

SOP#: RPS-23

Registering a Clinical Trial in dbGaP

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NCI Clinical Director Signature:



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POLICY

The Genomic Data Sharing (GDS) Policy applies to all NIH intramural research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data.

Investigators should work with their designated Genomic Program Administrator (GPA) to register all studies with human genomic data that fall within the scope of the GDS Policy, in the database of Genotypes and Phenotypes (dbGaP).

**For clinical trials, the study registration process will start once data for the project have been generated, processed and checked.

PURPOSE

This standard operating procedure provides instructions on registering a Clinical Trial in dbGaP.

RESOURCES

- Database of Genotypes and Phenotypes (dbGaP) [portal](#)
- CCR Genomic Data Sharing [Website](#)
- [NIH Genomic Data Sharing Policy](#)
- NIH Genomic Data Sharing [Website](#)

Genomic Program Administrators (GPA)

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PROCEDURES

Step 1: Study Registration Process

- Once data for your project have been generated, processed and checked, contact GPA via email informing them that you would like to register your study with dbGaP. Attach an electronic copy of the signed Institutional Certification (IC) Memo.
 - **NOTE:** You should register your study even if you have applied for and have been granted a data sharing exception.
- GPA will send you:
 - dbGaP study configuration template and
 - dbGaP Basic Study Information Sheet. Example templates of both are included in Appendices A and B.
- Complete the required information and email the following to the GPA:
 - Completed dbGaP study configuration information and
 - Completed dbGaP Basic Study Information Sheet
- GPA will:
 - Ensure that forms are completely and accurately filled out
 - Register the study in the dbGaP portal
 - Invite PI to review the registered study and determine who will be the data submitter – PI or designee as assigned by the PI

Step 2: Confirmation of Accuracy

- After the registration process is complete, an email invitation from dbGaP will be sent to the PI to review the study information.
- PI reviews the information for completeness and accuracy. For any questions or concerns on any aspect of the registered study, or if there are any errors in the registration data, please email your GPA admin for help.