

University Senate Research and Graduate & Professional Education Committee Members (RGPEC) Response to Charge S-2201-1: Approved Electronic Notebook Programs

A. Charge

Charge Number S-2201-1

Title	Approved Electronic Notebook Programs
Description	Investigate the use of electronic lab notebooks. Review the current policies and practice of notebook creation and cloud storage.

Recommend the best practices for maintaining the security, integrity, and accessibility of these notebooks.

B. Consultants to this Charge Report

Mike DiLalo, IT Services, Center for Advanced Biotechnology and Medicine Shawn Rumrill, Graduate Student, Center for Advanced Biotechnology and Medicine Dr. Michael Zwick, Senior Vice President for Research

C. Background

The active charge titled "Approved Electronic Notebook Programs" falls under the broader Data Management and Sharing Plans (DSP) category. According to the <u>National Institutes of</u> <u>Health</u>, data management is the "process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the data for its users." Good data management and sharing practices ensure the acceleration of biomedical research, including the discovery of novel drugs or pathways or the development of new medical devices that save countless lives worldwide. As noted below, there are several benefits to adopting the DSP:

- Conducting efficient research
- Accelerates research
- Enhances rigor and reproducibility while maintaining research integrity
- Preservation of data in the long term for future research
- Provides broad access to data
- Enhances transparency
- Ensures consistent and accurate use of data

In short, an effective DSP allows the sharing of scientific data that "expedites the translation of research results into knowledge, products, and procedures to improve human health" (<u>NIH</u> <u>Data Sharing Plans</u>).

Starting January 25, 2023, <u>NIH's new DMS policy</u> was enacted. The new policy has two requirements for all NIH-sponsored research generating scientific data. The NIH considers "scientific data" to be any data that validates or replicates research findings, whether they are used to support the scholarly publication. The following are the two requirements of the new DMS policy:

- 1. Submit a Data Management and Sharing (DMS) Plan outlining how scientific data and any accompanying metadata will be managed and shared, considering any potential restrictions or limitations.
- 2. Compliance with the Plan approved by the funding NIH Institute, Center, or Office.

Before January 25, 2023, DMS was mandated for large research grants, i.e., grants receiving over \$500,000 in direct costs. Moreover, research that generated large-scale genomic data is also needed to describe their DMS plans. The previous policy asked researchers to include a DSP plan within their application to outline how the data would be shared, primarily summarized in one paragraph. In contrast, the new DSP clearly outlines several elements that need to be addressed in the DMS plan in a 2-page document. These elements include (1) data type, (2) related tools, software, and code, (3) standards (applied to the scientific data), (4) data preservation, access, and associated timelines, (5) access, distribution, or reuse considerations, and (6) oversight of DMS. More detailed information about each element and sample DMS plans can be found on the NIH's website. The new NIH DMS policy will significantly impact the research community. Failure to comply could result in additional terms and conditions on a researcher's grant, termination of the grant, and inability to obtain future grants from the NIH.

D. Discussion

In response to charge S-2201-1, the Research and Graduate and Professional Education Committee (RGPEC) investigated the currently available and/or adopted DMS plans at Rutgers University.

The committee found a research guide on data management provided by the <u>Rutgers</u> <u>University Libraries</u>. The guide is modeled on the data management guides available at <u>MIT</u> <u>Libraries</u> and the <u>University of Minnesota Libraries</u>. The guide explains different steps in creating a sound and efficient DMS plan, including ethical and legal guidelines that researchers and scientists must be aware of and abide by. While the guide is an excellent first step, the contained information can be exhausting for researchers and scientists, especially for implementation purposes. Consistent DMS policies throughout the university would be better supported with standardized procedures and simple-to-use data management software tools.

An efficient DMS plan is heavily dependent on data preservation and data storage. Currently, Rutgers provides three cloud storage services: Box, Microsoft OneDrive, and Google Drive. In 2019, the university switched from Dropbox to Box for storing, accessing, and sharing files securely. A comparison of three cloud storage solutions can be accessed here. The committee found that each cloud service has limitations, especially concerning the sensitive nature of the research involving human participants and HIPPA regulation, which still needs to be clarified. In addition to cloud storage solutions described above, scientific data is stored in network servers, which vary from school, department, and lab. While the university recommends keeping all scientific data in the Box folder, there needs to be more ensuring and enforcing compliance to safeguard data. Moreover, switching between different cloud storage solutions every few years creates further complications, leading to possible data loss. This is because every department and school does not have the support of a dedicated information technology (IT) professional, creating difficulties in communication, expectations, and efficient data migration. In light of the new NIH's DMS policy, the Office of Research, Office of Information Technology, and University Libraries have already developed a working group to "develop short-term and long-term plans including information and contacts to assist with scientific data management, storage, and accessibility" (https://research.rutgers.edu/data-management-sharing-policy-2023). After contacting multiple stakeholders, including graduate students and faculty, the committee found no record of emails sent to the stakeholders, which are crucial in producing scientific data. A similar issue was found with the webinar event that focused on DMPTool for writing data management plans, organized by the Rutgers Research and Sponsored Programs. The committee identified a growing concern among graduate students and faculty, where participation of these two key stakeholders is missing in issues that directly impact them. The committee found a need to improve the communication between the crucial stakeholders and the University leadership involved in making decisions related to DMS.

