



WORKSHEET: NIH GDS Institutional Certification		
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The purpose of this worksheet is to allow the IRB Director or designee to evaluate whether an investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository. The IRB Office uses this worksheet to generate a GDS Institutional Certification Letter (HRP-528). It does not need to be retained.

Investigator Name	
Project Title	
IRB Number (if any)	
Name of Person Completing Checklist	

1 Institutional Certification Requirements (ALL must be checked "Yes")

<input type="checkbox"/> Yes <input type="checkbox"/> No	The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Limitations on the research use of the data, as expressed in the informed consent documents, are delineated. <input type="checkbox"/> N/A for submission to an unrestricted-access database.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The identities of research participants will not be disclosed to NIH-designated data repositories.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The protocol for collection of genomic and phenotype data is consistent with 45 CFR §46.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were or will be obtained.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Consideration was given to risks to individual participants and their families associated with the data submitted to NIH-designated data repositories and subsequent sharing.
<input type="checkbox"/> Yes <input type="checkbox"/> No	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.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The investigator's plan for de-identifying datasets is consistent with the standards outlined in Section IV.C.1 of the NIH Final Genomic Data Sharing Policy. (http://gds.nih.gov/PDF/NIH_GDS_Policy.pdf)

If you cannot select "Yes" to all items above, then stop. You cannot certify that the data submission criteria have been met. Communicate with the investigator to let her or him know that you cannot proceed with the Institutional Certification process without changes to the investigator's data sharing plan.

2 Unrestricted- or Controlled-Access Database

Choose the type of database to which the investigator will submit:

Unrestricted-Access Database Controlled-Access Database

If you selected Controlled-Access Database above, specify the data sharing limitations. These limitations must be included in the GDS Institutional Certification Letter to the NIH.