**Duke Global Health Institute Science Culture and Accountability Plan
(DGHI SCAP) 2018**

Duke University is committed to maintaining the highest quality and integrity in all of 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.

We have created this Science Culture and Accountability Plan to give you – our faculty and staff – an overview of the way our unit operates and the underlying principles and expectations for the research process and research community interactions.

1. Guiding Principles

The Duke Global Health Institute (DGHI), established in 2006, brings knowledge from every corner of Duke University to bear on the most important global health issues of our time. DGHI was established as a University-wide institute to coordinate, support, and implement Duke's interdisciplinary research, education, and service activities related to global health. DGHI is committed to developing and employing new models of research and education that engage international partners and find innovative solutions to global health challenges. DGHI works to reduce health disparities in our local community and worldwide. Recognizing that many global health problems stem from economic, social, environmental, political, and health care inequalities, DGHI brings together interdisciplinary teams from across Duke's schools and programs to solve complex health problems and to train the next generation of global health leaders.

Our vision – academic excellence to meet the global health challenges of today and tomorrow to achieve health equity worldwide – can be achieved only when we conduct the highest caliber research with ethical rigor. We want to ensure that our faculty, staff and students have the resources and knowledge they need to do their work at these high standards. We take research integrity very seriously and believe research teams should constantly be engaging in discussions about research integrity and accountability.

In alignment with the leadership of the Duke School of Medicine and the Department of Medicine, DGHI 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.

2. Structure of DGHI within Duke

DGHI sits at the intersection of the campus and health system at Duke. From this unique perch, we have access to resources across the University. Duke University has two Institutional Review Boards (IRBs) and the choice of which is used for DGHI research protocols will depend on the primary appointment of the principal investigator and/or the nature of the human subjects research in question. Both IRBs are accredited and have Federalwide Assurance numbers (FWAs). Clinical Research Units (CRUs) and Oversight Organizations (OOs) are the operating business units responsible for the integrity, financial accountability, regulatory compliance, quality, and academic productivity of studies in the Duke Health System (DUHS) IRB. DGHI has an Oversight Organization for our investigators, and we are happy to work with study teams as they move through the IRB process, including ensuring that all research personnel receive proper training.

Many of our global health research projects involve international collaborators, and any such research protocol reviewed by the DUHS IRB will also be submitted for IRB/Ethics Committee approvals at our partnering institutions.

As DGHI personnel, you are required to know and follow the DUKE UNIVERSITY Statement of Ethical Principles and Code of Conduct: https://oarc.duke.edu/sites/default/files/documents/2016_Code%20of%20Conduct_statement%20of%20ethical%20principles_updated%20links.3.7.2017.pdf

Within DGHI, John Bartlett and Kelly Deal lead the Oversight Organization for DUHS IRB protocols and are available to answer your research questions. Duke Research Integrity Officers are also available for consultation and to assist with specific issues around research integrity. Research navigators, funded through NIH's Clinical and Translational Science Award program, are also available to assist you in finding research resources and answering questions.

- John Bartlett: john.bartlett@duke.edu / (919) 681-8043
- Kelly Deal: Kelly.deal@duke.edu / (919) 681-7159
- Duke Research Integrity Officers: dukecoi@dm.duke.edu / (919) 684-3121
- MyResearchNavigator: myresearchnavigators@duke.edu / (919) 684-2243, option 4

3. Promoting culture of accountability and respect

A. Education of faculty, students and staff

It is our goal at DGHI to infuse our thoughts and actions with the principles of respect, beneficence and justice as denoted in the Belmont report (1979). All of our teaching, mentoring, and working relationships should be free from coercion or harassment, and conducted with an understanding of, and sensitivity to, multiple cultural contexts. Relationships with our partners (within and outside of Duke, local and global) will be

respectful. We intend to engage in exchanges for mutual benefit, promote dialogues among equals, and listen to each other in a manner that promotes mutual trust and respect. Everyone involved in research is expected to complete required ethical trainings on a regular basis. Compliance is monitored by DGHI.

DGHI offers two degree programs (undergraduate co-major and minor in global health, and Master of Science in Global Health), which both include training in research ethics. Undergraduate co-majors and minors complete a semester-long course in global health ethics, which includes training in research ethics. This requirement must be met prior to engaging in the global health experiential learning activity. Masters students complete the Responsible Conduct of Research (RCR) training prior to starting the program, take a semester-long course in global health research ethics, and participate in a fieldwork preparation course that emphasizes skills that promote research accountability (e.g., communication, data management, quality control). All students conduct their research under the mentorship of a faculty principal investigator (PI), who is ultimately responsible for research integrity in the team.

B. Scientific rigor and reproducibility
These principles are the foundation of good research. DGHI and Duke University have many resources available to assist in the process.

1. Communication

Principal investigators should develop and clearly communicate good research practices and processes within their research group. They set an example for their team, emphasizing high quality research, without pressure or focus on obtaining specific results. Community engagement and dissemination of research results is an extremely important aspect of our global health work, involving not only the standard academic and scientific venues, but also our local and/or international partners.

2. Methods & design

Each research study's research methods and design should be rigorous and solidly based in your specific field of scientific training. If you have questions about methodology, please speak with an appropriate colleague (e.g. a member of DGHI's Research Design and Analysis Core). Whether you are discussing your work casually or presenting more formally, we encourage constructive criticism and lively debate.

