



COGR Readiness Guide

COGR Review of the Final NIH Policy for Data Management and Sharing: *Budgeting & Costing*

December 19, 2022

Introduction to the COGR Review

The COGR Review of the Final NIH Policy for Data Management and Sharing is an important addition to the COGR [Readiness Guide](#). ***This review identifies implementation challenges related to budgeting, costing considerations, and other topics of concern, which could affect both central administration and PIs/researchers.*** Some of the issues identified may require NIH engagement, and as appropriate, COGR will partner with NIH to resolve these issues. In addition to this review, COGR expects to release a more traditional guidance document for the COGR membership in January 2023, which will be helpful as institutions prepare to submit funding proposals in compliance with the final NIH policy.

Most funding proposals that are submitted to NIH on or after January 25, 2023, are required to include a DMS plan under the new policy (i.e., projects that generate scientific data).¹ As this will represent a new compliance requirement for many PIs and researchers, it is critical for the community to address the issues raised in this review with both transparency and resolve—and by doing so, the policy implementation will be done in a manner that achieves the important goal of robust data sharing, which ultimately will advance the quality of research and the advancement of science for decades to come.

Another important driver for raising the topics included in this review is to address the ongoing concern around excessive administrative burden. ***In those cases where new administrative burden (and related cost burden) is highlighted, the important issue of “barriers to entry” must be considered.*** If the burden proves to be excessive, this could create a disincentive for smaller and emerging research institutions to participate in NIH-funded research programs. Consequently, as institutions consider the issues raised in this document (as well as in the COGR guidance document, which will follow in January), COGR is committed to: 1) identify those issues of concern, 2) engage constructively with NIH on those issues, and 3) arrive at collaborative solutions that will be beneficial to the entire research community.

While not all issues addressed in this review will be resolved before the January 25, 2023, policy implementation date, a commitment for these issues to be addressed over a reasonable timeframe will be helpful to research institutions and the research community as a whole. COGR looks forward to working with NIH and other stakeholders on the issues that follow (plus other issues that may arise) over the course of the implementation of the Final NIH Policy on Data Management and Sharing.

- 1) ***Leveraging “Just-in-Time.”*** All stakeholders acknowledge that implementation of the Final NIH Policy for Data Management and Sharing will create new, and in some cases,

¹ See the NIH explanation for [Research Covered by the 2023 Data Management & Sharing Policy](#) for more details.

unanticipated challenges for research institutions. While PIs and support staff will be thoughtful and diligent in submitting compliant DMS plans, in some cases, lack of definitive and clear guidance could impact DMS plans. Consequently, it is crucial for those PIs and institutions that properly submit DMS Plans to receive appropriate consideration during the JIT period so that exceptional funding proposals are not put at jeopardy.

- 2) **Limitations of a Single Line Budget Request.** This requirement may obscure additional detail required for compliance and budget management (key personnel effort, sub-awards, capital equipment, etc.). While there is “nice simplicity” of the single line, it is not clear that a single line suffices. Importantly, if a single line is the only expectation, institutions should not be subject to undue audit risk if it is determined, after-the-fact, the single line was not sufficient.
- 3) **Limitations of the Cost Estimator Tool.** The NIH “Budgeting for Data Management & Sharing” guidance is shown on the NIH “Scientific Data Sharing website.”² The guidance references as a Related Resource the NIMH Data Archive (NDA) [Data Submission Cost Estimation Tool \(XLS format\)](#) to estimate costs associated with DMS. While the calculator is helpful for budgeting purposes with selected ICs and selected projects (e.g., human subjects), it is not universally applicable. Such repository-specific calculators may not capture all associated costs (e.g., fringe benefits), which can result in an underestimation. These limitations should be made clear to the community. Also, efforts such as the FDP Pilot should be utilized to update the Cost Estimation Tool and develop new universal calculators.
- 4) **Clear Guidance Around Repositories.** The more information that can be presented in a funding announcement regarding the use of repositories and storage expectations, the better. This information could prove helpful from a budgeting standpoint (e.g., identifying the need for dedicated data manager support), as well as from the standpoint of understanding IC expectations.
- 5) **Perceptions Around Proposing DMS Costs.** While NIH has been clear there are no “penalties” if a budget request exceeds a certain threshold, there will be the perception that exceeding a certain threshold will be considered detrimental to the funding proposal. PIs need ongoing assurance that they can propose the full cost of the DMS budget without any negative consequences. Peer reviewer expectations should be clear, and there must be consistent and regular messaging by NIH that the budget request will not impact the potential for success.
- 6) **Alleviating the Modular Award (and Other Budget Cap) Squeeze.** It is unclear how DMS costs should be proposed for capped awards.³ One solution would be to allow a certain amount of DMS costs to be exempted from the cap. PIs have concerns that they cannot include the full costs associated with their DMS activities and meet the budget needs of the project within existing NIH caps; excluding DMS costs from the budget cap will alleviate this concern. PIs will be faced with the decision of budgeting for these costs or budgeting for the costs more traditionally associated with research. And since the budgeted amount and associated budget

² See <https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/budgeting-for-data-management-sharing>

³ See NIH Guidance: PHS 398 Modular Budget Form: Use the [Additional Narrative Justification](#) attachment of the PHS 398 Modular Budget Form” (<https://sharing.nih.gov/data-management-and-sharing-policy/planning-and-budgeting-for-data-management-and-sharing/budgeting-for-data-management-sharing>)

justification are the only components of the proposal related to DMS that the peer reviewers may actually review, this enhances the PIs' perception of the associated risk.

