

Scholarly Culture & Accountability Plan (SCAP)

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.

Under the School of Medicine (SOM) individual departments are tasked with developing policies and procedures to ensure scientific accountability and integrity. The Department of Head and Neck Surgery & Communication Sciences (HNS&CS) is committed to the development and implementation of a Scholarly Culture and Accountability Plan to ensure proper policies and procedures are in place to guarantee laboratory safety, proper basic science and clinical study procedures and the appropriate use of animals in research. These policies will reflect the highest professional conduct and promote a culture in which scientific review and data integrity is held to a higher level of accountability. The department will provide a mechanism in which concerns around scientific and data integrity can be reported and addressed.

The SOM recognizes scientific and data integrity expands across all levels from the department chairs to trainees and laboratory staff and that there is a need for training. HNS&CS strives to be a model for Scholarly Culture and Accountability within the SOM.

Principles

HNS&CS has prepared a Scholarly Culture & Accountability Plan following the guidelines provided. This plan embraces Best Practices in Research and details three levels of responsibility for promoting a culture that encourages responsible data management and produces data of the highest integrity – individual, division and department – and reflects these important principles:

- An environment where scientific integrity is paramount
- High-quality, reproducible data and results
- Constructive critiques of research
- Open discussions regarding research conduct or integrity

Every member of HNS&CS – faculty, trainees, staff and administrators – is expected to exemplify these values. The department has a shared commitment to the highest standards of science culture and accountability.

Questions or comments

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1. Improving the culture of scientific accountability within the research laboratory/program

The principles of scientific accountability apply to all levels of the research laboratory/program. Principal investigators within the research laboratory/program should discuss the expectations around data management, as well as scientific and data integrity with all members of the research team. Clear processes should be implemented in the research laboratory/program to monitor compliance with these policies.

- As a principal investigator, led by example and encourage scientific and data integrity through open and honest discussion of results. It is not about positive results but accurate results. There should be no encouragement or pressure placed on lab/program personnel to obtain specific results. The highest priority is scientific and data integrity through accurate results of all projects regardless of the perceived effect on the overall project, grant submission, or manuscript. There is a zero-tolerance policy with respect to data manipulation, alteration, or falsification.
- Place emphasis on high quality experimental design and engage appropriate collaborators, statisticians, and other relevant team members for constructive input prior to beginning experiments or clinical studies. Provide contacts to the appropriate resources in the department. Having well-defined study goals protects against fraud and improves the quality of results. Frame your research questions appropriately, allowing for negative and positive results to be interesting and useful to your lines of inquiry. Refrain from expectations that a particular result is more valuable than another. Plan for multiple methods, techniques, or analytic approaches for reproducing and comparing results from your experiments.
- Do not rely solely on trust and judgement of others. Examples exist where even the most seemingly trustworthy people have manipulated data. While you should trust and respect those you work with, scientific and data integrity should be reinforced with standard practices and processes instituted to ensure compliance. Cross-train lab personnel so that one person can independently verify the results of another, and so that no one person is alone in providing data or analysis.
- Implement policy to independently replicate study results within the laboratory/program. When applicable, develop an assay validation plan for routine assays. If possible, have different people perform experimental procedures (such as treating groups of mice with a drug) and experimental readouts (such as determining the phenotype of the treated mice). It is also good practice to require that persons assaying readouts be blinded to the experimental groups.
- Implement a policy of best practices with respect to research records, including basic laboratory notebooks or clinical research records. When possible, utilize electronic recording solutions that automatically record date and timestamps of entries and data changes. Provide resources to laboratory/program personnel on how to obtain access to university or departmentally supported software and electronic platforms. Develop a lab/program policy for entry into all research records or electronic platforms. Provide a policy clear to all lab/program personnel and ensure compliance. Incorporate regular reviews of research notebooks and electronic data when reviewing experiments or projects with laboratory/program personnel. Management may implement periodic audits of laboratory/program notebooks and electronic platforms to ensure proper level of documentation is provided for an experiment and would be acceptable for a third-party viewer. For clinical research, engage the HNS&CS CRU to ensure use and tracking of all

appropriate documents and maintenance in accordance with all regulatory and IRB requirements.

