

Science Culture & 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.

The School of Medicine has opted to allow individual departments to adopt their own policies and procedures related to scientific accountability and integrity. For this reason, the Department of Radiation Oncology is committed to ensuring that policies and procedures are in place to reflect the highest professional conduct and to promote a culture in which scientific results are critically reviewed with accountability for data integrity. Each laboratory maintains a Science Culture & Accountability Plan that is reviewed annually by the chair of the Department.

In the Department of Radiation Oncology, we recognize this requires the active participation of all parties in the research mission, all students, postdoctoral fellows, visiting scholars and staff are responsible for the documentation of all data generated in the process of performing research in their respective lab. In addition to being essential to the generation of scientific knowledge, proper data management is a laboratory practice that ensures reliability and reproducibility in all work.

Principles

Recognizing this, the Department of Radiation Oncology has prepared the following Science Culture & Accountability Plan. This plan promotes a culture that encourages responsible data management and produces data of the highest integrity and also reflects 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.

Each and every member of the Department of Radiation Oncology – faculty, trainees, staff and administrators – is expected to reflect and pursue these values. Ours is a shared commitment to the highest standards of scientific activity.

Recommended practices for improving the culture of scientific accountability within an individual laboratory:

It is expected that each faculty member will review the steps taken to comply with this policy at the annual review meeting with the chair of the Department.

- As a principal investigator, you must set the example for your team through honest and open discussion of results and through your emphasis on scientific integrity and data quality over positive results. Do not, in any way, encourage or put pressure on lab personnel to obtain specific results. Make it clear at all times that your highest priority is to obtain the

true result of all studies, irrespective of the effect such a result may have on the overall project, grant submission, or manuscript. Make it clear that you have a zero-tolerance policy with respect to data manipulation, alteration, or falsification.

- High-quality research begins with careful planning and study design. Engage appropriate collaborators, statisticians, and other relevant team members for constructive input before actual experiments or clinical studies begin. Having well-defined study goals protects against fraud and improves the quality of results. Frame your research questions in ways that test a hypothesis rather than “confirm” a result or model. This allows negative and positive results to be interesting and useful; that is, refrain from expectations that one type of result is more valuable than another. Plan for multiple methods, techniques or analytic approaches to test the same hypothesis or ask the same question, which will strengthen conclusions by comparing results using more than one approach for the experiments.
- Most of us rely on our trust in and judgment of others to ensure the integrity of our data. However, this alone is not sufficient. Examples exist where even the most seemingly trustworthy people have manipulated data. While you should continue to put your faith in others, you should reinforce this with specific practices and institute processes to ensure that your data is managed responsibly. Cross-train lab personnel whenever possible so that one lab member can independently verify the results of another. Primary data must be stored in a manner so that other scientists can independently analyze and generate data, so that scientific conclusions do not have to rely on a single person providing the analysis.
- 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. Ensure that entries are being made in a way that conforms to lab policy. Make this policy clear to all lab personnel and enforce it. We recommend you review people’s lab notebooks any time you meet with them to discuss data. Additionally, consider performing periodic audits of laboratory notebooks to ensure that a third-party reviewer would be satisfied with the level of documentation provided for an experiment. With regards to clinical research, maintain all appropriate documents in accordance with all regulatory and IRB requirements. Consider the implementation of competency training specific to individual lab or clinical research tasks.
- Rather than creating your own individual clinical research or laboratory database, consider leveraging institutional resources such as the Duke Biobank, REDCap databases, Pedigene or other similar centralized infrastructure that limits users, directly obtains input from source elements, and tracks all changes in the data elements or samples.
- For any data that is generated by instruments, such as plate readers, scintillation counters, cameras, flow cytometers, etc., require personnel to include the specific instrument, its location, and the date and time the analysis was performed in their lab notebook. This will make it easier to match the lab notebook with instrument-generated raw data. In addition, maintain frequent monitoring, calibration, and validation of all laboratory equipment.
- For any instrument-generated data, implement a procedure by which the raw instrument-generated data is permanently archived in a secure location that can only be accessed by you or a specific delegate. This may include digital data transferred to a secure server, data burned to CDs, or hard copy printouts archived in a place other than individual lab notebooks. Ideally, this data would be stored in a read-only format that could not be altered

