

Research Management Meeting

1

JUNE 1, 2022

Agenda

2

- **Welcome** - *Sarah T Axelrod, Rachel Cahoon*
- **New NIH Policy for Data Management and Sharing** - *Melissa Korf, Julie Goldman, Rachel Talentino*
- **Research Teams** - *Kelly Evans, Colleen Shanahan*
- **HUIT/ATS Updates** - *Simone Alpen*
- **Faculty Disclosure Website Update** – *Tracey Westervelt*
- **New NIH Harassment Reporting Policy** – *Sarah T Axelrod*

Implementing the New NIH Policy for Data Management and Sharing (Effective January 25, 2023)

Julie Goldman, Countway Library

Melissa Korf, Office of Research Administration, Harvard Medical School

Rachel Talentino, Office of the Vice Provost for Research

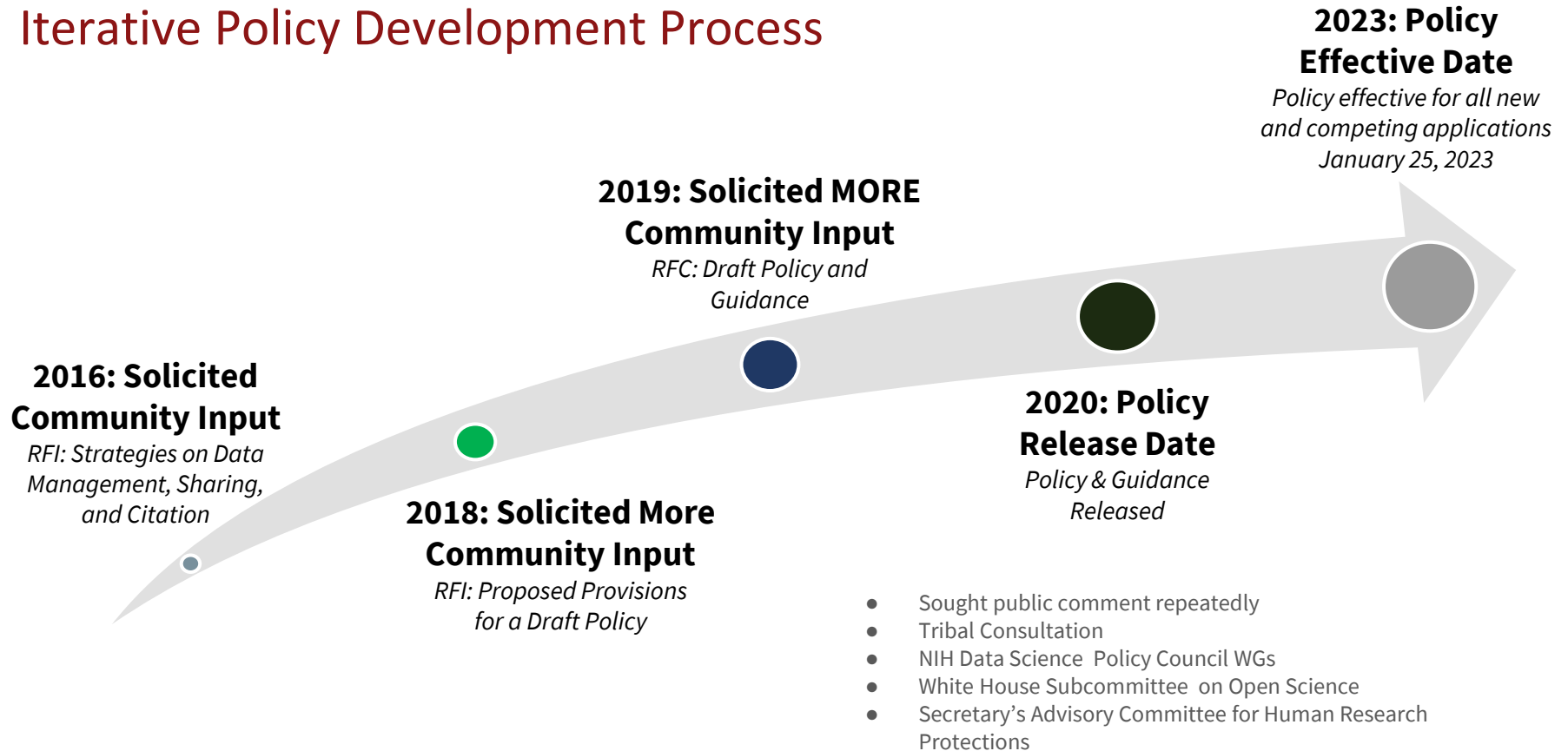
Research Management Meeting

June 1, 2022

Objectives

1. Policy Landscape
2. New NIH Policy Requirements
3. Available Resources

NIH Policy for Data Management and Sharing: Iterative Policy Development Process



Updates to NIH Policy for Data Management and Sharing

- For new and competing applications submitted on or after January 25, 2023, NIH will require researchers to prospectively plan for how scientific data will be preserved and shared through submission of a Data Management and Sharing Plan (Plan). Upon NIH approval of a Plan, NIH will expect researchers and institutions to implement data management and sharing practices as described.
 - Given the usual NIH application timeline, anticipate the first awards subject to the new policy to be received around September 2023 or December 2023
- The DMS Policy is intended to establish expectations for Data Management and Sharing Plans, which applicable NIH Institutes, Centers and Offices (ICO) may supplement as appropriate
- **Goal:** To promote positive change in data management and sharing culture

Source: [NIH Data Management and Sharing Policy \(Required in 2023\)](#)

NIH DMSP: Scope

- Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data
 - **Recorded factual material** commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications
 - Does not include lab notebooks, preliminary analyses, peer reviews, physical objects
- Anticipate that we may see NIH ICO-specific requirements, such as
 - [NIMH Data Sharing Policy](#)
 - [NHGRI Genomic Data Sharing Policy](#)

Policy Highlights

- Replaces the 2003 NIH Data Sharing Policy, which only required a Plan for projects over \$500K in annual direct costs
- Costs associated with data management and sharing may be allowable in proposal/award budgets
- Plans can be revised throughout the project (NIH prior approval may be required)
- Plans may be made publicly available and should not include proprietary or private information
