Research Quality & Data Integrity Review

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This is a self-assessment tool for Department of Medicine investigators. Use it to evaluate how well you and your research team are following the guidelines of the Science Culture and Accountability Plan.

Background

The Department of Medicine **Science Culture & Accountability Plan** (DOM-SCAP) sets expectations and provides recommendations for how department administrators, division leaders, and individual investigators can guarantee the responsible management and critical review of scientific data.

The DOM-SCAP 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 encourage open discussion of any concerns regarding research conduct or integrity.

Each member of the Department of Medicine — 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. Compliance with established policies that result in research excellence is our fundamental goal.

Download the DOM-SCAP document (file is stored on Duke Box; login with NetID required).

Annual assessment

The **Research Quality & Data Integrity Review** is a self-assessment form. Use it to evaluate how well your research team reflects the principles and guidelines of the DOM-SCAP.

The Department of Medicine requires each faculty investigator engaged in any research, including laboratory based or clinical, to complete the Research Quality & Data Integrity Review once each calendar year. Any investigator who serves as a PI of an IRB study or as PI of a laboratory based research group is expected to complete this survey and use this tool to enhance your research processes.

Before completing this form, you should engage the members of your research team to discuss how well you are protecting the integrity of the research process and its results.

How will the assessment data be used?

Upon submission, results of the form will be sent to you by email. Please save the confirmation message for your records.

Department leaders will review data collected through this review in order to identify your best practices, the resources you still need, and other requests that can be used by the School of Medicine and Duke University Health System to better support the research mission of the insitution.

The results also will be used by the vice chair for research to benchmark how well the Department meets the DOM-SCAP expectations.

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About you

Please provide the following information about yourself.

Your name *

Title First Last Suffix

Your email address

Your division *

Please select your division

Are you engaged in basic, translational or clinical research in the Department of Medicine? *

(•) Yes ( ) No

Your research focus

- [ ] Basic science
- [ ] Clinical science
- [ ] Translational or -omics

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Standard Operating Procedures

The Department of Medicine expects every investigator to develop a written Standard Operating Procedures (SOP) document for guiding data management in a laboratory or research team, specific to the needs of the respective research program.

If you engage in basic research, the expectation is that you have documented SOPs for the management of data in your lab.

Example SOP: Raphael Valdivia, Vice Dean for Basic Science, has provided an example of a data management SOP for his laboratory.

If you engage in clinical research, the expectation is that you are following the principles and standards of Good Clinical Practice (GCP) and have documented SOPs for the management of study data.

Good Clinical Practice checklist: A checklist of items relevant to ensuring adherence to GCP is available on the DOM website as a general guide. Some items on this checklist may not apply to your specific line of clinical investigation.

Investigators are expected to review the SOP with every new trainee and staff member, and have them sign and date a record of their review of the document (as is done for most lab SOPs).

Do you have an SOP for data management? *

- (•) Yes
- ( ) No

Attach a copy of your SOP.

Choose File No file chosen

Attach a copy of a second SOP.

Choose File No file chosen

Annual DOM-SCAP review with research team

It is the policy of the Department of Medicine that the DOM-SCAP be reviewed with all personnel engaged in support of your research on an annual basis. This is often best accomplished by the lead investigator reviewing the policy at a regularly scheduled research meeting. Please attach documentation demonstrating how you have accomplished this objective, including date, time, and the names of those present.

Have you reviewed the DOM-SCAP with your research team within the last 12 months? *

- (•) Yes
- ( ) No

Please attach a record of your DOM-SCAP review history.

Choose File No file chosen

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PI expectation setting

The primary investigator, or faculty lead, of a research program is expected to set the example for the entire team through honest and open discussion of results and through your emphasis on scientific integrity and data quality over positive results.

My highest priority is to obtain the true result of all studies, irrespective of the effect such results may have on the overall project, grant submission, or manuscript.

- ○ I agree
- ○ I disagree

Evaluate the following statements.

	1 – Never	2 – Some of the time	3 – As often as possible	4 – All the time
I promote honest and open discussions about research processes, results and analyses.	○ 1	○ 2	○ 3	○ 4
I emphasize scientific integrity and data quality.	○ 1	○ 2	○ 3	○ 4
I encourage senior members to make it clear that everyone's highest priority is to obtain true results, irrespective of the effect on the overall project.	○ 1	○ 2	○ 3	○ 4
I promote a zero tolerance policy with respect to data manipulation, alteration, or falsification.	○ 1	○ 2	○ 3	○ 4

Comments

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Planning and Design

High-quality research begins with careful planning and study design.

How often do you do the following?

	1 - Never	2 - Some of the time	3 - As often as possible	4 - All the time
I engage appropriate collaborators, statisticians, and other relevant team members for constructive input before actual experiments or clinical studies begin.	1	2	3	4
I develop well-defined study goals.	1	2	3	4
I plan for multiple methods, techniques or analytic approaches for reproducing and comparing results from my experiments.	1	2	3	4
I frame research questions in ways that allow negative and positive results to be interesting and useful.	1	2	3	4

Comments

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Integrity of Data

Most of us rely on our trust and judgment in others to ensure the integrity of our research. 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.

I have instituted processes to ensure that research data is managed in a manner consistent with DOM-SCAP principles.

○ Yes ○ No

How often do you do the following?

