



SOP: NIH GDS Institutional Certification					
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HRP-064	06.19.2019	1	J. Casanova	J. Bixby	1 of 1
<i>Supersedes previous version(s) dated: N/A</i>					

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 the Organizational Official has certified and communicated to the investigator.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.
- 2.2 Revised to clarify when IRB Certification is required and where documents are stored.

3 POLICY

- 3.1 Investigators must obtain certification from IRB staff prior to receiving award for research requiring submission of large-scale human genomic data or approval of funding.

4 RESPONSIBILITIES

- 4.1 The IRB Director or designee verifies for the Organizational 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 Populate “LETTER: NIH GDS Institutional Certification (HRP-528)” with submission-specific information. Pass the letter to the Organizational Official for review and certification.
- 5.3 Save a copy of the signed letter and Checklist in Protocol Section of HSRO Electronic system.
- 5.4 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.

6 MATERIALS

- 6.1 CHECKLIST: NIH GDS Institutional Certification (HRP-332)
- 6.2 LETTER: NIH GDS Institutional Certification (HRP-528)

7 REFERENCES

- 7.1 National Institutes of Health Final Genomic Data Sharing Policy (http://gds.nih.gov/PDF/NIH_GDS_Policy.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) (http://gds.nih.gov/pdf/PTC_for_IRBs_and_Institutions.pdf)