

DATA MANAGEMENT AND SHARING POLICY

SECTION H - SPECIAL CONTRACT REQUIREMENTS

187

****(INCLUDE THE FOLLOWING IN ALL SOLICITATIONS AND CONTRACTS FOR R&D REQUIREMENTS. IN ACCORDANCE WITH THE "NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 05 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS THAT HAVE R&D (RESEARCH & DEVELOPMENT) REQUIREMENTS.)****

ARTICLE H.32. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from any NIH-funded or conducted research, supported in whole or in part with direct costs from NIH regardless of NIH funding mechanism. NIH defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications that result from the publishing and peer review process, and which should be made accessible as soon as possible, and no later than the time of an associated publication or the end of the award/support period, whichever comes first. The PMC archive will permanently preserve and retain these manuscripts for use by the public, health care providers, educators, scientists, and NIH. NIH Policy directs electronic submissions to the NIH/NLM/PMC:

<https://www.ncbi.nlm.nih.gov/pmc/> .

Additional information is available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html> and <https://publicaccess.nih.gov/> .

302

****(USE BELOW FOR ALL CONTRACTS THAT REQUIRE A "DATA MANAGEMENT AND SHARING PLAN" FOR THE MANAGEMENT AND SHARING OF FINAL RESEARCH DATA. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 05 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **First Paragraph:** Select the appropriate sentence within (“[...]”) the brackets below. Make sure to delete the sentence you will not be using.

ARTICLE H.87. SHARING RESEARCH DATA

[The Data Management and Sharing Plan submitted by the Contractor is acceptable/The Contractor's Data Management and Sharing Plan, dated [\[Insert Date\]](#), is hereby incorporated by reference herein.] The Contractor agrees to adhere to its Data Management and Sharing Plan and shall request the prior written approval of the Contracting Officer for any changes in its Data Management and Sharing Plan.

NIH encourages, to the maximum extent practicable, the sharing of final research data to serve public health for the common good and this contract is expected to generate research data that must be shared with the public and other researchers. NIH's Data Management and Sharing policies may be found at the following websites:

- [NOT-OD-14-124 - NIH Genomic Data Sharing Policy;](#)
- [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: Elements of an NIH Data Management and Sharing Plan;](#)
- [NOT-OD-21-015 - Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing;](#) and
- [NOT-OD-21-016 - Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research.](#)

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including but not limited to the Privacy Act of 1974 (2020 Edition), the Privacy Rule (see HHS-published documentation on the Privacy Rule at <https://www.hhs.gov/ocr/index.html>), the Health Insurance Portability & Accountability Act of 1996 (HIPAA), and the Health IT for Economic & Clinical Health (HITECH) Act, which was enacted as part of the American Recovery & Reinvestment Act of 2009 (ARRA).

As per NIH Notice NOD-OD-21-013, "Final NIH Policy for Data Management and Sharing," respect for participant autonomy and maintenance of participant privacy and confidentiality can be consistent with data sharing. The rights and privacy of people who participate in NIH-funded research shall be protected at all times and Contractors shall anonymize and aggregate (or otherwise fully protect from release) any personally identifiable information (PII), HIPAA-protected personal health information (PHI), and/or HITECH-protected electronic health information which they receive, use, and/or reference; thus, data intended for broader use should be free of any and all personal identifiers that would permit linkages to individual research participants and/or variables that could lead to any disclosure of the identity of individual subjects, direct or deductive, for which the Government shall have no liability whatsoever.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

717

****(USE BELOW IN ALL SOLICITATIONS WHERE RESEARCH DATA, INCLUSIVE OF GENOMIC DATA, WILL BE GENERATED. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, NOT-OD-22-189, IMPLEMENTATION DETAILS FOR THE NIH DATA MANAGEMENT AND SHARING PLAN, AND NOT-OD-22-198, IMPLEMENTATION CHANGES FOR GENOMIC DATA SHARING PLANS INCLUDED WITH APPLICATIONS DUE ON OR AFTER JANUARY 25, 2023, AS APPLICABLE, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA GENERATION REQUIREMENTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Last Paragraph:** Include this bracketed (“[...]”) paragraph for Multi-Center Clinical Trials or Epidemiological Studies. Make sure to delete this paragraph if it is not applicable.

a. **Management and Sharing of Research Data**

[Note: This policy applies to all NIH contracts, regardless of dollar value or level or type of funding, degree of funding (whole or partial), or type of NIH funding mechanism, that are expected to generate research data.]