- Plan should be two pages or less
- Practices should be consistent with FAIR data principles
- NIH working on implementation resources:
 - Initial [FAQs](#) released January 25, 2022
 - [Scientific Data Sharing](#) site launched in April 2022

Source: [NIH Scientific Data Sharing](#)

NIH DMSP: Requirements

PLAN SUBMISSION

- With application
- Brief Plan description in Budget Justification
- Full Plan as a separate attachment

PLAN ASSESSMENT

- Peer review comment on (not score) budget
- NIH program staff assess Plans
- Plans can be revised

PLAN COMPLIANCE

- Incorporated into Terms and Conditions
- Monitored at regular reporting intervals – mechanisms and tools to support oversight under development
- Compliance may factor into future funding decisions

Source: [NIH Office of Science Policy presentation at FDP September 2021 meeting](#)

NIH DMSP: Allowable Costs

- **Reasonable costs allowed in budget requests**
 - Curating data/developing supporting documentation
 - Preserving/sharing data through repositories
 - Local data management considerations
- **NOT considered data sharing costs**
 - Infrastructure costs typically included in indirect costs
- Council on Governmental Relations (COGR), Federal Demonstration Partnership (FDP), and the Association of Research Libraries (ARL) working to enumerate the costs associated with data sharing and provide costing guidance.



NIH DMSP: Implications

- What does this mean for current research protocols?
 - Could existing consents pose an issue for future required sharing?
- How much variation will we see across NIH Institutes, Centers, and Offices (ICOs)?
- Implications for administrative and research support
 - Project/lab data managers, increased requirements for Institutional Certifications, prepping for repository deposit, etc.
- Data management systems and updates needed?
- How will the cost of compliance impact project budgets?
- What will NIH enforcement look like?
- Other implications on current and future NIH funded research?

Data Use Agreements (DUAs) and DMPs

- Refer to the [Harvard Policy on Data Use Agreements](#) for when a DUA is or may be required
- Only the Harvard Negotiating Offices (OSP, HMS ORA, SPH ORA) are [authorized to negotiate and sign](#) these Agreements, which can include terms regarding:
 - IP, sharing of results, or publication rights
 - Data use, storage, and destruction
- Submit [DUA requests](#) or consult your Negotiating Office if you are unsure if a DUA is needed

*Please note that the Data Safety submission required for every DUA is not equivalent to the DMSP required by the NIH.

