



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 conditions, 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 any specific limitations for the use of the data in the informed consent documents are delineated as follows:

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

- The identities of research participants will not be disclosed to dbGaP.
- [Name], the chairperson of the [applicable Institutional Review Board (IRB)], reviewed and verified that the following items were addressed:
 - The 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 investigator's plan for de-identifying datasets is consistent with the standards outlined in the NIH GWAS policy;
 - The risks to individuals, their families, and groups or populations associated with data submitted to dbGaP have been considered by the IRB; and
 - The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. Part 46.

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

Principal Investigator

Name _____

Signature _____

Date _____

IRB Chair

Name _____

Signature _____

Date _____

Scientific Director/ Designee (Signing Official)

Name _____

Signature _____

Date _____

Deputy Director for Intramural Research

Name Michael Gottesman, M.D.

Signature _____

Date _____

SAMPLE