NIH DMS Policy Central Reviewer Tip Sheet*

Application Instructions

- Review the Funding Opportunity Announcement (FOA) for any program-specific requirements
- R&R Budget
 - Refer GM and PI to resources posted on OVPR's <u>Federal Funders' Data Management</u>
 <u>Policies page</u> for resources related to the new policy requirements and budgeting of allowable expenses.
 - o Per NOT-OD-23-161, NIH has reversed the prior instruction to budget all direct costs needed to support data management and sharing activities in a single line item in the Other Costs section. Effective immediately, all direct costs associated with data management and sharing activities should be budgeted in the appropriate corresponding line item (personnel in the personnel section, equipment in the equipment section, etc.). If there are Other Costs appropriate to include in a Data Management and Sharing Costs line item, reflect these expenses in the Other Costs section with that label. Until the application package is updated in late September 2023 for deadlines on or after October 5, 2023, a line item specifically titled "Data Management and Sharing Costs" (without the quotation marks) must be included in the budget in order to avoid a system error, so if there are no such other costs to include, this line item must still be incorporated into the budget at \$0.

Budget Justification

- Even though NIH has reversed the instruction to include all direct costs associated with data management and sharing activities in a single line item, NIH will still require applicants to specify estimated data management and sharing cost details within the "Budget Justification" attachment of the R&R Budget Form or "Additional Narrative Justification" attachment of the PHS 398 Modular Budget Form. If a Data Management and Sharing Plan (DMS Plan) is required, a section clearly labeled "Data Management and Sharing Justification" must be included within the budget justification.
 - For modular budgets, the additional narrative justification is required and must include a section clearly labeled "Data Management and Sharing Justification" followed by the requested dollar amount.
- Verify that this section has been included if a DMS Plan is included in the submission.
 - If not, remind GM and PI to include this section.
- This section must provide a brief summary of the type and amount of scientific data to be preserved and shared and the name of the selected established repository(ies) for each data type. Even though direct costs associated with data management and sharing activities may be spread across multiple budget categories, this section is required and includes general cost categories (curation, developing supporting documentation, local data management activities, repository fees, etc.), including an amount for each category and a brief explanation. The recommended length of this section of the justification is no more than half a page.
- If this section is missing or seems incomplete, remind GM and PI that this summary is the only DMS Plan content reviewers will be able to review; they will not have access

to the full submitted DMS Plan. This section should communicate to reviewers that the PI has developed an appropriate DMS Plan and understands what will be needed to implement data management and sharing best practices.

- Research Strategy Approach
 - This section should include how the data will be collected, analyzed, and interpreted and reference the DMSP as appropriate.
- Other Plans
 - Verify that the completed DMS Plan has been attached in the new "Other Plans" section of the application.
 - This attachment should not include the budget justification language; justification for the costs budgeted as well as a brief summary of the DMS Plan must be included in the budget justification section described above.
 - Review the plan for Oversight of Data Management and Sharing (Element 6) to ensure that Harvard would not be committed to a process/action that is beyond current processes.
 - This section of the DMS Plan should focus on the roles and responsibilities within the research team for data management and sharing activities.
 Acceptable sample language for this section is as follows:
 - ☐ Monitoring of and compliance with this Data Management and Sharing Plan will be the responsibility of the project's Principal Investigator. The plan will be implemented and managed by professional staff working under the direction of the PI.
 - This section should *not* reference compliance systems or programs that do not exist at the University, such as the below:
 - ☐ The Office of Sponsored Programs at University X that will be administering this award has created a data management and sharing plan compliance system as part of their process for submitting the annual NIH progress report. That Office is collecting information related to the number of research participants that are deposited each reporting year.
 - If the proposal includes subrecipients (and Harvard is the Prime), this section should also indicate allocation of responsibilities between the Harvard PI and the subrecipient institutions.
 - Note: Please remember that the <u>NIH hyperlink policy</u> applies to DMS Plans as well, and the final, submitted DMS Plan should not include any hypertext (e.g., hyperlinks and URLs).
 - <u>Note:</u> The DMS Plan attachment will not appear in the application preview in ASSIST; it
 must be reviewed and downloaded separately.
- For program projects with multiple components:
 - Even though direct costs associated with data management and sharing activities may be spread across multiple budget categories in multiple components, the summary of the DMS Plan should be included within the budget justification corresponding to the Administrative Core.

