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| In order for the **NHLBI**/**NIH** to register your data into the dbGaP Submission System, please provide the information listed below and return to your **NIH Program Officer (PO)** and the **NHLBI/NIH** **mailbox** [nhlbigeneticdata@nhlbi.nih.gov](mailto:nhlbigeneticdata@nhlbi.nih.gov).  You may use the sample documents or any other format. Text boxes below are expandable. | |
| **PART I – Study Registration Information** | |
| Study name (Please align study name with the study name/title on the Study Config file submitted to dbGaP for data deposits): | |
| Is this a multi-center study? (Y/N) \_\_\_\_\_\_\_\_\_  IF YES, please list participating sites: | |
| Target data delivery date: (YYYY-MM-DD) | Target public release date: (YYYY-MM-DD) |
| Estimated number of study participants: | |
| Submitting Sequence Read Archive (SRA)? (Y/N) \_\_\_\_\_\_\_\_    IF YES, SRA data will be deposited in (check all that apply and fill in contact information for cloud providers):  NCBI  Google Cloud   1. Name and email of Cloud Service Administrator (Google): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. Name and email of Data Steward (i.e. Person submitting data): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   Amazon Web Service (AWS)   1. Name and email of Cloud Service Administrator (AWS): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 2. Name and email of Data Steward (i.e. Person submitting data): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Has this study been accepted for publication? (Y/N) \_\_\_\_\_\_\_\_\_\_\_ (If yes, please attach documentation) | |
| **PART II – Principal Investigator (PI) and Funding Information** | |
| PI name: | PI e-mail: |
| PI institution: | |
| Should the data be available for direct access by the primary study PI (not a collaborator or consortium)[[1]](#footnote-1)? (Y/N) \_\_\_\_\_\_\_\_\_ | |
| Secondary contact/Data Submitter name: | Secondary contact e-mail: |
| eRA Commons username (or NIH NED user ID):  **If not registered, please register at** <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. | |
| NIH Grant(s) or Contract Number(s): | NIH Program Officer:  Program Officer email: |
| NIH Institutes/Centers supporting the study: | |
| NIH Institutes/Centers that this study is a part of or collaborating with: | |
| **PART III- Study Description** | |
| Study type(s) (e.g., longitudinal, case-control, case set, control set, parent-offspring trios, cohort): | |
| Is this study related to a pre-existing registered dbGaP study? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_  IF YES, please provide the phs accession number and/or title of the study: \_\_\_\_\_\_\_\_\_\_\_\_ | |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **PART III (continued)- Study Description** | | | | | | | | Please check all data types expected for this study: | **General**  Individual Phenotype  Individual Genotype  Individual Sequencing  Supporting Documents  Metagenomic  Proteomic/Metabolomic  Images | | | **Sample Types**  Germline  Tumor/Normal  DNA  RNA  Mitochondria  Microbiome  From Repository | | **Array Data**  SNP Array  Expression Array  Methylation Array | | **Genotypes**  Array derived Genotypes  CNV calls from microarray  CNV calls derived from Sequencing  Genotype calls derived from Sequence  Somatic SNV (MAF)  Array CGH CNVs | | | **Sequencing**  Whole Genome  Whole Exome  Targeted Genome  Targeted Exome  Whole Transcriptome  Targeted Transcriptome  Epigenomic Marks  Sanger  16S rRNA | | **Analyses**  Association/Linkage Results  Array derived Expression  RNA Seq derived Expression  Array derived Methylation | | **PART IV – Genotype platform information** | | | | | | | | Name and version | | Vendor | # Probes | URL | Description (optional) | | | ***Example****: [GenomeWideSNP\_6] Affymetrix Genome-Wide Human SNP 6.0 Array* | | ***Example****:*  *Affymetrix* | ***Example****:*  *1880794* | ***Example****:*  [*http://www.ncbi.nlm.nih.gov/geo/query/acc.cgi?acc=GPL6801*](http://www.ncbi.nlm.nih.gov/geo/query/acc.cgi?acc=GPL6801) |  | | |  | |  |  |  |  | | |  | |  |  |  |  | | |  | |  |  |  |  | | | **PART V – Acknowledgement Statement(s)\*\*\*** | | | | | | | | *The suggested Acknowledgement Statement to accompany the dataset is*:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*\*\* The submitting PI should provide specific points that should be included in an acknowledgement, such as sources of support or collaborators who have made subjects or samples available. Consider citing a specific publication that comprehensively describes the origin of the dataset. | | | | | | | | **PART VI – Original Summary of Study** | | | | | | | | *Please provide an original description of the study.* | | | | | | |   Is the aggregate-level data appropriate for General Research Use[[2]](#footnote-2)? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_ | |
| If this study was initiated after January 21, 2019[[3]](#footnote-3), and local IRB approval (Full or Expedited) is required for secondary research[[4]](#footnote-4), does it also require continuing review and approval by the requesting institution’s IRB? (Y/N) \_\_\_\_\_\_\_\_\_\_\_\_  IF YES please provide justification for continuing review (i.e. longitudinal study, geographically isolated/sensitive populations, rare diseases, etc.): | |

1. The streamlined mechanism does not require that the PI submit a project data access request through dbGaP to gain access to the data they have submitted to dbGaP. [↑](#footnote-ref-1)
2. To be included in the [Compilation of Aggregate Genomic Data](http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study501.cgi?study_id=phs000501.v1.p1&pha=&phaf=), a collection of analyses across many dbGaP studies that can be accessed with a single Data Access Request. [↑](#footnote-ref-2)
3. The compliance date of the [HHS Revised Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html) is January 21, 2019. [↑](#footnote-ref-3)
4. Data Use Limitations are based on the participants’ informed consent, as assured by the study’s [Institutional Certification](https://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification_Pre2015.pdf). [↑](#footnote-ref-4)