One of the significant parts of the DMS plans is the organization of scientific research data in paper-based or electronic notebooks. Paper-based notebooks have various limitations, including maintenance, storage, sharing, and the inability to search based on indexing. Electronic lab notebooks (ELN) offer several advantages over paper-based systems, such as data organization, sharing, flexibility to add different kinds of data, storage, and accessibility. They are environmentally friendly as they replace traditionally paper-intensive documentation and storage. The committee found that the university needs to provide access to ELNs. The only exception is the Center for Advanced Biotechnology and Medicine, which allows full access to the LabArchives ELN after testing multiple ELNs (Rspace, LabGuru, and SciNote). The committee found that LabArchives has been adopted as the ELN by several universities and institutes, including California Institute of Technology, University of Pennsylvania, Fred Hutchinson Cancer Center, La Jolla Institute for Immunology, Massachusetts Institute of Technology, Monash University, to name a few. LabArchives is compliant with 21 CFR part 11, HIPAA, NIST 800-171 requirements, and is designed to maintain data security while providing secure data sharing options, i.e., LabArchives meet the new NIH's new DMS sharing policy. The committee also found that LabArchives ELN integrates with many popular software and solutions, such as Box (the university's widely recommended cloud storage solution, Canvas, Google, Microsoft Office solutions, OneDrive, Prism, Shibboleth, etc.). The committee identified LabArchives ELN as the best option to ensure effective research DMS considering the following parameters: interface, flexibility to adapt to different workflows, ability to handle multiple file formats and data size, integration with commonly used software applications, and costs.

Although some decanal units within Rutgers have begun to implement or plan for the adoption of ELNs, this charge affords the opportunity to think proactively about the possibility of a university-wide ELN initiative that would permit the integration of these research tools with current university initiates focused on cloud-based data storage and archival options for researchers. The goal is to support researchers across the university and its 29 decanal units with appropriate services that would meet the digital research needs of investigators within a single research group and provide the necessary digital compliance elements required by funding agencies for experimental data storage and reuse.

Furthermore, as more investigators opt in for digital research services such as electronic notebooks that connect to experimental data and other research products, such as graphics, videos, images and databases, the ability to collaborate would be enhanced in and among

research groups at Rutgers and externally with other institutions. Improved collaboration among researchers would require a plan for university-wide implementation as opposed in a haphazard way across decanal units. Such a digital research ecosystem would need to be added to central budget development since these initiatives are not included in current budgets.

E. Resolution

Be it resolved:

Given the need to improve existing data storage solutions with the implementation of new ELN, the University Senate recommends that the University, in an iterative process involving consultation with the University Senate, the Faculty Councils, and their constituents, will:

1. Implement Electronic Laboratory Notebooks (ELN) University-Wide:

Introduce an Electronic Laboratory Notebook (ELN) system across the entire university, focusing on research applications. Funding for the ELN system would be added to budget development within the Rutgers Central Administration since no current budgets exist. The system would be created through input and suggestions from the decanal units. A market survey of other competitors can be conducted to identify the best ELN for university-wide implementation. Ideally, the ELN would be linked to a digital research ecosystem university-wide. The ELN system would facilitate compliance requirements of funding agencies and support essential digital research needs from "experiments to publication, presentation, and dissemination." Services would be generated in parallel that would disseminate guidelines for maintaining the security, integrity, and accessibility of these notebooks to all involved parties, including undergraduate students, graduate students, postdoctoral researchers, research scientists, and principal investigators within research labs.

2. Establish and Maintain an Up-to-Date Webpage on DMS Requirements:

Develop and regularly update a dedicated webpage within the Office for Research website, offering a comprehensive overview of the latest DMS (Data Management and Sharing) requirements mandated by various funding agencies such as NIH, NSF, DOE, DOD, NASA, EPA, NEH, and others. This webpage will also provide examples and templates of previously prepared DMS plans submitted by Rutgers University faculty members (with prior permission obtained from the faculty in-charge). By serving as a template, it will expedite the grant application process, allowing Rutgers researchers to efficiently apply for funding without the time-consuming task of sifting through funding agency guidelines.

3. Exploring IT Support for All Decanal Units of Rutgers University

Evaluate the accessibility and availability of IT support for all academic units and departments within Rutgers University's decanal units. It places a particular emphasis on those departments that do not possess in-house IT support with a focus on allocating resources strategically and providing targeted support where it is most needed. This evaluation is vital for ensuring the security of sensitive data and adherence to pertinent regulations. Moreover, identify, document, and effectively communicate the essential regulatory requirements and accepted data storage standards to all relevant stakeholders.

Member Action:

Approve of the Response to Charge S-2110 as discussed during full RGPEC meeting 11/17/22:

Monica Mazurek, co-chair Detlev Boison, co-chair Sonal Gahlawat Chiara Manzini Adam Hamawy John Kettle Adam Kustka Paul Takhistov Malica Dock Debbie Borie-Holtz MIchael Kelly Mark Gregory Robson Wei Dai Amy Savage Jean Eloy

Do not approve of Response:

Abstain from Action: