

Submission of WHI Genetic Data to dbGaP by Ancillary Study Investigators
QUICK INFO SHEET
(Also see more detailed “Submission of WHI Data to dbGaP – Guidelines”)

Summary: If an Ancillary Study is submitting its data as a WHI Substudy, the procedure is to obtain Institutional certification, register the substudy with dbGaP, get a link file with Common-dbGaP Subject ID-dbGaP Sample IDs from the WHI-CCC, create a Subject-Sample mapping, and submit data to dbGaP via the submission portal.

1) WHI data should be submitted to dbGaP as a substudy to WHI (phs000200).

- a) PI obtains Institutional Certification (IC), as depositor of the data:
 - i) Use template IC: https://gds.nih.gov/Institutional_Certifications.html
 - (1) Template for WHI data is “For Studies Using Data Generated from Cell Lines Created or Clinical Specimens Collected BEFORE January 25, 2015” – – “that have consent”
 - (2) WHI consent group titles and modifiers are:
 - (a) Health/Medical/Biomedical-IRB (HMB-IRB)
 - (b) Health/Medical/Biomedical-IRB-Non-profit-use (HMB-IRB-NPU)
 - (3) Data Use Limitations (DULs) must be listed
 - (a) Print the IC, cut and paste DULs in before the page 3 signatures and rescan and sign to have a complete form, or
 - (b) Attach as an addendum, as long as it is clear that the signature covers the entire package.
 - ii) NOTE: Ancillary Study IRB cannot override the WHI parent consent group categories/DUL.
- b) PI works with the NHLBI Genomic Program Administrator (GPA) to register the substudy:

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 - i) Submit study registration form specific to the substudy
 - ii) Submit Institutional certificate (IC)
 - iii) Submit Acknowledgements to WHI-CCC (WHI-CCC keeps master list and updates dbGaP).
 - iv) Universal WHI Data Use Certificate (DUC) will automatically be used. No effort is needed by Ancillary Study PIs.
- c) PI submits files via the submission portal after registration is complete
 - i) An automatic submission invitation and instructions are sent to the substudy PI after the study is registered, and, if specified, secondary contact/data submitter.
 - ii) Submit study config document and other required files via the dbGaP submission portal.
 - (1) Refer to main WHI top level study in study config as much as possible to avoid duplication and make updates easier to manage (e.g., WHI study description, WHI study timeline).
 - iii) The lab data you submit to dbGaP should be linked **only** to the WHI dbGaP Subject ID (ID used to uniquely identify a WHI participant’s data [phenotype or genotype] on dbGaP).
 - (1) WHI blind duplicates do not have associated covariate data and are not to be submitted to dbGaP.
 - (2) ***The link between the dbGaP Subject ID and the WHI Common ID or Draw/Vial ID is never to be submitted to dbGaP. The WHI Common ID or Draw/Vial ID is never to be submitted to dbGaP.***
 - iv) Notify the WHI-CCC when registration is complete and the substudy accession number is assigned.

2) Requests for an exception to be a ‘stand-alone’ study per a condition of the funding agency (e.g., consortium studies with several cohorts).

- a) PI confirms with PD/PO of funding award and submits request to the WHI Project Office.
- b) PI ensures correct consent groups and DULs are applied.
- c) PI notifies WHI-CCC of phs number once registered.

- d) Refer to WHI as much as possible
 - i) E.g., WHI study description, WHI study timeline in Study config.
 - ii) Standalone studies should ensure the correct acknowledgements for WHI are used.

I. Glossary of Terms (work in progress)

GPA = Genomic Program Administrator. Person responsible at dbGaP for registering the study.

dbGaP Curator (phenotype and genotype) = person(s) responsible for QC of submitted phenotype and genotype data.

PD/PO = Project Director/Project Officer of the funding award. Provides oversight to dbGaP submission.

DUL = Data Use Limitation. Listed on template Institutional Certification (IC) per IRB review of the data to be posted by the submitting institution.

DUC = Data Use Certification.

DAC = Data Access Committee. Each institute has their own DAC and DAC chair, responsible for reviewing data access requests and ensuring the use of the data complies with the data use limitations.

DAR = Data Access Request. Application to request data from dbGaP.

II. Attachments/Appendix:

[WHI template IC](#)

WHI data use limitations as they appear on dbGaP

WHI DUC

WHI acknowledgements

WHI study config – example

WHI IDs