



SOP: NIH Genomic Data Sharing (GDS) Institutional Certification

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1 PURPOSE

- 1.1 This procedure establishes the process to certify approval for investigator submission of large-scale human genomic data to an NIH-designated data repository under the NIH Genomic Data Sharing (GDS) Policy.
- 1.2 For studies where Northwestern is the IRB of Record, the process begins when an investigator submits a Modification (MOD) submission to the IRB Office for certification of the genomic data sharing plan.
- 1.3 For studies where Northwestern relies on another IRB, this process may be done during the Initial Submission.
- 1.4 For multi-site or collaborative research studies:
 - 1.4.1 Each site/institution contributing samples can submit its own Institutional Certification, OR
 - 1.4.2 One site/institution can submit an Institutional Certification on behalf of multiple sites/institutions. The submitting institution, based on its own review or with assurance from the other institutions, must ensure that the expectations and conditions of the Institutional Certification are met for the entire project.
- 1.5 The process ends when the IRB Executive Director has signed the Institutional Certificate, and the IRB Analyst has communicated to the investigator.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 12/01/2024.

3 POLICY

- 3.1 Investigators must request certification from the IRB Office prior to investigator submission of large-scale human genomic data or approval of funding.

4 RESPONSIBILITIES

- 4.1 The IRB Manager, or designee, verifies for the Executive Director that all data meet the criteria for submission to the data repository.

5 PROCEDURE

- 5.1 Use WORKSHEET: NIH GDS Institutional Certification (HRP-332) to evaluate and document whether the investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository.
- 5.2 Determine the most appropriate type of NIH GDS Institutional Certification Form and pass the form to the Executive Director or designee for review and certification. Obtain the IRB Office Executive Director's signature on the NIH certification form.
 - 5.2.1 If IRB review of the data sharing plan (in the protocol or as a separate document) has already occurred, an [NIH Institutional Certification with](#) or [without consent](#) is appropriate. This includes IRB review conducted by an External IRB.
 - 5.2.2 If IRB review of the data sharing plan (in the protocol or as a separate document) has not yet occurred, a [NIH Provisional Institutional Certification](#) is most appropriate. This includes IRB review conducted by an External IRB. Once IRB review occurs, an NIH Institutional Certification with or without consent is now required.
- 5.3 Communicate certification approval to the investigator and provide a copy of the signed NIH GDS Institutional Certification form for the investigator to forward to the NIH.



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6 MATERIALS

- 6.1 WORKSHEET: NIH GDS Institutional Certification (HRP-332)

7 REFERENCES

- 7.1 [NIH Genomic Data Sharing Policy | Grants & Funding](#)
- 7.2 [NIH Institutional Certifications | Grants & Funding](#)
 - 7.2.1 [NIH Completing an Institutional Certification Form | Grants & Funding](#)
- 7.3 [NIH Genomic Data Sharing Policy | Grants & Funding](#)
- 7.4 [NOT-OD-14-124: NIH Genomic Data Sharing Policy](#)
- 7.5 [NIH Genomic Data Sharing Policy Frequently Asked Questions \(FAQs\) | Grants & Funding](#)
- 7.6 [NIH Scientific Data Sharing: Policies and Access to Data | Grants & Funding](#)
- 7.7 [NIH Provisional Institutional Certification Form](#)