once it is deposited. The Department of Radiation Oncology will provide server space for investigators to permanently maintain all raw/source data that becomes part of any published manuscript. 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 archiving in your own lab. Similar to data analysis performed for your laboratory-generated data, when possible, perform an independent analysis of data generated by collaborators to verify accuracy.
- To the extent possible, independently replicate study results. For example, 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.
- You or a designate should re-analyze all critical studies, such as those included in grant or manuscript submissions, starting with the archived raw data. You may consider including a person with the appropriate expertise outside your lab. For clinical or translational studies, this can be accomplished by having study results independently analyzed by a statistician separate from the investigative team.
- Develop a process 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. For example, when you meet with a lab member to review new data, the lab member can provide you with a dated version of the experiments and results, which you can keep in a separate notebook for each lab member. This notebook will serve to document your own review of the raw data. These records will not only allow you to document the intellectual progress of specific projects to develop future hypotheses or research plans, but also when needed, to support intellectual property claims. Furthermore, if questions of data integrity were to arise, such a notebook would serve to document that you reviewed all critical studies as the data were generated 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 Department and SOM will collaborate to develop these new modules). In addition, individuals should also take advantage of programs offered through the SOM that are 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 opportunity for further education in research management and oversight.
- If you have concerns about the integrity of someone's data, be it in your lab or someone else's, you should feel comfortable voicing your concerns. This is true whether you think a certain analytic method needs to be better validated or if you suspect scientific misconduct.
- Raising concerns about data integrity is not the same thing as accusing someone of scientific misconduct. The Department of Radiation Oncology wishes to promote a culture in which all aspects of scientific findings are 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 – in other words, it need not be reserved solely for cases of suspected scientific misconduct. It is through this process that we all can work together to ensure the highest possible quality of science at Duke.

- Have a mechanism in place within your 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 lab engages in translational or 'omics research, discuss with your staff involved in these studies the challenges inherent to this kind of research. Review the existing and new resources available across Duke, especially those to make your research more reliable and transparent.

Recommended safeguards to ensure data integrity within your lab

The Department of Radiation Oncology believes that the proper accountable unit for ensuring data integrity is each individual laboratory. For this reason, all labs within the Department of Radiation Oncology should follow the key principles and steps outlined in this Science Culture & Accountability Plan. Although this document outlines the best practices with regards to scientific accountability, we also recognize that within each lab not all steps, or the same set of activities, may be appropriate. Ultimately, the Department requires that the Faculty maintain evidence of compliance, as suggested below.

- Labs must ensure that all divisional investigators and personnel engaged in scientific research complete all required institutional training modules in responsible data management. These will be developed and monitored for compliance through central SOM resources, similar to the IRB modules required for studies involving human subjects.
- Labs must ensure that all investigators implement and maintain policies for responsible data management within their labs or research groups. Labs must also establish mechanisms by which the validity and integrity of critical data generated 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
- Labs 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 at the annual retreat of the Radiation Oncology & Imaging Program.
- Review and follow best practices for data integrity and manuscript preparation as required by the top journals in your field(s).
- Labs must identify a Laboratory Integrity Coordinator, to whom any concern or question about research data management can be taken by any individual inside or outside the lab.
- Lab managers are 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, analysis and publication.
- Labs are encouraged to require that faculty and staff complete the Data Integrity and Security class presented by DOCR or similar on-line module training as

appropriate.

- Encourage lab personnel to discuss any concerns they may have with the primary investigator or other investigators at Duke.

Departmental efforts to promote a culture of scientific accountability.

The Department of Radiation Oncology leadership will also take steps to support, guide and ensure a culture of scientific integrity, including the actions listed below.

- Outline a chain of persons available to address research integrity concerns. These individuals will be available to assist faculty and staff within the labs and will be ready to address potential concerns raised. Concerns should be raised and addressed initially to the departmental vice chair for basic and translational research, but in case of perceived conflict of interest, concerns may be raised directly with the chair.
- Work with the SOM to develop institutional policies and modules in training of responsible conduct of research and ensuring data integrity.
- 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.
- Institute unannounced research reviews to allow investigators to explain and demonstrate their processes and procedures for data integrity and analysis confirmation. Allow this to be a learning experience for the investigator, and share lessons learned with the rest of the department as appropriate.
- Confirm that each clinical research staff 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) to complete role-based training in Informed Consent Process, Data Integrity and Security and Study Documentation, as required for CITI certification.
- Develop and refine educational modules based on staff requests and findings from audits and IRB reviews, including a new series of “How To” vignettes as well as workshops and financial management training.
- Develop an annual competency evaluation of specific skills required for research roles.
- 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: <http://ori.hhs.gov/>
 - Guidelines for the Proper Handling of Digital Image Data: <http://jcb.rupress.org/content/166/1/11.full>
 - Online Learning Tool for Research Integrity and Image Processing: <http://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.