3. Data management, storage, provenance

All data should be stored and appropriately indexed to allow access in the future. If you need assistance setting up your data collection, management or storage, please contact Patrick Daniels, DGHI's IT manager (patrick.daniels@duke.edu / 919-660-2401). He can further clarify these instructions and discuss other needs that might be specific to your project.

To be stored safely, health data should be stored on secure servers (protected data network [PDN] space – see section 5, "Data storage," at the end of this document for details).

For short term data storage and data transfer, Duke recommends using Box.com (Duke has a business associate agreement [BAA] with this company and it is approved for protected health information. See section 5, "Data storage," at the end of this document for details). If you have any questions about your choices, please contact Patrick Daniels for guidance.

The Duke Office of Clinical Research (DOCR) and the Duke Social Science Research Institute (SSRI) offer assistance (some free and some paid) for many data-related project tasks, including consultancies on data collection and data storage. When looking for appropriate research software, it is best to first consider companies with whom Duke has a BAA, such as RedCap or Qualtrics.

C. Voicing Concerns
Every individual engaged in research is responsible for familiarizing themselves with this plan and should conduct their research in a manner that is compatible with this plan. If you have concerns about anything, it is preferable to work within your research group if possible. Lapses in communication, or concerns about research integrity, can be brought forward to John Bartlett and/or Chris Tobias for discussion and problem-solving.
- John Bartlett: john.bartlett@duke.edu / (919) 681-8043
- Chris Tobias: Christine.tobias@duke.edu / (919) 684-0722

If you have concerns and are in any way uncomfortable contacting DGHI leadership, there are other ways at Duke to raise concerns:

- The School of Medicine uses IntegrityLine (1-800-826-8109) a service that can be used by anyone to anonymously express concerns about research integrity or professionalism.
- Duke Research Integrity: https://medschool.duke.edu/research/ethics-integrity-compliance/researchintegrity-office
- Occupational and Environmental Safety Office: https://www.safety.duke.edu/
- Duke Animal Care and Use Program: https://sites.duke.edu/oawa/
- Duke Clinical and Translational Research: https://medschool.duke.edu/research/clinical-and-translational-research
- Office for Institutional Equity: https://oie.duke.edu/

4. Additional resources at or beyond Duke:

Advancing Scientific Integrity, Services and Training Office: https://medschool.duke.edu/research/research-support-offices/advancing-scientific-integrity-services-and-training-office/scientific-culture-and-accountability

The Duke Faculty Handbook outlines Duke's Policies Related to Research and Research Misconduct:
https://provost.duke.edu/wp-content/uploads/FHB_App_P.pdf
https://medschool.duke.edu/research/ethics-integrity-compliance/misconduct-research

The School of Medicine now requires all faculty and staff engaged in research to participate in responsible conduct of research (RCR) education. RCR programs are also required for all graduate students and post-docs, and recipients of NIH training grants, a Research Ethics course is required for medical students during their 3rd year of scholarly research, and an RCR program is required for Duke undergraduate students supported by NSF or NIH research funding.
https://medschool.duke.edu/research/ethics-integrity-compliance/responsible-conduct-research-program

A research integrity session is included in the School's new faculty orientation.
https://medschool.duke.edu/about-us/faculty-resources/faculty-development/our-programs/new-faculty-orientation

MyRESEARCHhome is a customizable dashboard designed to guide researchers through the Duke research system with additional support provided by the Office of Research Initiatives. https://medschool.duke.edu/research/research-support-offices/office-research-informatics/myresearchhome

The School of Medicine and other Duke Schools have recently acquired iThenticate licenses for research faculty. Please contact asistoffice@duke.edu (if you are in the School of Medicine) or researchinitiatives@duke.edu (for other Schools) to inquire about licenses if you are interested in scanning manuscripts, grant applications, or thesis documents through this plagiarism detection software.

The Trent Center for Bioethics, Humanities, and History of Medicine teaches courses and provides consultation to Duke faculty, students, and staff in bioethics and research ethics. https://trentcenter.duke.edu/

The Office of Research Integrity within the Department of Health and Human Services maintains an active website on the scientific community and culture with current events, articles, and resources. https://ori.hhs.gov/

5. **Data storage:**

   Details for requesting PDN space:

   1) IRB or eIRB number or protocol for this project
   2) Preferred acronym for project
   3) Duration of the project, expiration of project plus number of years you need to keep data in archive

4) Storage space needed (min 20GB for initial project) (approx. $1/Gb/Year)
5) Fund code for the project (to pay for storage)
6) PI for project (this is the person who must approve access for additional personnel)
a) Point of contact for project, if not the PI
7) Personnel who need access (NetIDs please) (**NOTE:** Anyone who needs access should be listed on the IRB protocol.)
8) PI departmental affiliation
9) Brief description/summary of project
10) Type of data being collected (SSN, PHI, Education Record, etc)
11) Is a virtual machine (VM) needed for this project?
12) Confirmation that all project laptops used with this project are encrypted [this includes Duke hardware and non-Duke hardware]

For setting up Duke Box account for the project:

1) Project name (reasonably short acronym)
2) People needing access to space (name/email address and NetID)
3) Permission levels for access
4) IRB protocol associated with project, and IRB doc if available