

TEMPLATE

To: NIH

From: Institutional Official

Date:

Regarding: Submission to GWAS Repository

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I am the responsible Institutional Official for the University of Southern California. By way of this letter, I hereby certify that I have approved the submission of data from the following research project to be submitted to the NIH GWAS data repository:

“Study # HS-XX-XXXX, “Title “ PI: Dr. XXXX”

This approval assures that:

- The data submission is consistent with all applicable laws and regulations, as well as institutional policies;
- The identities of research participants will not be disclosed to the NIH GWAS data repository; and
- The USC IRB and/or Privacy Board, as applicable, reviewed and verified that:
  - The submission of data to the NIH GWAS data repository 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;
  - 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.
- The data to be submitted is appropriate for the following research uses:
  - All cases may be utilized for cancer research. Data from specimens obtained using the version of informed consent that disclosed the use for other chronic diseases may also be used for the study of other chronic diseases.
- The data to be submitted is subject to the following specific exclusions under the relevant informed consents:
  - Data from specimens obtained using an informed consent where the individual indicated “no” to sharing of their specimen with other researchers may not be included.