**NHGRI Basic Study Information**

Version 2023-1-12

For the National Human Genome Research Institute (NHGRI) to register your data into the dbGaP Submission System, please provide the information listed below and return to your NHGRI Program Officer (PO) and/or the NHGRI Genomic Program Administrator (GPA). The registration of your study in dbGaP should be described in and consistent with your approved Data Management and Sharing Plan.

You may use this sample document or any other format.

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| PART I – Principal Investigator (PI) and Funding Information | | | | | |
| PI name | | | Click or tap here to enter text. | | |
| PI email | | | Click or tap here to enter text. | | |
| PI institution | | | Click or tap here to enter text. | | |
| PI assistant/submitter name | | | Click or tap here to enter text. | | |
| PI assistant/submitter email | | | Click or tap here to enter text. | | |
| Do you have an eRA Commons account?  If YES, go to the next field.  If NO, register at <https://www.era.nih.gov/reg-accounts/register-commons.htm> | | | | | |
| NIH Grant or Contract Number | | | Click or tap here to enter text. | | |
| NIH Protocol Number(s) (Intramural Research Program only) | | | Click or tap here to enter text. | | |
| NIH Program Officer | | | Click or tap here to enter text. | | |
| NIH Institutes/Centers supporting the study | | | Choose an item.  Choose an item.  Choose an item.  Choose an item. | | |
| PART II – Study Registration Information | | | | | |
| Study name | | | Click or tap here to enter text. | | |
| Estimated # of study participants | | | Click or tap here to enter text. | | |
| Access type | | | Controlled Access Unrestricted Access | | |
| Submission location(s) (check all that apply) | | | AnVIL  dbGaP SRA  Other: Click or tap here to enter text. | | |
| PART III – Study Description | | | | | |
| Target data delivery date | | | | Click or tap to enter a date. | |
| Target public release date | | | | Click or tap to enter a date. | |
| Expected data types and other study information (check all that apply). **Note that phenotypic data and metadata associated with the study should be submitted.** | | | | | |
| **Check all data types expected for this study:**  Phenotype  Links to public NCBI databases  Documents  Images  Other files not covered and / or any other notes about expected data: Click or tap here to enter text. | **Molecular**  Sequence-based Multi Sample Genotype Files  Array-based Multi Sample Genotype Files  Single Sample Genotype Files Derived from Sequencing  Imputed Genotypes (IMPUTE, Others?)  Tumor/Normal Variations / Somatic SNV (.MAF)  CNV calls from microarray  Methylation Array Data or Summaries  Expression Array Data or Summaries  CNV calls derived from Sequencing  Other, Please Specify:  Click or tap here to enter text. | | | **Subjects and Samples**  Germline  Tumor/Normal  DNA  RNA  Mitochondria  Microbiome  From Repository  Other (specify): Click or tap here to enter text. | Other files not covered and/or any other notes about expected data:  Click or tap here to enter text. |
| **Links to public NCBI databases**  GEO  SRA  GenBank  Trace | **Sequence**  **Please select one storage option:**  Cloud Data Storage for Sequence Data (e.g., AnVIL)  NCBI Storage for Sequence Data (e.g., SRA, Amazon Cloud, Google Cloud)  **Please select the following submission options:**  Whole or Targeted Genome  Whole or Targeted Exome  RNA Seq – Whole or Targeted Transcriptome  MethylSeq/Epigenomic Marks  Microbiome Sequence (Metagenome, 16S rRNA, 18S fRNA, ITS)  Other (specify): Click or tap here to enter text. | | | **Association Analyses**  SNP Based Association Results  Gene Based Association Results  Other (specify): Click or tap here to enter text. |
| Part IV – Policy Requirements for Large-Scale Human Genomic Data | | | | | |
| The Institutional Certification (IC), provided by the submitting investigator and a signing official (SO) at the investigator's institution, assures NIH that submission of large-scale human genomic data to an NIH-designated data repository is consistent with the NIH GDS Policy, the informed consent of the original study participants, and/or the preferences of the original study population. To learn more about ICs, the role of an IRB in reviewing an IC, what institutions are expected to certify, and more, see [About Institutional Certifications](https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/about-institutional-certifications). | | | | | |
| Do you have an institutional Certification(s) (IC) to submit these data? | | Yes  No | | | |
| If YES, send the IC(s) to your NIH Program Officer and the Genomic Program Administrator along with this document.    If NO, follow the instructions for [Completing an Institutional Certification Form](https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form). Human genomic studies cannot be registered until the NIH Institute/Center verifies that this certification has been met. | | | | | |
| Part V – Acknowledgement Statement(s) | | | | | |
| This is how future users will be expected to acknowledge this dataset in publications once it is released.  Please provide specific points that should be included in the Acknowledgment, such as sources of support or collaborators who provided subjects or samples. NIH support must be specifically acknowledged by including the grant number. Consider citing a publication that comprehensively describes the origin of the dataset. | | | | | |
| Click or tap here to enter text. | | | | | |

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| Part VI – Request for an Exception for Samples Lacking Explicit Consent for Future Research Use and Broad Sharing | |
| NHGRI expects all human data generated by NHGRI-supported research will be derived from specimens or cell lines for which explicit consent for future research use and broad sharing can be documented. NHGRI recognizes that not all studies are able to meet this expectation. For these studies, an exception may be requested with strong justification. | |
| Are you requesting an exception to submit data derived from cell lines or specimens for which explicit consent for future research use and broad sharing cannot be documented?  **If YES, provide the name or description of the human specimen(s)/cell line(s), rationale for the proposed use, and a written justification using the Request for an Exception to the Explicit Consent Expectation template. Append the completed template to this document before submitting it to your PO and/or GPA.** | Yes  No |