- 7) **“Default” Budget Factors should be Considered.** In light of the “newness” of the NIH policy for many PIs and the corresponding uncertainty of how to develop the appropriate amount for a DMS budget request, use of “default” budget factors (as a percent of the direct cost budget) rather than a dollar amount could be an effective solution. Such an approach would level the playing field in the short-term—and in the long-term after DMS budgets are better understood, how best to propose DMS costs can be reevaluated.
- 8) **Distinguishing between Labor and Non-labor Costs is Imperative.** Costs associated with personnel may be challenging to identify and, consequently, should allow for efficient and realistic budgeting methodologies (see next bullet point below). Non-labor costs (e.g., storage, repositories, data security, etc.) may be easier to project, though they still should allow for efficient and realistic budgeting methodologies.
- 9) **Simplifying Effort Reporting Expectations.** To the extent possible, proposing labor and personnel costs (specific to data management activities only) should be simplified. Budgeting for certain personnel (key personnel, post-docs, etc.) could be based on an accepted *de minimus* budget factor, or something similar, which will recognize this cost element but will not require effort reporting or other documentation (specific to data management activities only). In fact, this approach could be considered for central administration (when applicable), in addition to personnel in the lab. In the case of graduate students, additional solutions will be needed for other costs associated with personnel (i.e., fringe benefits, tuition remission, etc.).
- 10) **Personnel with “Significant” DMS Responsibilities.** On the other hand, if an individual (e.g., data manager) will contribute their time above a certain threshold, and this time can be reasonably projected, the time and effort for this individual should be proposed accordingly. However, including a data manager in the budget request cannot be perceived as directing resources away from other aspects of the research—otherwise, PIs will be reluctant to propose these positions.
- 11) **Allowability of Post-performance DMS Costs is Essential.** These costs have been suggested by NIH to be an allowable cost if pre-paid in advance of the end of the period of performance. At the same time, this creates an inconsistency with the accepted costing principles described [in 2 CFR Part 200.403\(h\)](#).⁴ As such, institutions will need to develop solutions, with the full support from NIH, that allows for a mechanism to recover these future (and potentially significant) costs—and importantly, without audit risk applicable to any concerns related to costs incurred outside of the period of performance (but paid inside the end-date of the award). This could include the creation of a “reserve” account or other accounting methodologies to ensure these funds are available at future (post-performance) dates.
- 12) **NIH Confidence in Institutional Cost Models.** NIH support for flexibility in establishing cost models is important (e.g., shared service centers). When institutions are able to develop cost

⁴ 2 CFR 200.403(h) Cost must be incurred during the approved budget period. The Federal awarding agency is authorized, at its discretion, to waive prior written approvals to carry forward unobligated balances to subsequent budget periods pursuant to 200.308(e)(3).

models that are appropriate within the context of the institution’s financial enterprise, this will provide a mechanism for fair recovery of DMS costs.

- 13) **“Low” and “High” Data Density Programs.** Considering all the challenges that will be associated with budgeting, NIH should consider varying budget expectations for “low” data density versus “high” density programs. Low data density proposals could include simplified budgeting procedures (some of which have been suggested above), while high data density proposals could include more appropriate levels of detail.
- 14) **Expectations for Monitoring and Oversight.** To date, monitoring expectations are not specified. Since data sharing is already required for some NIH awards, it’s unclear what additional steps NIH expects will be needed under the new policy. Consequently, it is unrealistic, perhaps impossible, to budget for these types of costs. Further, updates to the data plan during the period of performance may require reporting in the RPPR, though this requirement is not well understood. Institutions will establish appropriate oversight and monitoring and NIH should be supportive of institutional practices around monitoring—rather than creating auditable standards. Further, it is suggested that the NIMH sample DMSPs posted on the [NIH Scientific Data Sharing site](#) be revised or removed as institutions have expressed substantial angst and confusion over the language in the sample plans for Element 6 (Oversight of Data Management and Sharing). As written, it is inconsistent with current practice in which PIs generally assume responsibility for adherence to the written plan.
- 15) **Standards for Enforcement and Audit.** By acknowledging the many challenges raised in this COGR Review, we encourage NIH to establish standards for enforcement and audit to be premised on reasonableness and fairness, rather than prescription and precision. Especially during the first year of implementation, the trajectory of the learning curve will be severe for NIH and the research community, so some form of a grace period is warranted. The planned FDP pilot will provide an opportunity to uncover challenges and develop solutions—and after the FDP pilot is completed, it will be appropriate to use the results of the pilot to inform policy updates, realistic enforcement strategies, and appropriate audit standards.

The issues and concerns raised in the COGR Review are a robust list of topics for consideration. We also recognize that leading up to and upon implementation of the new NIH policy, additional issues and concerns may arise . As new issues arise, we encourage the COGR Membership to reach out to NIH, the FDP, other stakeholders, and COGR. And as COGR engages in clarification on the important topics raised in this review, we will keep the community updated.

If you have questions or concerns, contact:

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