NIH Genomic Data Sharing (GDS) Institutional Certification

July 1, 2019

***<NOTE: This letter should be provided to the NIH Institute or Center (IC) sponsoring the research for which you are providing Institutional Certification.>***

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| --- | --- |
| Investigator Name: |  |
| Project Title: |  |
| IRB ID: |  |
| Grant Title:  |  |
|  Grant ID: |  |
| Type of Database: | *<Unrestricted-Access or Controlled-Access>* |
| Data Use Limitations: | *<Include limitations from “WORKSHEET: GDS Institutional Certification (HRP-332)” or type “None”>* |

Dear Sir or Madam:

I certify, on behalf of *<Name of organization>*, that *<name of investigator>*’s submission described above meets the following requirements per the National Institutes of Health Final Genomic Data Sharing Policy:

* The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies;
* Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated;
* The identities of research participants will not be disclosed to NIH-designated data repositories; and
* An IRB, privacy board, and/or equivalent body, as applicable, has reviewed the investigator’s proposal for data submission and assures that:
	+ The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;
	+ Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
	+ Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
	+ To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; and
	+ The investigator’s plan for de-identifying datasets is consistent with the standards outlined in the GDS Policy.

Please let us know if you need additional information.

Sincerely,

Organization Official *<or designee>*

cc: *<Investigator>*

*<Protocol Contact>*

*<Others as deemed appropriate by the Organizational Official>*