



National Institutes of Health,  
Bethesda, Maryland 20892

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To: [Name], GWAS Program Administrator, [NIH IC]

From: Michael Gottesman, M.D., Deputy Director for Intramural Research, Office of the Director

Subject: Certification of [NIH IC] to Accompany Submission of the Dataset for [name of study] to the NIH Database of Genotypes and Phenotypes (dbGaP)

[NIH IC] hereby assures that submission of data from [name of principal investigator] for the study entitled [name of study] to dbGaP meets the following expectations, as defined in the [NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies \(GWAS\)](#):

- The data submission is consistent with all applicable laws and regulations, as well as the NIH GWAS policy referenced above.
- The appropriate research uses of the data and the uses that are specifically excluded by the informed consent documents are delineated as follows:

[Insert appropriate language for any Data Use Limitation(s) for each Consent Group]

Are the aggregate-level data appropriate for general research use<sup>1</sup>?  Yes  No

- The identities of research participants will not be disclosed to dbGaP.

[Name of the applicable Institutional Review Board (IRB)] has 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.

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<sup>1</sup> Aggregate-level data include summary statistics from the research study, such as allele frequencies or effect sizes and p-values for test of association. If "yes" is checked, your aggregate-level data will be included in the [Compilation of Aggregate Genomic Data](#), a collection of analyses across many dbGaP studies that can be accessed with a single Data Access Request.

We hereby assure that submission of these data to dbGaP is consistent with the above statements and meets the expectations as defined in the NIH GWAS Policy.

**Principal Investigator**

Name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

**IRB Chair/Designee**

Name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

**Scientific Director/Designee (Signing Official)**

Name \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

**Deputy Director for Intramural Research**

Name Michael Gottesman, M.D.

Signature \_\_\_\_\_

Date \_\_\_\_\_