The purpose of this worksheet is to allow the HRPP 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 3.301 (HRP-528) - LETTER - NIH GDS Institutional Certification. 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")

☐ Yes ☐ No	The data being submitted is consistent with the NIH grant and IRB-approved protocol.
☐ Yes ☐ No	The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
☐ Yes ☐ No	Limitations on the research use of the data, as expressed in the informed consent documents, are delineated. ☐ **N/A for submission to an unrestricted-access database.**
☐ Yes ☐ No	The identities of research participants will not be disclosed to NIH-designated data repositories.
☐ Yes ☐ No	The protocol for collection of genomic and phenotype data is consistent with 45 CFR §46.
☐ Yes ☐ No	Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants.
☐ Yes ☐ 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.
☐ Yes ☐ No	To the extent relevant and possible, consideration given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing.
☐ Yes ☐ 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. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)

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, make sure that these limitations are included in the GDS Institutional Certification Form or Letter to the NIH.