**Sample Institutional Certification for Single Site Studies**

[Date]

[Name of GPA]

GWAS Program Administrator

[Institute], NIH, DHHS

[address]

Bethesda, MD 20892-7395

Re: Institutional Certification of [name of institution] to Accompany Submission of the Dataset for [name of study] to the NIH Database of Genotypes and Phenotypes (dbGaP).

Dear [Name of GPA],

The [name of institution] hereby assures that submission of data from the study entitled [name of study] to dbGaP meets the following expectations, as defined in the [*Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS*](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html)*)*:

* The data submission is consistent with all applicable laws and regulations, as well as institutional policies.
* The appropriate research uses of the data and the uses that are specifically excluded by the informed consent documents are delineated.

***Data Use Limitation(s):*** *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Are the aggregate level data appropriate for general research use[[1]](#footnote-1)? Yes No

* The identities of research participants will not be disclosed to dbGAP.

An Institutional Review Board and/or Privacy Board, as applicable, reviewed the investigator’s proposal for data submission and assures that:

* + The protocol for the collection of genotype and phenotype data to be submitted to dbGaP was consistent with 45 CFR Part 46.
  + Submission of data to dbGaP and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained.
  + The risks to individuals, their families, and groups or populations associated with data submitted to dbGaP have been considered.
  + The investigator’s plan for de-identifying datasets is consistent with the standards outlined in the NIH GWAS policy.

Sincerely,

Authorized Institutional Official:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Aggregate-level data include summary statistics from the research study, such as allele frequencies or effect sizes and p-values for test of association. 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-1)