- o The DMS Plan itself should be included in the Overall Component under "Other Plan(s)."
- Costs associated with subrecipients should be incorporated into the subrecipients' budget and appropriately justified in their budget justification.

Verifying the Accuracy of the GMAS DMS Questions

- GMAS Question: Does this award/proposal require a data management and/or sharing plan?
 - When Harvard is the Prime
 - Unless the proposal is requesting a mechanism that NIH has explicitly indicated as not subject to the policy (see FAQ A.4 in the NIH FAQs), the answer to this question must be yes.
 - O When Harvard is the Subrecipient:
 - Unless the proposal is requesting a mechanism that NIH has explicitly indicated as not subject to the policy or we have received explicit, written confirmation from the Prime that there is no role for Harvard in the activities described in the DMS Plan, the answer to this question must be yes.
- GMAS Question: Does this request include a new/updated data management and/or sharing plan?
 - Whenever there is a <u>new (initial) or updated</u> data management and/or sharing plan document that has not previously been recorded in GMAS or reviewed by Harvard included with the specific request, this question should be answered yes.
 - If the question is answered yes, verify that a copy of the new/updated DMS Plan has been uploaded to a folder labeled "Data Management Plans" in the Segment document repository.
 - When Harvard is a subrecipient, this question should be answered no if we have not received a copy of the DMS Plan from the Prime.
 - The intent of this question is to facilitate document management and track document(s) received with that specific request. As such, we would not update the answers to this question post-submission in the event we received a copy of the DMS Plan later (as in the case of Harvard as the subrecipient) as it would record inaccurate data regarding documents reviewed within the request.

Best Practices with Subawards

- When Harvard is the Prime
 - The Harvard PI should discuss roles and responsibilities with regards to data management and sharing activities with any subrecipients while preparing the proposal materials
 - Outline agreed upon roles and responsibilities in Element 6 of the DMS Plan (Oversight of Data Management and Sharing)
 - Share a copy of the final DMS Plan with the subrecipient and obtain their approval of the final DMS Plan prior to submission, ideally as part of the institutionally approved subaward proposal package (but Subrecipient PI approval is sufficient).
 - Retain a copy of the subrecipient's approval of the DMS Plan in GMAS with the other proposal documentation from that subrecipient.

- If the proposal is funded, the DMS Plan will be incorporated into the resulting subaward agreement, and this will help avoid delays in the subaward process due to disagreement regarding the contents of the DMS Plan.
- Any time the DMS Plan is updated, be sure to confirm with the Harvard PI that the subrecipient has agreed to any changes to the DMS Plan, particularly those that impact the role of the subrecipient in data management and sharing activities.

• When Harvard is the Sub

- Harvard PI should discuss roles and responsibilities with regards to data management and sharing activities with the Prime PI while preparing the proposal materials
 - Outline agreed upon roles and responsibilities in Element 6 of the DMS Plan (Oversight of Data Management and Sharing)
- Harvard PI should request a copy of the final (or near final) DMS Plan from the Prime PI as part of finalizing the proposal.
- o When Harvard PI receives a copy of the final (or near final) DMS Plan from the Prime PI:
 - Harvard PI should review DMS Plan to ensure that the role described for the Harvard team is as expected and achievable
 - Harvard PI should review with their Grant Manager to ensure that appropriate costs related to data management and sharing activities have been included in the Harvard budget.
 - Grant Manager should upload a copy of the PI-reviewed DMS Plan in the GMAS request repository for central review with the other relevant subaward proposal documents.
 - Central reviewer will review DMS Plan to ensure that roles and responsibilities for the Harvard team are clearly articulated in Element 6 (Oversight of Data Management and Sharing)
 - ☐ If roles and responsibilities are unclear, provide this feedback to the Harvard PI and recommend the DMS Plan be updated to include this prior to submission. Approval of the subaward proposal *does not* need to be held waiting for these revisions.
 - Both DMS-related questions in GMAS should be answered "yes".
- In the event that information on the DMS Plan cannot be obtained from the Prime PI or it is otherwise unclear if the Harvard team will have any responsibility for DMS Plan activities, the first DMS-related questions in GMAS should be answered "Yes" and the second should be answered "No"
 - Approval of the subaward proposal does not need to be held waiting for a copy of the DMS Plan.
 - If the proposal is selected for funding, a copy of the final DMS Plan must be obtained prior to execution of any resulting subaward agreement.