NIH encourages, to the maximum extent practicable, the sharing of final research data to expedite the translation of research results into knowledge, products, services, and/or procedures to improve the human health condition. This contract is anticipated to generate such research data. Therefore, the Offeror shall submit to the Contracting Officer (CO) its Data Management and Sharing Plan, which also includes genomic data, as an attachment to its technical proposal or state why such data sharing is not possible. If data sharing is limited, the Offeror shall explain the rationale and nature of such limitations in its Data Management and Sharing Plan. An Offeror’s Data Management and Sharing Plan, including those that include genomic data, will no longer undergo peer review but be subject to NIH staff review and acceptance prior to award. NIH's Data Management and Sharing Policy may be found at the following Web site:

[NOT-OD-21-013: Final NIH Policy for Data Management and Sharing.](#)

NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources are found at: <https://grants.nih.gov/policy/sharing.htm>.

[If the resultant contract is part of a collaborative program involving multiple sites, all data management and sharing shall be governed by a data management, sharing, and

dissemination plan to be jointly developed prior to award. A Coordinating Center's proposal shall describe the methods by which to coordinate such data management, sharing, and dissemination planning and implementation efforts. In its proposal the Coordinating Center shall include a budget with all proposed costs and justification for/of any costs of such collaborative effort(s).]

SECTION M - EVALUATION FACTORS FOR AWARD

779

****(USE BELOW WHEN THE RESULTANT CONTRACT WILL GENERATE RESEARCH DATA AND MANAGEMENT AND SHARING OF THAT DATA MUST BE ADDRESSED BY EITHER PROPOSING A DATA MANAGEMENT AND SHARING PLAN OR PROVIDING A JUSTIFICATION FOR NOT SHARING DATA. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 05 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA MANAGEMENT AND GENERATION REQUIREMENTS. **Note:** *The plan or documentation as to the rationale for not providing a plan shall be evaluated by program staff and shall not be scored. However, weaknesses in a plan or in the rationale for not permitting the sharing of research data may be part of discussions.*)****

M.11. EVALUATION OF DATA MANAGEMENT AND SHARING PLAN OR ANY EXCEPTIONS

The Offeror's plan for the management and sharing of final research data, or, if data sharing is not possible, the Offeror's documentation of its inability to share research data, with justified limitations or exceptions, shall be assessed for appropriateness, adequacy, and reasonableness.

780

****(INCLUDE BELOW WHEN THE CONTRACT WILL GENERATE RESEARCH DATA AND SHARING OF THAT DATA IS REQUIRED. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 05 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA MANAGEMENT AND GENERATION REQUIREMENTS. **Note:** *The plan shall be evaluated by Program staff and shall not be scored. However, weaknesses in a plan should be part of discussions and shall be resolved before award.*)****

M.12. EVALUATION OF DATA MANAGEMENT AND SHARING PLAN

An Offeror's plan for the management and sharing of final research data (Data Management and Sharing Plan) shall be assessed for appropriateness, adequacy, and reasonableness.

If an Offeror's proposal does not include a Data Management and Sharing Plan (Plan) or if the Plan in an Offeror's proposal is considered "unacceptable," and the Government includes Offeror's proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), the Offeror will be afforded the opportunity to further discuss, clarify, and/or modify its Plan during discussions and in its Final Proposal Revision (FPR). However, if the Plan is still considered "unacceptable" by the Government after discussions, the Offeror may not be further considered for award.