Data Management Planning Tool (DMPTool)

This plan is based on the "Harvard Medical School Biomedical DMP Template" template provided by Harvard University (harvard.edu) - (ver: 5, pub: 2021-10-25).

expand all | collapse all

+ Data Collection (0 / 2)

Give a brief description of the data, including any existing data or third-party sources that will be used, in each case noting its content, type and coverage. Outline and justify your choice of format and consider the implications of data format and data volumes in terms of storage, backup and access.

What data will you collect or create?

- What type, format and volume of data?
- Do your chosen formats and software enable sharing and long-term access to the data?
- Are there any existing data that you can reuse?

B / I / [List] / [Link] / [Image]

Save

Harvard example answer

Below are sample texts that can be modified (as relevant) to answer the question

Data Formats for Harvard Dataverse	Immediately after collection, quantitative data will be converted to Stata, SPSS, R, Excel, CSV formats. These formats are fully supported by the Harvard Dataverse, which will perform archival format migration; metadata extraction; and validity checks. Deposit in these formats will also enable online analysis; variable-level search; data extraction and re-formatting; and other enhanced access capabilities. Documentation will be deposited in PDF/a, or plain-text formats, to ensure long-term accessibility, with any accompanying sound (in WAV), video, or images separate from the documentation deposited as JPEG 2000 files (with lossless compression) or uncompressed TIFF files.
General	This project will produce primarily scientific data, on an ongoing basis, that will consist of reported publications and intellectual property rights filings. Data types include (1) experimental procedures utilized to obtain data; (2) materials utilized during experimental procedures; (3) methods used for data measurements; (4) data measurements and analysis and DNA and protein sequences; (5) publications in the form of scientific manuscripts; and, (6) patents.
General	We will be working with [sequencing/imaging/mass spectrometry/structure/etc.] data. This data is to be generated [in-house/by a core facility/etc.], and we expect [N] datasets totaling at approximately [size] [units] total.
General	We can supplement our data by comparing it to that in public repositories, such as [the TCGA/1k Genomes/etc.].

Guidance | Comments

Harvard | DMPTool

- Harvard Biomedical Data Management: Data Management Plans
- Webinar Video: Let's Talk Data

expand all | collapse all

Data format +

Find support for working with your data: Research Data and Scholarship

- When saving data, it is important to not only consider where you are saving it but also how you are saving.
- As you shift from saving your data as you work on it to saving it to preserve it long term, something to consider is your file formats. When saving data over the long term, we recommend saving in formats that are as open, lossless, and unencrypted as possible.
- Open (non-proprietary) formats are those that can be used and implemented by anyone. In practice, this means that files stored in open formats can be opened and used by a variety of proprietary, free, and open-source software tools rather than just a single piece of software. Open, non-proprietary, formats are far more likely to remain usable over the long term even if the software that created them is not available or no longer functional.
- The Library of Congress maintains a list of recommended file formats for long-term preservation which has been adapted in the table below. The following is not meant to be an exhaustive list, but to highlight especially common file formats and data types. Note that "open" file formats are not necessarily lossless.

GUIDANCE & RESOURCES



A free tool to create data management plans that fulfill the requirements of different funders

1. Go to <https://dmptool.org>
2. Login using your Harvard Key
3. Use the NIH Template* with Harvard Guidance
 - a. [Complete Instructions](#)

* Also Available: [Harvard University General Dmp Template](#)

University-Wide Working Group

Want to join the effort? Contact julie_goldman@harvard.edu.

