

**NIH "FORMS-H" Grant Application Forms and Instructions
Coming for Due Dates on or after January 25, 2023**

Forms G Changes	Additional Notes
<p>Important – Do Not Include Personal Identifiable Information (PII) Or Protected Health Information (PHI) In the Application</p>	<ul style="list-style-type: none"> • Sensitive PII (e.g., Social Security Number, personal financial information, Alien Registration Number) and PHI (e.g., personal medical conditions) require strict handling due to the increased risk to an individual if the data is compromised. Documents containing sensitive PII or PHI must not be included in the application.
<p>Resubmission Applications – MPI Change, Address in the Introduction & MPI Plan</p>	<ul style="list-style-type: none"> • For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided in the introduction.
<p>Renewal Applications – MPI Change, Address in the MPI Plan</p>	<ul style="list-style-type: none"> • For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided
<p>Data Management and Sharing Plan – for Training, Fellowship & Career Development Applications</p>	<ul style="list-style-type: none"> • Although the 2023 NIH Data Management and Sharing Policy is not applicable to Institutional Training & Fellowship grant applications: the attachment field was added as 13. Other Plan(s) for Institutional Training Grants and 17. Other Plan(s) for Fellowships for potential future use. • The Data Management and Sharing Plans, discussed below, will apply to Career Development Applications starting in January 2023.
<p>Data Management and Sharing Plan - Budget</p>	<ul style="list-style-type: none"> • Special Instructions for Applications Submitted with a Data Management and Sharing Plan: If a Data Management and Sharing Plan is required in the proposed application, personnel costs specific to Data Management and Sharing activities must not be included under section A & B of the RR budget under Personnel, but listed as a specific line item under Section F.8.-17 Other Direct Costs. • NIH recognizes that making data accessible and reusable for other researchers may incur costs. If a Data Management and Sharing Plan is required in the proposed application (see instructions for the “Other Plan(s)” attachment on the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form, as applicable), costs to support these activities, including personnel costs (e.g., personnel who will be curating data for the project) must be noted as a single line item. The line item must be titled "Data Management and Sharing Costs" (without quotation marks, but following exact phrase and spacing). The line item must only be used for Data Management and Sharing costs and cannot include or be combined with any "Other" costs. If no cost will be incurred, enter "0" in the "Funds Requested" column. Details regarding Data Management and Sharing costs must be specified in the Budget Justification attachment, pursuant to the instructions. • Allowable and Unallowable Costs: Allowable costs submitted in budget requests must be incurred during the performance period, even for scientific data and metadata preserved and shared beyond the award period. Budget requests must NOT include: Infrastructure costs that are

	<p>included in institutional overhead (for instance, NIH Grants Policy Statement Section 7.3 Facilities and Administrative costs); costs associated with the routine conduct of research, including costs associated with collecting or gaining access to research data; or costs that are double charged or inconsistently charged as both direct and indirect costs. For more information, see Budgeting for Data Management & Sharing on the NIH Scientific Data Sharing website and additional details to help Develop Your Budget.</p>
<p>Data Management and Sharing Plan – Budget Justification & Additional Narrative Justification</p>	<ul style="list-style-type: none"> • If a Data Management and Sharing Plan is required in the proposed application (see instructions for the “Other Plan(s)” attachment on the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form, as applicable), include a brief justification of the proposed activities that will incur costs. The Data Management and Sharing justification must be clearly labeled as “Data Management and Sharing Justification” in the within the budget justification attachment. Provide a brief summary of type and amount of scientific data to be preserved and shared and the name of the established repository(ies) where they will be preserved and shared. Indicate general cost categories such as curating data and developing supporting documentation, local data management activities, preserving and sharing data through established repositories, etc., including an amount for each category and a brief explanation. Specify in the justification if no costs will be incurred for Data Management and Sharing, if applicable. The recommended length of the justification should be no more than half a page. For more information, see Budgeting for Data Management & Sharing on the NIH Scientific Data Sharing website and additional details to help Develop Your Budget • If submitting a Modular Budget, an Additional Narrative Justification is Required for Applications Submitted with a Data Management and Sharing (DMS) Plan. The Additional Narrative Justification follows the same guidance as the Budget Justification instructions for non-Modular grants.
<p>Data Management and Sharing Plan – *New* 11. Other Plan(s) upload</p>	<ul style="list-style-type: none"> • Who Must Complete This Section: Refer to the list of NIH activity codes subject to the DMS Policy and your Funding Opportunity Announcement to determine if your application is required to provide an attachment and address a Data Management and Sharing (DMS) Plan. Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a Data Management and Sharing (DMS) Plan. Scientific data is defined as the 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. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens. • The NIH Genomic Data Sharing Plan expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan. • Applicants subject to both the NIH Data Management and Sharing Policy and the NIH Genomic Data Sharing Policy must attach a single Plan

