

# NHGRI Extramural Investigators: Preparing For and Submitting Data Under the GDS Policy

## 1. Include a Genomic Data Sharing Plan (DSP) in your Grant Application

- Address how you will share any genomic data generated in your grant project in the “Resource Sharing Plan” section of the grant application or as per instructions in a Funding Opportunity Announcement (FOA) or Request for Proposals (RFP) for a contract.
- Contact your Program Officer or the NHGRI Genomic Program Administrator (GPA) with any questions.
- For more information, refer to: [Guidance for Institutions Submitting Grant Applications and Contract Proposals under the NIH Genomic Data Sharing Policy for Human and Non-Human Data](#).
- If your study generates human genomic data (or if your research institution otherwise requires IRB approval), submit your research protocol (including your data sharing plans) to all relevant IRBs, and/or Privacy Boards, and/or equivalent body, as applicable for a review and concurrence.

**Requests for Exceptions to the data sharing expectation: If you are requesting an exception to dbGaP data deposition for your study, include a justification in your DSP for why data sharing through dbGaP would be inappropriate.**

## 2. Scientific Review of Grant Application

## 3. Prepare and Submit Just-In-Time Information

- Submit the following forms:
  1. [Institutional Certification \(IC\)](#)
    - If your study generates human genomic data, prepare an [IC](#) signed by the following:
      - Authorized Institutional Signing Official\* from your institution.
      - Study investigator
  2. NHGRI Extramural Genomic Data Sharing Plan (GDSP) Form

\*An Institutional Signing Official is generally a senior official at an institution who is credentialed through NIH eRA Commons system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to NIH.

- Work with your Program Director and the NHGRI GPA to finalize and approve your Just-In-Time Information.

Note: All GDSP forms containing a request for an exception will be sent by the GPA to the NHGRI Director, who must review and approve the exception.

**4. The NHGRI GPA registers the study in the dbGaP submission system.**

- After your grant or contract has been awarded, the NHGRI GPA will register your study in dbGaP, if you are generating human genomic data. Within 48 hours of the registration process, the PI and assistant/submitter will be sent an automatic invitation from dbGaP which includes instructions on the data cleansing and submission process. The invitation expires in 7 days and should be accepted even if nothing more is done until later in the project period.

**5. Proceed with your study to generate genomic data**

- Include any updates on progress made toward your genomic DSP as part of your annual research reporting requirement

**6. Upload Data into dbGaP**

- Grantee will be provided with instructions from dbGaP on how to upload data to the dbGaP submission portal. For further instructions on submitting data, look over the [dbGaP submission process](#) and the [dbGaP Study Submission Guide](#).
- *Privileged Access Period:* Once you initiate data submission, you will enter a period of privileged data access, which NHGRI defines as 6 months or the period defined within the RFA or Notice of Grant Award. During this period, your data will not be available to other investigators through dbGaP while you perform data analysis and prepare for any publication of data.

**7. dbGaP Study Release**

- Data will be released six months after initiation of data submission OR at the time of first publication (whichever occurs first).