Name	Position	Unit/School
Julie Goldman	Research Data Services Librarian	Harvard Library, Countway Library, Harvard Medical School
Melissa Korf	Director, Grants & Contracts Administration	Research Administration, Harvard Medical School
Rachel Talentino	Senior Research Compliance Officer	Office of the Vice Provost for Research, Harvard University
Kae Audette	Information Security Risk & Consulting Specialist	Information Security, Harvard University Information Technology
Vanessa Barton	Assistant Director of Faculty Programs and Proposal Support	Research Strategy & Development, Chan School of Public Health
Alain Bonacossa	Senior Director for Research Administration and Research Integrity Officer	Harvard Business School
Carolina Harvey	Manager, Grants & Contracts Pre-Award Contact	Office for Sponsored Programs, Harvard University
Rob Kirsh	Director of Pre-Award	Office for Sponsored Programs, Harvard University
Pernille Konow	Manager, Research Administration Support Services	Research Administration, Harvard Medical School
Kathleen Ledyard	Senior Sponsored Research Administrator	Department of Chemistry and Chemical Biology, Faculty of Arts and Sciences
Dana LoSasso	Grants & Contracts Officer	Office for Sponsored Programs, Harvard University
Katie Mika	Data Services Librarian	Harvard Library, Harvard Dataverse
Megan Moore	Associate Director, Pre-Award	Office for Sponsored Programs, Harvard University
Patrick O'Neill	Director of Research Administration	Sponsored Programs Administration, Chan School of Public Health
Jason Wells	Senior Research Computing Systems Professional	Research Computing, School of Engineering and Applied Sciences
Krista Valladares	Project Manager, Research Computing and Research Data Management	Strategic Initiatives, Harvard University Information Technology

Harvard Data Management Resources

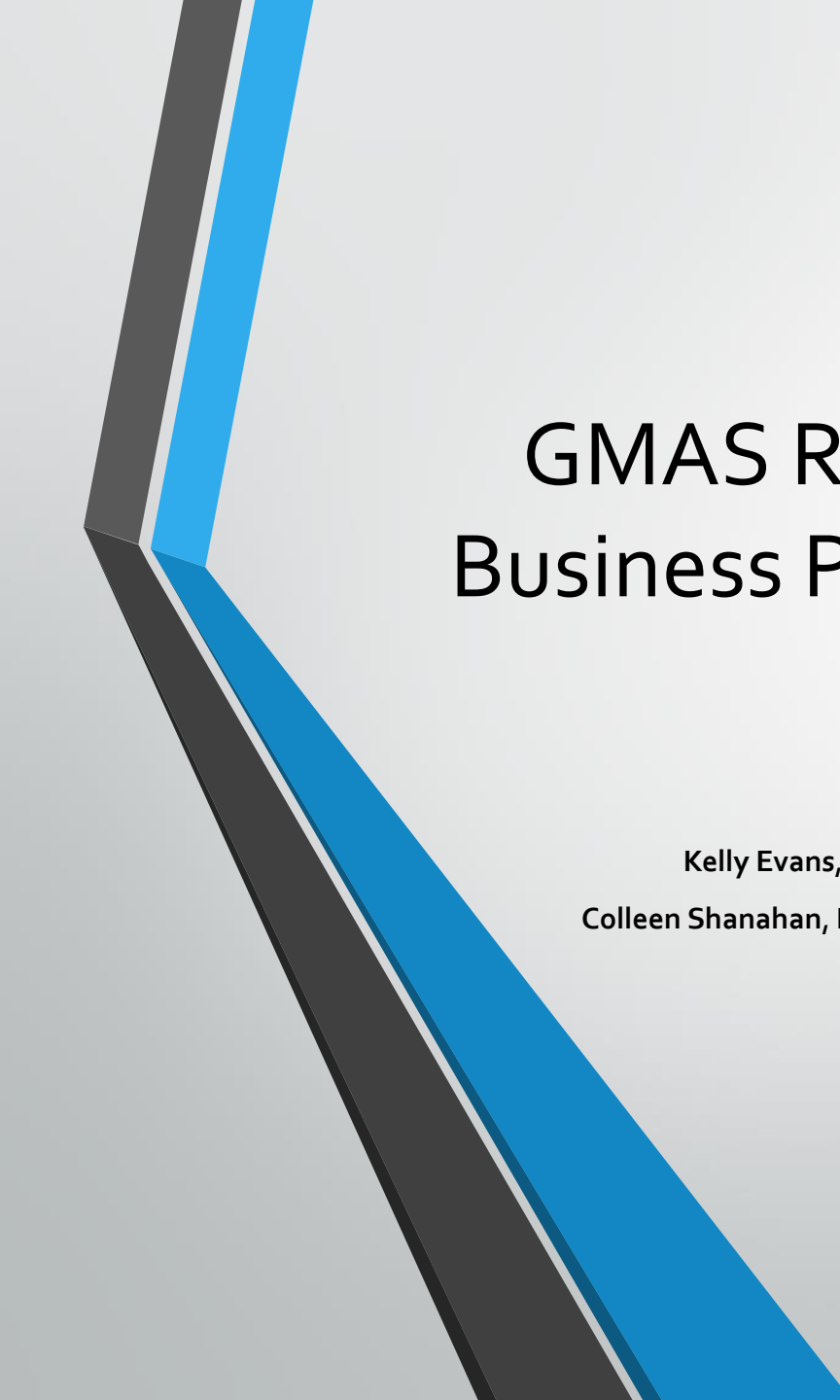
- [Research Data Management @Harvard](#)
- [Office of the Vice Provost for Research: Research Data Management](#)
- [Harvard Library DMPTool and Data Management Plans](#)
- [Harvard Information Security: Data Security Levels - Research Data Examples](#)
- [Harvard Office of Technology Development](#)
- [Harvard Biomedical Data Management Website](#)
- [Harvard Medical School Office of Research Administration](#)
- [Harvard Catalyst: The Harvard Clinical and Translational Science Center](#)

