



SOP: NIH Genomic Data Sharing (GDS) Institutional Certification

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-064	Executive Director, IRB Office Northwestern University	11/22/2018	Page 1 of 1

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 the IRB Office for certification of the genomic data sharing plan.
- 1.3 The process ends when the Institutional Official has certified and communicated to the investigator.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 08/01/2015

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 Office Executive Director, IRB Manager, or designee verifies for the Institutional Official that all data meet 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 If requested by the Principal Investigator, populate “LETTER: NIH GDS Institutional Certification (HRP-563)” with submission-specific information. Pass the letter to the Institutional Official or designee for review and certification. Obtain the IRB Office Executive Director’s signature on the NIH certification form [and the letter, if applicable].
- 5.3 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification letter for the investigator to forward to the NIH.
- 5.4 Scan and upload a copy of the signed NIH certification form [and the letter, if applicable] in the electronic IRB system.

6 MATERIALS

- 6.1 WORKSHEET: NIH GDS Institutional Certification (HRP-332)
- 6.2 LETTER: NIH GDS Institutional Certification (HRP-563)

7 REFERENCES

- 7.1 National Institutes of Health Final Genomic Data Sharing Policy (<https://www.gpo.gov/fdsys/pkg/FR-2014-08-28/pdf/2014-20385.pdf>)
- 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://irb.northwestern.edu/sites/irb/files/files/gwas_ptc-1.pdf)