- Require all laboratory personnel to record in laboratory notebook or electronic platform specific instruments, location of equipment, date and time of use and analysis for any data that is generated by instruments, such as plate readers, scintillation counters, cameras, flow cytometers, etc. This is done to ensure matching the laboratory notebook or electronic platform with instrument-generated raw data and allows for frequent monitoring, calibration, and validation of all laboratory equipment use in generating research data.
- It is recommended that laboratory/program management implement competency training specific to the individual research laboratory or clinical research tasks.
- A procedure by which the raw instrument-generated data is permanently archived in a secure location that can only be accessed authorized personnel is required for all instrument generated data. This may include digital data transferred to the department's or other secure server, data burned to CDs, or hard copy printouts archived in an alternate location from the laboratory notebook. Data should be stored in an unalterable, read-only format. PIs will ensure laboratory personnel have access to the appropriate departmental servers. The U.S. Department of Health and Human Services requires that all project data be retained for at least 3 years after the funding period ends.
- Develop a plan with collaborators to ensure data integrity. For example, you may request a copy of the raw data generated by your collaborators for redundant archiving on the secure department server. Similar to data analysis performed for your laboratory-generated data, when possible, perform an independent analysis of data generated by collaborators to verify accuracy.
- Develop a plan for re-analysis of all critical studies, such as those included in grant or manuscript submissions, starting with the archived raw data. Consider including a person with the appropriate expertise outside the research laboratory. For clinical or translational studies, this can be accomplished by having study results independently analyzed by a statistician separate from the investigative team. Provide research personnel contacts for departmental resources such as biostatisticians, so they are easily accessible.
- Develop a process (e.g., PI notebook or electronic platform) in which you document critical results, the date you learned of them, your interpretation of these results, and conclusions or discoveries that these results imply. Additionally, document procedures you have taken to confirm the validity of the results, such as your own review of the raw data and your re-analysis and conclusions. These records will allow documentation of the intellectual progress of specific projects to develop future hypotheses or research plans, and if needed, to support intellectual property claims. In questions of data integrity, a laboratory notebook would serve to document that all critical studies were verified to the full extent possible.
- All individuals engaged in research will be required to complete online training modules, similar to those required by IACUC and the IRB, that emphasize these principles. The modules will be developed in the SOM. PIs or their designee will need to provide a list of training required to laboratory/program personnel. In addition, individuals should be encouraged to take advantage of programs offered through the SOM designed to address research integrity. Additional competency training for investigators and their research staff can include the current core curriculum from Duke Office of Clinical Research, i.e., Informed Consent Process, Study Documentation, Data Integrity and Security, and annual Human Subject Research Overview for clinical investigators. At a faculty level, participation in institutional programs such as LEADER will provide an opportunity for

further education in research management and oversight.

- Provide a mechanism in which anyone having concerns about the data integrity, analytic methods, or scientific misconduct, be it in your lab or someone else's, can comfortably voice their concerns. Raising concerns about data integrity is not the same thing as accusing someone of scientific misconduct. It is HNS&CS's goal, through implementation of the SCAP, to have a culture in which all aspects of scientific findings are critically reviewed becomes common practice. 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. Working through this process as a department will ensure the highest possible quality of scientific research at Duke.
- Develop a mechanism within the laboratory or research team to prevent misconduct and handle research- related complaints, reflecting a no-tolerance policy related to falsifying data, deceptive advertising, or enrollment of subjects not qualified to be in studies.
- If your laboratory/program engages in translational or 'omics' research, plan biannual discussions with your staff about the challenges inherent to that research. Review the existing and new resources available across Duke, especially those to make your research more reliable and transparent.

