



Science Culture and Accountability Plan (SCAP)

Duke University is committed to maintaining the highest quality and integrity of all its scientific enterprises. Consistent with this commitment, the Duke Clinical Research Institute (DCRI) implements mechanisms to guarantee the responsible management and critical review of scientific data.

The DCRI 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 and accountability for data integrity is clearly delineated. In addition, Institute policies allow concerns about data integrity to be raised without fear of reprisal and are the foundation by which these concerns are addressed fairly and expeditiously.

At DCRI, we recognize this requires the active participation of all parties in the research mission, from faculty and staff to therapeutic area leaders and, ultimately, the Institute Director.

Principles

The DCRI's Science Culture and Accountability Plan (SCAP) details how we promote a culture that encourages responsible data management, produces data of the highest integrity, and reflects these important principles:

1. We foster an environment where scientific integrity is the highest priority
2. We emphasize high-quality, reproducible analyses and results
3. We value constructive critiques of research
4. We support open science, including allowing others to validate our findings

Every member of the Duke Clinical Research Institute – faculty, trainees, and staff – is expected to reflect and pursue these values. Ours is a shared commitment to the highest standards of scientific integrity.

Responsibility

1. Recommended practices for improving the culture of scientific accountability within individual research teams

The principles above establish our standards for ensuring data integrity and for maintaining compliance with the SCAP. Individual researchers should discuss these expectations with their teams, and develop actionable plans to monitor compliance with these policies.

- As a principal investigator, you 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 staff or other faculty 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 do not condone data manipulation, alteration, or falsification.
- High-quality research begins with careful planning and study design. Engage appropriate collaborators, including statisticians, and others with relevant expertise 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 allow negative and positive results to be interesting and useful to your lines of inquiry: that is, refrain from expectations that one type of result is more valuable than another. Plan for multiple methods, techniques or analytic approaches for reproducing and comparing results from your experiments.

- Most of us rely on our judgment of and trust in others to ensure the integrity of our data. However, this alone is not sufficient. Even the most seemingly trustworthy people have manipulated data. While you should continue to put your faith in others, you must reinforce this with specific practices and establish processes to ensure that your data is managed responsibly. Cross-train personnel so that one person can independently verify the results of another for studies in which results will be submitted to a regulatory authority (e.g. FDA).
- Implement a policy of best practices with respect to research records. When possible, use 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 international standards for data integrity, such as Good Clinical Practice. Make this policy clear to all personnel and enforce it. Request periodic audits to ensure that a third-party reviewer would be satisfied with the level of documentation provided for a study. Maintain all appropriate documents in accordance with the relevant regulatory and IRB requirements. Consider the implementation of competency training specific to individual tasks.
- Scientific data are a valuable resource. Rather than create a stand-alone research database, work with personnel who are skilled in data collection and management to create a database that has integrity: it identifies authorized users, directly obtains input from source elements, and tracks all changes in the data elements or samples.
- Develop a plan with collaborators to ensure data integrity. For example, request a copy of the raw data generated by your collaborators for archiving. When possible, perform an independent analysis of data generated by collaborators to verify accuracy.
- You or a designee should re-analyze all critical studies, such as those included in grant or manuscript submissions, starting with the archived raw data. A person who has the appropriate expertise and is not a member of your investigative team may be a good addition.
- If you have concerns about the integrity of someone's data, whether in your study 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 Duke Clinical Research Institute promotes 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 is a routine part of the critical review process: 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 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 who are not qualified to be in studies.



2. Recommended safeguards to ensure data integrity within your accountable unit

All Functional Groups, Key Research Programs, and business units ('accountable units') within the Duke Clinical Research Institute should follow the key principles outlined in this Science Culture and Accountability Plan. Within each accountable unit, not all steps, or the same set of activities, may be appropriate, and multiple accountable units may be required to fulfill research needs. Ultimately, the Duke Clinical Research Institute requires that the lead(s) of each accountable unit maintain evidence of compliance with the SCAP on behalf of their units, as outlined below.

