work with integrity.
- All research faculty, staff, and trainees involved in research will fulfill the RCR training requirement for faculty and staff by completing one online, self-directed course (RCR 100) every three years and one collaborative, face-to-face program (RCR 200) every three years. https://dosi.duke.edu/RCR
- All research faculty, staff, and trainees involved in research must complete the Duke Health affiliated web-based biomedical modules within the Collaborative Institutional Training Initiative (CITI) for certification in Human Subject Protection (HSP) Training.
- Quarterly DPHS faculty meetings and faculty/staff/student Town Halls will have research as a standing topic to discuss tools, topics, and requirements related to research integrity.
- Faculty and staff are encouraged to attend the Duke Office of Clinical Research (DOCR) Research Wednesday sessions for updates on regulations/compliance, new tools for facilitating high quality research, and other topics germane to research integrity.
- DPHS holds monthly research staff meetings to disseminate updates and information via the DPHS Clinical Research Unit Research Practice Manager.
- DPHS requires all faculty and staff to attest to a Professionalism Plan.

### B. Recommended Practices to Promote Scientific Rigor and Reproducibility

*Research Methods and Study Design*

- In general, the value of research lies in the importance of the question and the quality of the answer, not in what the answer turns out to be. Members of DPHS should take pride in addressing problems of significance and in applying the most rigorous methods to arrive at an answer.
- Department researchers should engage collaborators appropriately, including statisticians and other relevant team members, for constructive input prior to research implementation (data collection, processing, and analysis).
- It is important that faculty reserve time for learning new approaches and tools to improve the quality of our research and the integrity with which we conduct it.

*Data Management, Storage, and Provenance*

- The Department has a zero-tolerance policy with respect to data manipulation, alteration or falsification.
- Principal investigators ensure implementation and maintenance policies for responsible data management within research groups, including mechanisms by which the validity and integrity of critical data generated by every team member can be confirmed.
- All research programs within the Department are expected to develop Data Management and Sharing Plans (DMSPs) on how to manage, process, store, and share data for their individual research programs.
- The PopHealth DataShare maintains an approved data management plan (per Duke Research Quality Management Program requirements).
- If possible, have multiple personnel perform data analyses so that no one person is alone in providing data or analysis.

*Communication*

- With respect to internal communications about research, research teams should regularly present their research findings to other investigators and teams outside their own group in a forum that allows open and critical discussion of the data and its analysis. Examples include participation in other research team meetings, regularly scheduled multi-disciplinary group meetings thematically organized around common research interests, DPHS work-in-progress research talks, monthly research seminars, brown-bag methods meetings, town halls, and faculty meetings.
- With respect to external communication about research, investigators are encouraged to undergo training for interacting with the media to help ensure that the results of DPHS research are communicated clearly to the public.

**C. Voicing Concerns**

DPHS seeks to create a respectful and inquisitive environment that welcomes constructive criticism of our research practices and open discussion of any concerns regarding research conduct or integrity. Faculty, staff, or trainees who have concerns regarding the integrity of any aspect of the Department's scientific work or of a Departmental research worker are encouraged to raise their concern. DPHS has provided explicit guidance on raising concerns in a Professionalism Plan, which all faculty and staff attest to when they join the Department.

Note that raising concerns about data integrity is not the same thing as accusing someone of scientific misconduct. It is the goal of DPHS, through implementation of the SCAP, to establish a culture in which it is common practice for all aspects of scientific research to be critically reviewed. This includes all steps in the scientific process, from study design to data acquisition to methods of analysis to the formulation of conclusions. Raising and responding to questions about data integrity should be a routine part of the critical review process; it should not be reserved solely for cases of suspected scientific misconduct.

The most appropriate person to whom concerns should be raised depends upon the parties involved and the seriousness of the concern, and are detailed in the DPHS Professionalism Plan and below (specific to research integrity concerns):

- Vice Chair for Research for DPHS (Hayden Bosworth, PhD)
- Anonymous Duke Integrity Hot Line (1-800-826-8109)
- Research Integrity Office (https://medschool.duke.edu/research/ethics-integrity- compliance/research- integrity-office)
- Occupational and Environmental Safety Office (https://www.safety.duke.edu/)
- The NIH Office of Research Integrity: (http://ori.dhhs.gov/)