

SOP: NIH Genomic Data Sharing (GDS) Institutional Certification

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.
- 1.2 The process begins when an investigator contacts IRB staff for certification of the genomic data sharing plan.
- 1.3 The process ends when an IRB Manager (i.e., when an IRB transaction is in queue) or the Education and Quality Improvement Program (EQUIP) (no IRB transaction in queue) has certified and communicated to the investigator.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

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

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 Use HRP-332 - WORKSHEET - NIH GDS Institutional Certification to evaluate and document whether the investigator's genomic data sharing plan meets the criteria for submission to a NIH-designated data repository.
- 5.2 Populate the applicable NIH Extramural Institutional Certification form.
 - 5.2.1 Provide NIH Provisional Institutional Certification when required by investigators prior to IRB review of the data sharing plan.
- 5.3 Save a copy of the signed form in IRB Office records.
- 5.4 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification form for the investigator to forward to the NIH.

6 MATERIALS

- 6.1 HRP-332 - WORKSHEET - NIH GDS Institutional Certification

7 REFERENCES

- 7.1 National Institutes of Health Final Genomic Data Sharing Policy
(<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>)
- 7.2 NIH Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications Under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)
https://sharing.nih.gov/sites/default/files/flmng/GDS_Points_to_Consider_for_Institutions_and_IRBs.pdf

- 7.3 NIH Institutional Certification Forms <https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form>
- 7.4 Provisional Institutional Certification
https://sharing.nih.gov/sites/default/files/flmngr/GDS_Provisional_Institutional_Certification.pdf