Sources & References

- [NOT-OD-21-013: Final NIH Policy for Data Management and Sharing](#)
- [NOT-OD-21-014: Supplemental Information to the NIH Policy for Data Management and Sharing](#)
- NIH Office of Science Policy [FAQs for the NIH Policy for Data Management and Sharing \(DMS Policy\)](#)
- NIH Office of Science Policy website on Scientific Data Sharing: <https://sharing.nih.gov>
- NIH Office of Science Policy “[Update on Implementation of the NIH Data Management and Sharing Policy](#)” presentation at FDP September 2021 Meeting
- NIH Office of Data Science Strategy “[Agency and Institutional Considerations to Build and Maintain Data Management and Sharing Infrastructure](#)” presentation at FDP May 2022 Meeting
- COGR NIH Data Management and Sharing (DMS) Policy Resource Page: <https://www.cogr.edu/nih-data-management-and-sharing>

Research Teams

Kelly Evans, Colleen Shanahan



GMAS Research Teams Business Process Guidance

Research Management Meeting – June 1, 2022

Kelly Evans, Director of Pre-Award Services, HMS Office of Research Administration
Colleen Shanahan, Manager, Grants & Contracts Operations, Office for Sponsored Programs

Research Team Guidance Committee

Co-Chairs: Colleen Shanahan, OSP & Kelly Evans, HMS

- Nicole Boquet, Wyss
- Catalina Diaz, SPH
- Jonathan Eaton, HMS
- Kate Graff, SEAS
- Carolyn Jones, FAS
- Michael Kazmierski, OSP
- Jennifer Lech, FAS
- Rachel Link, SPH
- Oscar Romero Gonzalez, HUIT
- Sarah Svensen, HKS
- Adair Swain, OSP
- Faina Thompson, GSE

Guiding Questions

- Who should be on the Research Team?
- When does the Research Team need to be updated?
- Why does it matter?
- Who does what?

Good News

Who should be on the Research Team?

- Reduced number of roles are required

When does Committed Effort need to be updated?

- Not as often as you think

Single Location for Guidance: GMAS Website

GMAS system job aids

- Confirm Research Team
- Edit Research Team

Business Process Guidance

- Managing the Research Team
- Roles & Responsibilities

Effective Date:
July 1, 2022





Questions?

Reach out to your committee
representative

HUIT/ATS Updates

Simone Alpen

HUIT Updates

Administrative Technology Services | Research Administration and Compliance Systems

June 1, 2022

Agenda

- Research Administration Portal
- GMAS
- Research Suite
- Research Management Project



