

# Step by step instructions on how to add / modify an Open Science Data Plan deliverable

*Data Plans are living documents and might need to be updated throughout the award term. Below are the steps to add or modify your data plan.*

1. From your deliverables tab, click on the 'Add Deliverable' button. A separate window will open to add deliverable. If you do not see the separate window, be sure that your pop-up blocker is turned off. Select the 'Open Science Data Plan/Opt-Out' deliverable from the list of deliverable types. Type in the deliverable description if desired, then click save. The newly created deliverable will then appear in your list of deliverables.

The screenshot shows the 'Add & Upload Deliverable' window in a browser. The window has a title bar 'Altum ProposalCentral Post Award System - Google Chrome' and a URL 'aha-staging.proposalcentral.com/ProposalCentral/Awardee/AwardeeDelvr/UploadDeliverables.aspx?DelvrID=18&AwardID=153561&ProposalID...'. The form contains the following fields:

- Deliverable Type: Open Science Data Plan/Opt-Out
- Deliverable Type Description: Open Science Data Plan/Opt-Out
- Deliverable Description: Please provide a meaningful description for this deliverable

Buttons for 'Save' and 'Cancel' are at the bottom. A red arrow points to the 'Add Deliverable' button in the background. A callout box says: 'When you click on "+Add Deliverable", a separate window will appear. Be sure your pop-up blocker is turned off if you do not see this window. Once you have selected the correct deliverable type, click save.' Another callout box says: '1) Select "Open Science Data Plan/Opt-Out" from the drop down options. 2) Type in a description if desired.'

The background shows a table of deliverables:

Due Date	Deliverable Type	Deliverable Description	PI	Status
03/17/2022 12:00 AM	Award Project Budget (Period 1)			Approved - Final
03/17/2022 12:00 AM	Concern Other Industries			Approved - Final
03/17/2022 12:00 AM	Award Bank Information			Approved - Final
03/17/2022 12:00 AM	Award Animal Subject Use Form	Raj Amin(PI)	Award Animal Subject Use Form	Submitted - Final
03/27/2022 12:00 AM	Precision Medicine Platform	Raj Amin(PI)	Precision Medicine Platform	Submitted - Final
05/31/2023 12:00 AM	Open Science Data Plan/Opt-Out		Raj Amin(PI)	
05/31/2023 11:59 PM	Data Deposit Confirmation		Raj Amin(PI)	

Callouts for the table rows:

- Click on the '+' icon to start editing your deliverable.
- Once you click save, your newly created deliverable will show up in your list of deliverables in the deliverable tab.

2. Click on the '+' icon on the right to start editing your deliverable. Note there are two radio buttons: 'Data Plan' and 'Data Plan Opt-Out'. Selecting the appropriate radio buttons will populate different questions to answer.
  - a. Selecting 'Data Plan' radio button:  
Answer the presented questions regarding your data plan. Make your repository selections by selecting from the "Repository List - Options", then move your selection with the arrow buttons in the center to "Repository List - Selected". When finished, be sure to click save before clicking 'Submit to Grant Maker as Final' button.

Select the 'Data Plan' radio button.

**Data Plan**  **Data Plan Opt-Out** **Note:** The Data Plan or Opt Out tab selection is based on your last submission, if submitted before. To change the tab selection and its details, 1) use the Clear button in the current tab to remove the saved data 2) Select the Data Plan or Opt Out tab and enter data appropriately.

Please describe the data (i.e., recorded factual material) that would be necessary to validate your research findings. This should just be a few sentences that describe the data and accompanying metadata. Please do not reference potential publication or presentation of your results.

Sample data plan 1: Our research will generate mechanistic data on the regulation of the Sbf complex involved in autophagy and myocardial ischemia/reperfusion. Specifically, the data content will focus on Sbf/MTMR13 and PI3KC2 genotype and phenotype analysis in flies, human and rat cells and mice, with an emphasis on the cellular basis for the starvation-induced Sbf/MTMR13 interactions and modifications that promote Rab21 GTPase activity. Meta data will also be included in the selected repositories.

Sample data plan 2: The existing genomic and phenotypic data from the Framingham Heart Study and the Atherosclerosis Risk in Communities Study that will be used in this study are already available in

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\* Approximate date of when the data will be shared.

1/1/2025

Please explain any limits to data sharing that might be required.

We do not currently have any limits on data sharing.

\* Where will the data be made available? Select all that apply.

Repository List - Options

ClinicalTrials.gov  
ClinVar  
COSMIC  
dash (general)  
database of Genotypes and Phenotypes  
Database of Single Nucleotide Polymorphisms  
Dataverse (general)  
Electron Microscopy Databank  
European Genome-phenome Archive (EGA)  
European Nucleotide Archive (ENA)



Use the buttons in the center to move repository selections from the left to the right.

Repository List - Selected

Other  
International Mouse Phenotype Consortium  
Metabolomics Workbench  
Protein Data Bank in Europe (PDBe)

If 'Other' is selected, a new set of questions will populate. Answer the questions pertaining to the other repository. If the other repository is not approved, or if it was selected in error, simply select 'Other' from the list on the right and use the arrow buttons in the center to remove.