	including elements for both policies.
<p>Data Management and Sharing Plan – Format</p>	<ul style="list-style-type: none"> • A sample format is provided on the Data Management and Sharing Plan Format Page to assist applicants with preparation of this attachment. Do not include hyperlinks in this attachment. Recommended not to exceed two pages. • Follow the expectations of the NIH Policy for Data Management and Sharing and address the Elements of an NIH Data Management and Sharing Plan described below • Additional expectations: A Data Management and Sharing Plan should reflect the proposed approach at the time the application is prepared. For some programs and data types, NIH and/or NIH Institutes, Centers, Offices, or programs have developed additional data sharing requirements (e.g., specifying which scientific data to share, relevant standards, repository selection, timelines) that apply and should be reflected in a Plan. These additional requirements may be listed on NIH Institute and Center Data Sharing Policies or in specific funding opportunity announcements. Note that some NIH Institutes, Centers, Officers, or programs have developed additional expectations for sharing genomic data that may be listed on NIH Institute and Center Genomic Data Sharing Expectations or in specific funding opportunity announcements.
<p>Data Management and Sharing Plan -- Elements</p>	<ul style="list-style-type: none"> • Data Type: Data Type: Briefly describe the scientific data to be managed, preserved, and shared, including a general summary of the types and estimated amount of scientific data to be generated and a description of which scientific data from the project will be preserved and shared as well as the rationale for doing so. Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data. • Related Tools, Software and/or Code: State whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software. If specialized tools or software are needed, provide the name(s) of the needed tool(s) and software and specify how they can be accessed. • Standards: State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources (e.g., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation), and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist. • Data Preservation, Access, and Associated Timelines: Provide plans and timelines for data preservation and access, including the name of the repository(ies) where scientific data and metadata arising from the project will be archived (do not include hyperlinks); how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools; and when (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) the scientific data will be made available to other users (e.g., the larger research community, institutions, and/or the broader public) and for how long. See Selecting a Data Repository on the NIH Scientific Data Sharing website.

	<ul style="list-style-type: none"> • <u>Access, Distribution, or Reuse Considerations:</u> NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data generated from NIH-funded or conducted research, consistent with privacy, security, informed consent, and proprietary issues. Describe and justify any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements, or any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data. State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval). • Genomic Data Sharing Policy: For proposed research subject to the GDS Policy, state whether data, including genomic summary results, will be made available through controlled or unrestricted access; see instructions for describing Genomic Summary Results in Data Management and Sharing Plans. <p>If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures). See NIH’s Scientific Data Sharing page for additional information on protecting human research participant privacy when sharing data.</p> <p>For proposed research generating human genomic data within the scope of the GDS Policy, applicants should complete the Data Management and Sharing Plan anticipating sharing according to the assurances of the Institutional Certification.</p> <p>If there is any element of the Institutional Certification that the institution (in consultation with the IRB) has determined cannot be met, please state which element and provide a detailed explanation for why the element cannot be met. In such cases, the data management and sharing plan should describe how genomic data will be shared to the maximal extent possible (for example, sharing data in a summary format).</p> <p><u>Oversight of Data Management and Sharing:</u> Describe how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom at the applicant institution (e.g., titles, roles).</p>
<p>Data Management and Sharing Plan – Genomic Data Sharing</p>	<ul style="list-style-type: none"> • As detailed above: Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan. Formerly this information was included in the Resource Sharing Plan.