Increase efficiency



Improve transparency



Reduce reliance on email

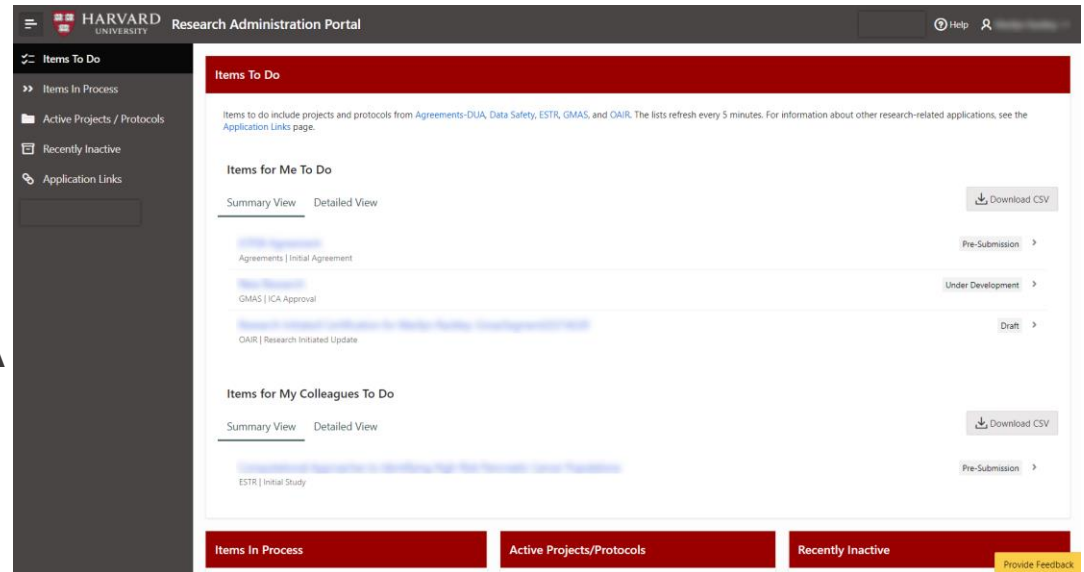
Research Administration Portal

NOW AVAILABLE! - New tool for faculty and researchers

<https://adminportal.research.harvard.edu/>

The Research Administration Portal shows faculty and researchers their outstanding research administration and compliance activities and provides an overview of their portfolio.

The application includes projects and protocols from **AGREEMENTS-DUA**, **DATA SAFETY**, **ESTR**, **GMAS**, and **OAIR**.



Research Administration Portal

Let researchers know that items that need their attention are easily accessed in the Portal

Examples include:

- A DUA that needs to be submitted
 - An IRB protocol where the IRB has requested clarifications
 - A funding proposal that needs to be signed
-
- ✓ Each item includes a direct link to the page where the task can be completed
 - ✓ Each item has associated help text to guide the researcher through next steps
 - ✓ Separate pages display additional information about the researcher's portfolio

Next Up (target: late summer)

- To-dos from ecrt and the Harvard Training Portal
- Delegate functionality

GMAS | What are we working on?

Summer Release (target: July)

- Document repository bulk actions—lock, unlock, delete
- Daily/weekly digest
- Subagreement list screen enhancements
- Other enhancements and bug fixes

Subagreement Project (target: late summer/early fall)

- The Subagreement Committee is focused on the design of new, **comprehensive workflow for subagreements and amendments** including dashboards, notifications, and other enhancements.
- The Training and Communications Working Group is focused on **communication and training** resources—including job aids and videos—for all roles engaged in the subagreement process.

GMAS | Digest

Coming soon!

- Inspired by the Subagreement Committee, the digest is an opt-in email digest—either daily or weekly
- Summarizes the GMAS events within an individual’s portfolio
- Pilot – March through June
 - “Enjoying seeing the digest come in”
 - “I’m finding it helpful as a department level person because it makes steps. . . visible to me without needing to navigate to each project everyday to check on what's happened”

May 16, 2022 GMAS activity summary for Meredith Irwin

This report shows all actions taken on any GMAS projects that are in your portfolio. Please send any questions or feedback to contactgmas@harvard.edu

Howard Hughes Medical Institute
 Decoding the mitochondrial proteomes of six pathogenic protists
[8338824-01](#) PI: Manoj Duraisingh Dept: 23440 SPH*Immunology+Infectious Diseases Prime

Time	GMAS link	Action taken	Person
10:45am	Initial proposal #6465796	Request Under Internal review	Maura Duff

NIH/NIAID
IMPAC-TB: Immune Mechanisms of Protection against Mycobacterium tuberculosis Center (IMPAC-TB)
[7658994-01](#) PI: Sarah Fortune Dept: 23440 SPH*Immunology+Infectious Diseases Fund 109786 Prime

Time	GMAS link	Action taken	Person
10:22am	Action memo #85	Revision committed	Elaine Kiley
Action memo comment: This action corrects all start dates for Group 04 accounts. Dates are changed to 4/1/2022.			