Please enter the name of the repository

The RCSB bank focuses upon protein modeling and folding which influence enzymatic activity. <http://www.rcsb.org/pdb/home/home.do>

Since you intend to submit your data to a repository not on the pre-approved list, please explain the reason

The RCSB bank is protein modeling and folding bank. Thus our acetylation assays will allow us to share the impact of FXN acetylation on protein folding, enzyme activity and the ability to interact with the other players in the Fe-S biosynthetic pathway.

How will others be able to access the data?

All these are open access.

Does this repository confirm to the "acceptable repository" criteria set forth on our website?

Please select your answer

Yes

No

Uncertain

How will the grant recipient ensure that key datasets are preserved to ensure their long term value?

International Mouse Phenotype Consortium

Protein Data Bank in Europe (PDBe)

Metabolomics Workbench

These are all open access.

Be sure to click save before submitting.

Save Cancel Clear

\*If you select 'Other' from the list of repositories, another set of questions will populate for you to answer. Please answer the provided questions regarding the repository that is not part of AHA's approved repositories list. AHA staff will review if the proposed repository is acceptable. If the other repository is not approved, or if selected 'other in error, simply remove it from the list by using the arrow buttons in the center, and the subsequent questions will also be removed. Be sure to click save before submitting.

b. Selecting 'Data Plan Opt-Out' radio button:

If selecting an opt out, please explain why the Open Data policy should be waived. All Opt-Out requests will need to be approved. Generally, most opt-out requests fall into one of the following categories, however you can provide other rationale as well. Here are the definitions of the categories:

- Human Subject Grounds: As the National Science Foundation explains, “[H]uman subject’s protection requires removing identifiers, which may be prohibitively expensive or render the data meaningless in research that relies heavily on extensive in-depth interviews.” Data sharing may not violate privacy regulations stipulated by HIPAA or fail in any way to safeguard the rights of research participants. It is the responsibility of the applicant to make a case for why the use of the HIPAA Safe Harbor de-identification method would not be feasible for their data.
- Superseding Regulations Grounds: Governing laws or institutional policies may limit the release of certain data.
- Intellectual Property (IP) Grounds: Although data sharing may not protect IP, opt-out requests citing protection for potential or anticipated IP will not be approved until after IP rights are established.

Once you have typed in your rationale as to why you want to opt out of data sharing and made the appropriate selections, be sure to click save before submitting.

Data Plan  Data Plan Opt-Out

Note: The Data Plan or Opt Out tab selection is based on your last submission, if submitted before. To change the tab selection and its details, 1) use the Clear button in the current tab to remove the saved data 2) Select the Data Plan or Opt Out tab and enter data appropriately.

Select the 'Data Plan Opt-Out' radio button.

Please describe the data (i.e., recorded factual material) that would be necessary to validate your research findings. This should just be a few sentences that describe the data and accompanying metadata. Please do not reference potential publication or presentation of your results.

There are two datasets used in this proposal: 1. United States Renal Data System (USRDS): The USRDS is a national data system that collects, analyzes, and distributes information about CKD and ESKD in the US. Final-action Medicare claims, available for the vast majority of patients regardless of age, constitute the backbone of the USRDS. Additional data are collected through CMS forms (Medical Evidence Report, CMS-2728; Death Notification, CMS-2746). In addition to Institutional (Part A) and Physician/Supplier (Part B) claims, detailed prescription drug claims are available through Medicare Part D since 2006, in which >70% of ESKD patients on dialysis enroll. 2. Merged USRDS and DaVita clinical data: DaVita Kidney Care, a division of DaVita, Inc., based in Denver, CO, is a leading dialysis provider and owns and manages >2510 outpatient dialysis facilities serving >198,000 patients. DaVita clinics are located throughout the US in urban, rural, and suburban areas. DaVita Clinical Research has developed a comprehensive database that captures detailed clinical, laboratory, and treatment data on patients receiving care at their facilities. All data are captured using a standardized electronic health record; all laboratory samples are analyzed centrally using standardized methods. The NIDDK

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\* Please explain how sharing your data would violate governing laws and/or institutional policies. Include links or copies of any documentation to support your assertion.

Data sharing limitations are different for the two datasets used in this proposal: 1. For the USRDS, the USRDS Coordinating Center provides data to anyone who submits a qualified request and receives approval by the NIH-NIDDK. However, per our data use agreement with the USRDS we are unable to share the data directly. 2. For the merged USRDS and DaVita clinical data, sharing of data from the electronic health records by DaVita, Inc., is not allowed by specific language in the contract and data use agreement. We will make all programs used to conduct the analyses available upon receiving a reasonable request.

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On what grounds are you seeking an exemption? Perceived lack of data value to other is not sufficient grounds for exemption.

Intellectual Property Grounds

Financial Grounds

Human Subjects

Superseding Regulations Grounds

Other

Be sure to click 'Save' before submitting.