

Research Integrity Office 5057 Woodward, Suite 2317 Detroit, MI 48202 (313) 577-9064

Institutional Certification Genetic/Genomic Data Sharing

Date:

RE: Wayne State University Institutional Certification to Accompany Submission of the Dataset for Study Title:

to the NIH-supported Repository:

To Whom It May Concern:

Wayne State University hereby assures that submission of data from the study entitled [Insert Study Title] meets the following expectations, as defined in the NIH Genomic Data Sharing Policy (Notice Number: NOT-OD-14-124):

- 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 document are delineated.
- Data Use Limitation(s):
- The aggregate-level data are appropriate for general use? If no, explain:
- The identities of research participants will not be disclosed to the NIH data repository.
- An Institutional Review Board (IRB) reviewed and verified 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 NIH Genomic Data Sharing Policy (see section IV.C.1.).

Sincerely,	
Investigator:	
Name:	Title:
Signature:	Date:
Authorized Institutional Official:	
Name:	Title:
Signature:	Date [.]