Just-In-Time (JIT) Stage**

 Review GMAS JIT Request to identify whether an updated DMS Plan is being provided as part of the JIT response.

- If there is no updated DMS Plan included with the request or an indication that the
 previously submitted DMS Plan has been approved, ask the GM and PI whether they
 have received a request for an updated DMS Plan.
- If an updated DMS Plan is being submitted with the JIT materials:
 - o Review the updated DMS Plan as described in the Proposal Stage.
 - Upload the updated plan to the "Data Management Plans" folder in the Segment Repository (as well as including it in the JIT Request repository).
- Note: Any updated DMS Plan must be submitted by the AOR to NIH for NIH to accept the updated DMS Plan as final.
- <u>Note:</u> Institutes, Centers, and Offices (ICOs) may develop their own forms to meet ICO-specific policies or requirements. If you see one of these forms, let your office's representative to the University-wide working group know to raise general awareness.
- Note: If the turn-around time requested by NIH is not a reasonable timeframe in which to update the DMS Plan as requested, let NIH know a more appropriate timeframe. The below sample language may be used for these communications:
 - Dear [NIH Program Officer],

Thank you for your request regarding JIT documentation for Grant Number XXX. As the
authorized organizational representative, I am writing on behalf of the President and
Fellows of Harvard College and Prof, to request until [insert a date that is
at least 5 business days from when the JIT request was first received] to submit our just
in-time response in order to allow sufficient time to gather, review, and submit the
necessary information [, including collecting the requisite documentation from our
subrecipients].

Please let us know if you have any questions. We will follow up with the required information as soon as we have completed our internal review.

At Award Stage**

- Central Reviewer reviews Notice of Award (NoA) to confirm that the correct version of the DMS Plan has been incorporated by reference into the NoA.
 - o If not, verify with GM and PI the correct DMS Plan version that should be referenced
 - If the reference in the NoA is correct, ensure that version of the DMS Plan is uploaded properly to GMAS
 - If the reference in the NoA is not correct, reach out to NIH Grants Management
 Specialist to request correction of the reference in the NoA
- If Harvard is a subrecipient, review the incoming subaward agreement to ensure that the final DMS Plan is included in the agreement package.
 - o Review DMS Plan to ensure that
 - roles and responsibilities for the Harvard team are clearly articulated in Element
 6 (Oversight of Data Management and Sharing)
 - the DMS Plan in the subaward agreement is the same as the one received during the proposal stage (if one was received at that stage)

- If either of the above is not true, work with the Harvard PI to review and/or request changes to the DMS Plan, as appropriate, prior to execution of the subaward agreement.
- o If both of the above are true, the central reviewer's review of the DMS Plan is complete.
- o If the pass-through entity (PTE) refuses to provide a copy of the DMS Plan, request that language be added to the subaward agreement to confirm that Harvard has no responsibilities under the DMS Plan. The subaward agreement must include such a statement or a copy of the DMS Plan in order to proceed to execution.
- If Harvard is the prime, ensure that the most recent version of the DMS Plan is attached to the subaward agreement issued to any subrecipients.

Resources

- eRA System Validations and the Actions You Can Take to Address Them
- NIH Scientific Data Sharing site

^{*}This document reflects university guidance on best practices for a review when the PI has submitted the proposal materials for review within the deadline set by the central reviewing office. When a proposal is submitted after the deadline, adjustments may be made to accommodate the timeline available for central office review.

^{**}The guidance in these sections is based on our understanding of what we can expect from NIH at these stages. These sections will be updated as we obtain further information regarding these stages.