2. Recommended safeguards to ensure data integrity within the laboratory

All laboratories within HNS&CS should follow the key principles and steps outlined in this Scholarly Culture & Accountability Plan. Although the SCAP outlines the best practices with regards to scientific accountability, it is recognized that within each laboratory/program not all steps, or the same set of activities, may be appropriate. Laboratories/programs are encouraged to establish levels of accountable units to better interface with investigators and laboratory/program personnel.

- Laboratories/programs must ensure that all investigators and personnel engaged in scientific research complete all required institutional training modules in responsible conduct of research (RCR). These will be developed and monitored for compliance through central SOM resources, similar to the IRB modules required for studies involving human subjects.
- Laboratories/programs must ensure that all investigators implement and maintain policies for responsible data management within their labs or research groups. Laboratories/programs must also establish mechanisms by which the validity and integrity of critical data generated by every investigator can be confirmed. These mechanisms should not place an undue burden on the investigators but should ensure that investigators are adhering to policies of responsible data management. These policies should be reviewed at least once a year by the Vice Chair of Research or a delegate.
- Laboratories/programs must ensure that all investigators regularly present their research findings to other investigators outside their own lab or research group in a forum that allows open and critical discussion of the data and its analysis. Examples include participation in other lab meetings, regularly scheduled multi- disciplinary group meetings thematically organized around common research interests, or a divisional work- in-progress series. To monitor compliance, we suggest maintaining log sheets of faculty participation in these conferences.

- Review and follow best practices for data integrity and manuscript preparation as required by the top journals in your field(s).
- Vice Chair of Research is expected to confirm that each investigator is aware of the various school, department and division resources that support researchers and their activities, including access to statistician input and review of study design, analyses and publications.
- Vice Chair of Research is encouraged to require that faculty and staff complete the Data Integrity and Security class presented by DOCR, as appropriate.

3. Departmental efforts to promote a culture of scientific accountability.

HNS&CS leadership will also take steps to support, guide and ensure a culture of scientific integrity, including the actions listed below.

- HNS&CS Vice Chair of Research and Chief Administrative Officer will organize SCAP working group meetings with laboratory PIs and quarterly meetings with laboratory managers and staff to provide a forum for faculty and staff to raise any concerns about their research laboratory environment and findings from audits and IRB reviews, when needed.
- Work with the SOM to develop institutional policies and modules in training of responsible conduct of research and ensuring data integrity
- Work with all the Centers or Institutes in which faculty from HNS&CS reside to ensure alignment and integration with their programs of scientific accountability.
- Develop a mentorship program for new investigators that includes an emphasis on the principles outlined above. Strengthen the understanding that adhering to the SCAP principles is relevant to how we provide patient care and useful to future studies in humans.
- Confirm that each clinical research staff member takes the Human Subjects Research at Duke training course and annual recertification, as currently mandated by the SOM.
- Require each investigator with active IRB protocol(s) completes role-based training in Informed Consent Process, Data Integrity and Security and Study Documentation, as coordinated by the HNS&CS CRU.
- Promote the sharing of best practices regarding data integrity through a central resource of documents and materials available to all HNS&CS faculty and trainees. Provide software solutions, analytical support and other resources as appropriate.
- Validate the HNS&CS CRU's research data security plan in the IRB application.
- Develop training and resources regarding conflict of interest and implementation of material transfer agreements and data use agreements.
- Educate the faculty and staff of the Department about available resources and reporting mechanisms for scientific accountability, such as:
 - The NIH Office of Research Integrity <https://ori.hhs.gov>
 - Guidelines for the Proper Handling of Digital Image Data. *What's in a picture? The temptation of image manipulation* <https://rupress.org/JCB/article/166/1/11/34064/What-s-in-a-picture->

[The-temptation-of-image](#)

- Online Learning Tool for Research Integrity and Image Processing
<https://ori.hhs.gov/education/products/RlandImages/default.html>
- The Compliance and Fraud Hotline: To anonymously report a suspected compliance violation or concern, the Compliance and Fraud Hotline at Duke is at 800-849-9793.