	1 - Never	2 - Some of the time	3 - As often as possible	4 - All the time
I cross-train personnel so that no single person is solely providing data or analysis.	○ 1	○ 2	○ 3	○ 4
I cross-train personnel so that one person can independently verify the results of another.	○ 1	○ 2	○ 3	○ 4

Whenever possible, do you employ blinding in your research methods?

○ Yes ○ No ○ N/A

Research Records

Implementing a policy of best practices with respect to research records, including basic laboratory notebooks or clinical research records is an important safeguard.

I have implemented a policy of best practices with respect to research records, including basic laboratory notebooks or clinical research records.

○ Yes ○ No

My research program uses an electronic recording solution that automatically records date and timestamps of entries and data changes.

Yes No N/A

What electronic data recording product or system do you use?

How often do you do the following?

	1 - Never	2 - Some of the time	3 - As often as possible	4 - All the time
I communicate best practices to all lab members.	1	2	3	4

Which of the following data repositories do you use to store your research data?

- Duke Biobank
- REDCap database
- PEDIGENE
- Other

If you do not use a shared data repository, why not? What impediments do you find in doing so, and what steps would you recommend the DOM follow to ensure that shared resources are fully implemented?

Research notebook

Develop a process (e.g. PI notebook) in which you record critical results, interpretations, conclusions or discoveries. This will allow you to document the intellectual progress of specific projects to develop future hypotheses or research plans, and if needed, to support intellectual property claims. Furthermore, if questions of data integrity were to arise, such a notebook would serve to document that you verified all critical studies to the full extent possible.

I have a process in which I document critical results, the date I learn them, my interpretation of these results, and conclusions or discoveries that these results imply.

Yes No

I document procedures that I have taken to confirm the validity of my team's results, such as a review of the raw data and re-analysis and conclusions.

Yes No

How well are the research notebooks or electronic folders for your research team updated?

	1 - Never	2 - Some of the time	3 - As often as possible	4 - All the time
Title is descriptive in nature.	1	2	3	4
Date is clearly stated.	1	2	3	4
Objectives include rationale, questions to be asked, anticipated results.	1	2	3	4
Plan includes experimental outlines, controls, analysis, etc.	1	2	3	4
Results includes summary, discussion, links to data, etc.	1	2	3	4
Conclusions include assessment and next steps based on the results.	1	2	3	4
Group meetings include presentation of research objectives and findings, including documentation of the meeting and discussion .	1	2	3	4
Retention of publications and manuscripts reflects the research and data noted above.	1	2	3	4

Instrumentation

For any data that is generated by instruments, such as plate readers, scintillation counters, cameras, flow cytometers, etc., require personnel to document in their lab notebooks the specific instrument, its location, and the date and time the analysis was performed. This will make it easier to match the lab notebook with instrument-generated raw data. In addition.

I require personnel to note instrument information (name, location, date and time of analysis) when recording any data that is generated by instruments.

Yes No N/A

How well do you do the following?

	1 - Never	2 - Some of the time	3 - As often as possible	4 - All the time	N/A
Maintain frequent monitoring, calibration, and validation of all laboratory equipment	○ 1	○ 2	○ 3	○ 4	○ 5
Review lab notebooks to confirm personnel are noting instrument information as required.	○ 1	○ 2	○ 3	○ 4	○ 5

I have implemented a procedure to permanently and securely archive raw data generated by an instrument that can only be accessed by me or a delegate.

○ Yes ○ No ○ N/A

Comments

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Collaboration

When collaborating with investigators outside of one's own research program, developing a plan for collecting, managing and vetting data with and among collaborators is principal to ensuring data integrity.

I request a copy of the raw data generated by my collaborators for archiving in my own program.

Yes No N/A

When possible, I perform an independent analysis of data generated by collaborators to verify accuracy.

Yes No N/A

Replication

Independent replication of experiments or trials is highly recommended.

How often do you do the following?

	1 – Never	2 – Some of the time	3 – As often as possible	4 – All the time	N/A
I request an independent analysis of results from basic science studies by a person with the appropriate expertise outside my lab.	1	2	3	4	5
I request an independent analysis of results from clinical or translational studies by a statistician separate from the investigative team.	1	2	3	4	5

Comments

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Regulatory and training

As in investigator, is is important that you are current with all compliance training in the institution. In addition to required regulatory modules such as IACUC and IRB, 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.

Are you current with all required training?

○ Yes ○ No

Have you completed the LEADER program in the School of Medicine?

○ Yes ○ No

How often do you do the following?

	1 - Never	2 - Some of the time	3 - As often as possible	4 - All the time	N/A
I confirm that members of my research team are current with their required training.	○ 1	○ 2	○ 3	○ 4	○ 5
I encourage lab personnel to complete additional competency training such as current core curriculum from Duke Office of Clinical Research.	○ 1	○ 2	○ 3	○ 4	○ 5

Voicing concerns

Raising concerns about data integrity is not the same as accusing someone of scientific misconduct. The Department of Medicine 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. It is through this process that we all can work together to ensure the highest possible quality of science at Duke.

Do you have a mechanism in place within your program to address allegations of perceived misconduct?

- ○ Yes
- ○ No

Do you encourage your personnel to contact the division's research integrity coordinator with their questions and concerns if they are not comfortable coming to you?

- ○ Yes
- ○ No

Comments

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Final thoughts

Summarize your recommendations as to what the Department of Medicine may do to further support your research efforts and compliance with Department of Medicine and School of Medicine policies regarding data management and scientific integrity.

Add your suggestions