AIDS Prevention Initiative in Nigeria, Ltd/Gte.
 Engaging Indigenous Organizations to Sustain and Enhance Comprehensive Clinical Services for the Prevention, Care and Treatment of HIV/AIDS in Nigeria under PEPFAR
[6587523-02](#) PI: Phyllis Kaniki Dept: 23440 SPH*Immunology+Infectious Diseases Fund 109745 Prime

Time	GMAS link	Action taken	Person
10:38am	Notice issued Feb 11, 2022	Notice reviewed by central	Chhanda Deb
10:44am	Notice issued Feb 11, 2022	Notice Accepted and applied	Chhanda Deb
10:45am	Action memo #12	Revision committed	Chhanda Deb
Action memo comment: This action removes Y10 from At-Risk status per Amendment #5 Fully Executed 5/13/22. *Please note that terms and conditions have been modified for Y5*. Please note: Use of animals or human subjects (or human subjects data/tissue) under this award is permissible only when the protocol(s) has been reviewed and approved by the IRB or IACUC, as applicable.			

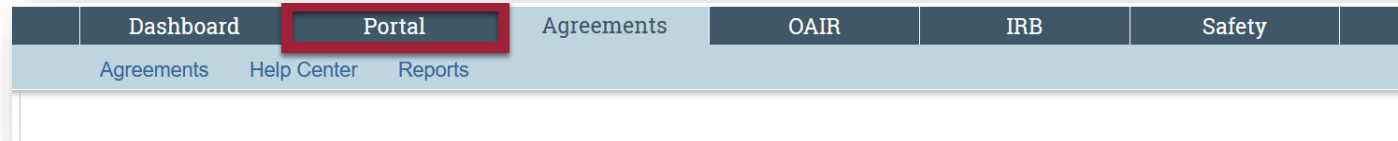
💡 Tip: cleaning up your portfolio will make this digest even more useful! Email contactgmas@harvard.edu, if you need help! 💡

Research Administration and Compliance Suite

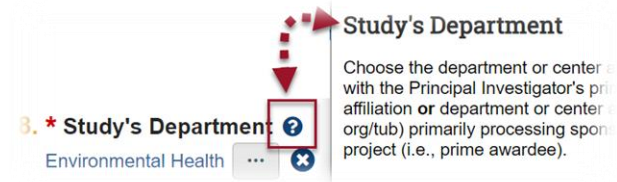
ESTR-IRB, Agreements-DUA, Data Safety, and Outside Activity and Interest Reporting (OAIR)

Suite-wide minor upgrade planned for late July

- Release details will be available in June
- Includes enhancements to navigation and workspace views, along with new cross-navigation with the Research Administration Portal



Context-relevant help now available in ESTR-IRB, Agreements-DUA, Data Safety SmartForms!



Research Management Project

Vision

Develop and integrate innovative IT solutions for researchers and administrators to meet current and future regulatory changes while reducing administrative burden. These solutions support our goal to consistently facilitate the University's research mission from financial, compliance, and administrative perspectives.

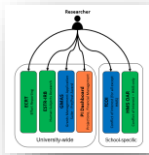
Principles

- “One Harvard” approach
- Balance compliance with efficiency
- Synchronize data
- Optimize researcher and administrator experience
- Commitment to user focus
- Iterate on our successes and the foundation we've built

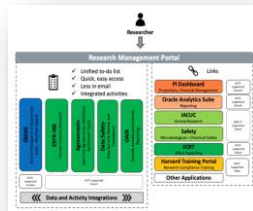
Benefits + Outcomes

- Maximize responsiveness to regulation changes
- Increase transparency
- Improve data integrity
- Address gaps and duplications
- Streamline processes
- Researchers spend more time on their research, less time navigating systems and requirements