- Accountable unit leaders must ensure that all investigators and personnel engaged in scientific research complete all required institutional training modules for the responsible management of data.
- Accountable units must ensure that all investigators implement and maintain policies for responsible data management within their research groups. Accountable units 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 or the accountable unit, 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 accountable unit lead, or an appropriate representative of the accountable unit lead.
- Accountable units must ensure that all investigators regularly present their research findings to other investigators outside their own research group in a forum that allows open and critical discussion of the data and its analysis. Examples include participation in other research group meetings, regularly scheduled multi-disciplinary group meetings that are organized around common research interests, or a therapeutic area work-in-progress series. In order to monitor compliance, we suggest maintaining record 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).
- Report any concern or question about research data management to the Duke Clinical Research Institute Quality Assurance group.
- Accountable unit leaders must confirm that each investigator is aware of the various resources that support researchers and their activities, including access to statistician input and review of study design, analysis and publication.
- Accountable units are encouraged to require that faculty and staff complete training in data integrity and security, as appropriate.

3. Duke Clinical Research Institute efforts to promote a culture of scientific accountability

The Duke Clinical Research Institute leadership will also take steps to support, guide, and ensure a culture of scientific integrity, including, but not limited to, 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 therapeutic areas and domains and will be ready to address potential concerns raised from outside the research group. Concerns should be raised and addressed initially to a therapeutic area leader, but in case of real or perceived



conflict of interest, concerns may be raised to an Associate Faculty Director or the Duke Clinical Research Institute Director.

- Work with all the departments and divisions in which faculty from the Duke Clinical Research Institute reside to ensure alignment and integration with their programs of scientific accountability. Hold regular Executive Quality Council (EQC) meetings to oversee quality at the highest levels of DCRI.
- Ensure the Duke Clinical Research Institute Quality Assurance group implements and enforces appropriate SOPs and conducts routine audits (current practice).
- Establish a team of functional Quality Managers to ensure SOP and Regulatory compliance and facilitate a culture of first time quality.
- Seek opportunities to share best practices broadly across the organization, such as in our Ops Symposium, Quality Matters Forum, and other cross functional communication forums.
- Ensure coordination with the University's Chief Compliance Officer (current practice).
- Maintain statisticians' independence from PIs on projects to promote data integrity and audit protection (current practice).
- Ensure that all data analyses are conducted by statisticians who are independent from project PIs (current practice, see attached sample SOP list related to data handling and data analysis).
- Ensure our mentorship program for new investigators 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 is useful to future studies in humans.
- Institute project 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 organization, as appropriate.
- Confirm that each member of the clinical research staff takes the Good Clinical Practice training and periodic recertification, as currently mandated by the School of Medicine.
- Require each investigator with active IRB protocol(s) to complete Human Subjects Protection training, as well as Data Integrity and Security, and Study Documentation training, as appropriate and as coordinated by the Clinical Research Unit.
- 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.
- Require Responsible Conduct of Research training, with evaluation every three years for research roles. (current practice)
- Promote the sharing of best practices regarding data integrity through a central resource of documents and materials available to all DCRI faculty and trainees. Provide software solutions, analytical support and other resources as appropriate.
- Educate the faculty and staff of the Institute about available resources and reporting mechanisms for scientific accountability, such as:
 - The NIH Office of Research Integrity (<http://ori.dhhs.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, call the Compliance and Fraud Hotline at Duke, 800-849-9793.



Change History:	Revised 1 March 2019
Revised language in Section 1 under 'Responsibility' to more specifically reflect DCRI practices.	
Updated phrasing in Section 2 under 'Responsibility' from 'research domain' to 'accountable unit'.	
Updated Section 3 under 'Responsibility' to reflect opportunities and trainings available and/or applicable to DCRI faculty and staff.	