Sample Institutional Certification

[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 certifies that submission of data from the study entitled [name of study] to dbGaP meets the following expectations, as defined in the <u>Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)</u> (Notice Number: NOT-OD-07-088):

- 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):	
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- The identities of research participants will not be disclosed to dbGAP.
- An Institutional Review Board and/or Privacy Board, as applicable, reviewed and verified that:
 - 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 policy;
 - o It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository; and
 - The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. Part 46.

Sincerely,		
Authorized Institutional Official:		
Name:	Title:	
Signature:	Date:	
Investigator:		
Name:	Title:	
Signature:	Date:	