

Core Elements for National Institutes of Health (NIH) Data Use Certification Agreements

May 21, 2008

Investigators and institutions seeking data from the National Institutes of Health (NIH) GWAS data repository will be asked to submit a Data Access Request (DAR) and a Data Use Certification (DUC) agreement that is co-signed by the investigator and his/her designated Institutional Signing Official(s). Although the requirements within the DUC may vary depending on the dataset being accessed and/or the NIH Institute/Center that is responsible for the dataset, each Data Use Certification will include the core elements listed below. The list is intended to provide investigators, Institutional Review Boards, and others interested in the NIH GWAS data access policy with additional information about the content of the DUC agreements.

1. Research Use — Investigators agree to use the data only for the research use described within the DAR and approved by the NIH Data Access Committee (DAC).
2. Data Confidentiality — Investigators agree to keep the data confidential.
3. Sale of data — Investigators agree not to sell any of the data elements from datasets obtained from the NIH GWAS repository.
4. Data Security — Investigators agree to follow appropriate data security protections, ensuring physical security, information technology security, and user training per the good practices listed on the dbGaP website (http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf), or as specified by specific GWAS programs.
5. Legal obligations — Investigators agree to follow all applicable laws, regulations, and local institutional policies/procedures for handling data.
6. Non-Identification — Investigators agree not to attempt to identify or contact individual participants from whom data within a dataset were obtained.
7. No distribution — Investigators agree not to share with individuals (except those at the investigator's institution who are identified within the DAR) any of the data elements from datasets in the NIH GWAS data repository.
8. Public listing of approved research uses — Investigators agree to a public listing within the NIH GWAS data repository of a summary of approved research uses along with the Principal Investigator's name and organizational affiliation.
9. Violations reporting — Investigators agree to immediately report violations of the GWAS policy to the appropriate Data Access Committee.

Core Elements for National Institutes of Health (NIH) Data Use Certification Agreements

10. Publication — Investigators agree to acknowledge the NIH policy with regard to publication, i.e. the investigator(s) contributing data to dbGaP will retain the exclusive right to publish analyses of the dataset for a defined period of time following the release of a given genotype-phenotype dataset, and secondary users will not submit for publication their analyses or conclusions during the embargo period. Publication exclusivity is expected to extend to all forms of public disclosure, including meeting abstracts, oral presentations, and publicly accessible electronic submissions (e.g., websites, web blogs).
11. Intellectual property — Investigators agree to acknowledge the NIH policy with regard to intellectual property.
12. Annual reporting — Investigators agree to provide annual progress reports to the relevant DAC(s) on research using NIH GWAS datasets.
13. Changes to the research project — Investigators agree to report to the NIH any changes to the research project and any other changes, such as a change of the Principal Investigator's Institution. Investigators also agree to submit a new DAR and DUC reflecting such changes if requested to do so by the NIH.
14. Destruction of data — Investigators agree to destroy the GWAS datasets and any copies of the datasets when the data access approval period expires and/or upon request by the NIH.
15. Violations, Non-compliance, Terminations — The DUC provides information about violations of and non-compliance with the terms and conditions within the DUC as well information about circumstances which could result in termination of access to the GWAS data repository.
16. Contact information — The DUC provides contact information for the DAC and for the individual(s) who should be notified of data security incidents or violations of the GWAS policy.
17. Renewal — The DUC specifies the length of time the datasets can be kept before the data access request must be renewed and provides information about the renewal process.