



WORKSHEET: NIH GDS Institutional Certification

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.

1. Institutional Certification Requirements (ALL must be checked “Yes”)

Yes or No?	Institutional <u>Certification</u> Requirement
<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"/> NA 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 and explicitly disclosed to study participants from whom the data were or will be obtained. ⁱ
<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, including unrestricted access to genomic summary results.
<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, including unrestricted access to genomic summary results.
<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. 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 Databaseⁱⁱ Controlled-Access Databaseⁱⁱⁱ

Check if applies:

Sensitive genomic summary results^{iv} are only to be made available through controlled-access.

Explanation: Click or tap here to enter text.

If Controlled-Access Database selected above, specify one of the data use limitations^v below for appropriate secondary use. These limitations must be included in the GDS Institutional Certification to the NIH.

General Research Use: Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the [dbGaP Collection](#).

Health/Medical/Biomedical: Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

Disease-specific: Use of the data must be related to the specific disease.

List disease: Click or tap here to enter text.

Other: Click or tap here to enter text.

Additional modifiers, if appropriate (check all that apply):

<input type="checkbox"/> IRB Approval Required	<input type="checkbox"/> Publication Required	<input type="checkbox"/> Collaboration Required	<input type="checkbox"/> Not-for-profit Use Only	<input type="checkbox"/> Methods Development Research	<input type="checkbox"/> Genetic Studies Only
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ⁱ For studies using data from specimens collected before the effective date of the GDS Policy, January 25, 2015, review should ensure the data submission is not *inconsistent* with the informed consent provided by the research participant. NIH will accept data derived from de-identified cell lines or clinical specimens lacking consent for research use that were created or collected before the effective date of the GDS Policy. After the Policy effective date, NIH expects *explicit* consent for broad sharing and for data that will be submitted to unrestricted-access data repositories. <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>

ⁱⁱ Data made publicly available to anyone.

ⁱⁱⁱ Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

^{iv} Genomic summary results (GSR) are results from primary analyses of genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant (e.g., genotype counts and frequencies; allele counts and frequencies; effect size estimates and standard errors; likelihoods; and p-values). GSR may be considered to have particular sensitivities related to individual privacy or potential for group harm.

^v Standard NIH data use limitations: https://osp.od.nih.gov/wp-content/uploads/standard_data_use_limitations.pdf. Additional modifiers to standard data use limitations may be indicated if appropriate and should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.