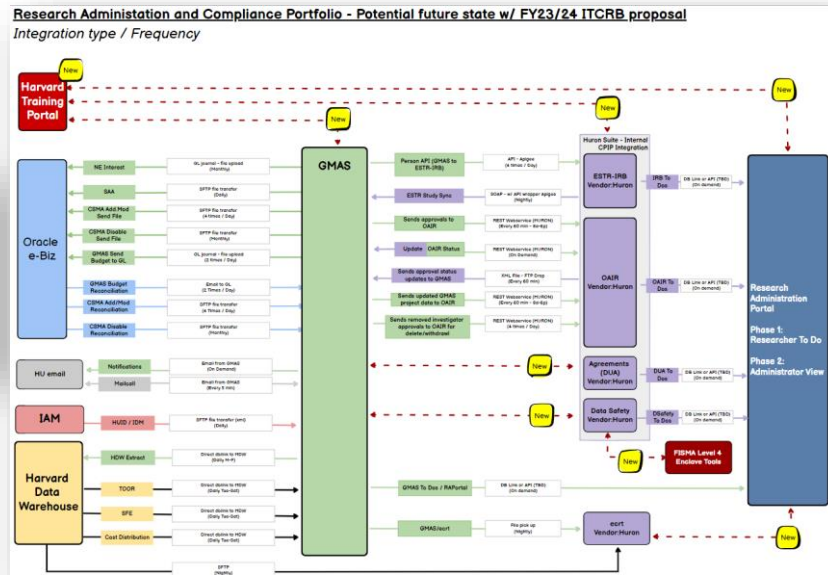
Research Management Portal



Past
Disconnected



Present
Consolidated



Future
Integrated

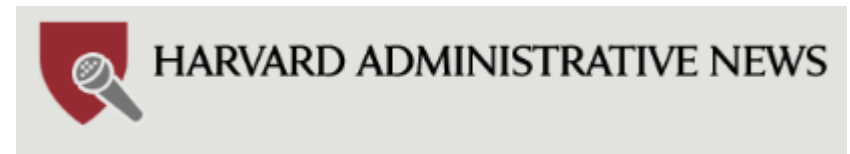
Research Management Portal

Project Tracks	Examples
Integrations + Reporting	<p>Integrations</p> <ul style="list-style-type: none">• GMAS ↔ Harvard Training Portal• GMAS ↔ Agreements (Data Use Agreements)• Research Administration Portal ↔ Harvard Training Portal• Reporting• User-friendly data models to support users• Dashboards and reports to monitor compliance, manage workload
Portal	<ul style="list-style-type: none">• Administrator-focused version of the Research Management Portal• Expansion of the researcher version of the portal
Expansion + Enhancements	<ul style="list-style-type: none">• GMAS, Agreements, and OAIR enhancements to support the new federal requirements for faculty disclosures and Other Support documentation• Enhance the Agreements/Data Use Agreement and Data Safety systems per emerging FISMA requirements

Stay Informed

The screenshot shows the top of the Harvard University website. At the top left is the Harvard University logo and name. Below that is the title "Research Administration and Compliance Systems" with the subtitle "Facilitating Research at Harvard". A dark red navigation bar contains the following links: HOME, System Information (with a dropdown arrow), User Resources, and Releases. Below the navigation bar is a "PI Dashboard" section featuring a photograph of a tree and the text "Learn more about PI Dashboard here." with left and right navigation arrows. Below this is a "WELCOME" section with a paragraph of text: "Research Administration Systems team partners with the business groups to provide the technology needed to support the grants management process including project delivery, product management, and end user support."

<https://ras.fss.harvard.edu/>



<https://admin-eneews.eureka.harvard.edu/home>

Faculty Disclosure Website Update

Tracey Westervelt

New NIH Harassment Reporting Policy

Sarah T Axelrod

Harassment Reporting

39

History

- **3 agencies have issued requirements for harassment reporting – NIH, NSF, NASA**
- **Harvard developed guidelines for reporting**
- **Each school identified a School Official who is responsible for reporting potential issues**

Harassment includes sexual harassment, sexual misconduct, bullying, retaliation, or hostile working conditions

Harassment Reporting

40

NIH update – issued May 10, 2022, (NOT-OD-22-129)

- **Effective July 9, 2022**
- **Requires notification to NIH, within 30 days if:**
- **PD/PI or other Senior/Key personnel are removed from their position or are otherwise disciplined by the recipient institution due to concerns about harassment**
- **Updated requirement regarding notification if changes in PI or institution are due to harassment**