NIH Updates

Council on Government Relations

OFFICE OF POLICY FOR EXTRAMURAL RESEARCH ADMINISTRATION

June 6, 2024

Overview

- Data Management and Sharing
- Closeout
- Research Security/Disclosures

DATA MANAGEMENT AND SHARING (DMS)

National Institutes of Health
Office of Extramural Research

Federal Demonstration Partnership (FDP) DMS Pilot Updates

- Phase 1 tested the effectiveness and usability of two DMS Plan templates developed in collaboration with representatives from participating ICs.
- FDP gathered data from the researcher/faculty perspective as well as the NIH program perspective.
- Next, we will pull together feedback from NIH IC perspective and extramural researcher perspective to create a new iteration of a DMS Plan template.

NIH Program Official Observations - Format

- Using a table format to line up elements and sub-elements would help track writing necessary information in the plan.
- Applicants often provide conflicting information across elements of the plan.
- Determination of genomic data/GDS applicability in the DMS plans is difficult without additional information from grant applications in many cases (e.g., reading information in Research Strategy for # of samples, etc.).

NIH Program Official Observations - Content

- Often unclear which data will be generated versus shared.
- Plans lack important details: species/source, formats shared, amount, metadata.
- All data proposed in the Research Plan of the grant applications should be discussed in the DMS plan - not always the case.
- When multiple data types are proposed, certain elements for each data type were often missing.
- Data should be shared at the time of publication or at the end of the grant period, whichever comes first (many only mentioned one or the other).
- Many plans do not name an established repository, or state that data will be shared only through “publication” and “conferences” or “by-request.”
- Often, limitations on sharing data are not well-justified and vague reasons are provided (e.g., (“ethical issues”, “privacy”, “sufficient quality”).

Data Management and Sharing – What's Next?

- FDP Pilot Team continues to work on new proposed DMS template.
  - Will hold roundtable sessions with pilot participant institutions to ensure new template meets their needs and is user friendly.
- Phase 2 of the FDP Pilot will kick off with a small working group in October to brainstorm steps to catalogue the activities that should be included in a cost/effort calculator.
- NIH is obtaining OMB clearance of RPPR questions to track compliance with the DMS policy (see NOT-OD-24-123).
  - Questions will be implemented in FY 25.

CLOSEOUT

National Institutes of Health
Office of Extramural Research

Unilateral Closeout Reporting

- NIH is currently undergoing an OIG of our closeout procedures. OIG identified that NIH was not taking timely unilateral closeout actions and was not reporting recipients in Sam.gov (formerly FAPIIS).
- On January 23, 2024, NIH issued NOT-OD-24-055, NIH Enforcement of Unilateral Closeout Reporting in the System for Award Management Responsibility/Qualification.
- NIH is required to submit Responsibility/Qualification determinations for any entities that do not submit all required closeout reports within one year of the period of performance end date (2 C.F.R. § 200.344(i)). Additionally, NIH is required to close these awards with the information available within one year of the period of performance end date (2 C.F.R. § 200.344(h)).
- Recipients may comment on the report displayed on SAM.gov via the Contractor Performance Assessment Reporting System (CPARS) to provide a public statement in response to NIH's report (2 C.F.R. § 200.341(b)(4)).
- The Responsibility/Qualification record will remain in SAM.gov for 5 years.

Learn more: NOT-OD-24-055

PROGRAM SUPPORT CENTER – PAYMENT MANAGEMENT SYSTEM: ID.ME

ID.me and Payment Management System Issues

- NIH is in the process of working with the NIHs Center for Information Technology (CIT) to determine how ID.me is designed and to discuss options for protection of PII. We plan to work with Program Support Center (to report and provide data that shows several disruptions with our project across many of our recipients.
- We are awaiting outcomes and will keep the community informed via a Guide Notice once we have clarity.
- For now, this challenge resides with the Program Support Center, Payment Management System at: https://pms.psc.gov.
- OPERA continues to share feedback from our ICs and the recipient community.

RESEARCH SECURITY/ DISCLOSURES

Common Forms for Biographical Sketch and Current and Pending (Other) Support: NIH Implementation

- Planned NIH Implementation:
  - Effective for all applications and RPPRs submitted on or after **May 25, 2025**, Applicants/Recipients must use the Common Forms for both Biographical Sketch and Current and Pending (Other) Support.
  - Applicants/Recipients will be required to obtain an ORCID ID and enter it in the Persistent Identifier (PID) section of the Common Forms. They must also link their ORCID ID to their eRA Commons Personal Profile.
  - NIH will have a separate supplement form to collect the three required agency specific data elements (i.e., Personal Statement, Contributions to Science and Honors) to adhere our Peer Review Regulations at 42 Code Federal Regulations Part 52.

Send inquiries to: nihosbiosketch@nih.gov

Common Forms for Biographical Sketch and Current and Pending (Other) Support: SciENcv Implementation

- Applicants/Recipients will be required to use Science Experts Network Curriculum Vitae (SciENcv) for completing and certifying the Common Forms.
- SciENcv will generate a digitally certified PDF for use in application submission.
- OPERA is working with SciENcv to develop compatibility features [e.g., Application Programming Interface (API)] to assist entities with full implementation in May 2025.
  - External API will assist applicants with populating data from internal systems into SciENcv
  - Internal API will allow NIH to capture structured data from the Common Form

Send inquiries to: nihosbiosketch@nih.gov

Research Security Program Guidelines – NIH Comments

- In April, agencies were given the opportunity to review and comment on the updated Draft Guidelines for Research Security Programs.
- NIH recommendations included:
  - Incorporating institutional certifications into Sam.gov as part of the standard assurances.
  - Use of the term “certify” rather than “attest” throughout, in line with the recommendation above.
  - Clarifying edits regarding the term “sensitive R&D”. Suggested referring to risks, and risk mitigation instead.
  - Foreign travel security training should be required for all covered individuals, rather than just those participating in sensitive R&D.
  - The criteria for agencies to implement additional requirements should align with the disclosure policy memorandum.
- Updated draft expected soon.