

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 Institutional Official or designee has certified and communicated to the investigator.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 4/17/24.

3 POLICY

- 3.1 Investigators must request certification from Research Administration 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 for the IO or designee that all data meet criteria for submission to the data repository.

5 PROCEDURE

- 5.1 Use 3.214 (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 an NIH-designated data repository.
- 5.2 Populate either the NIH Extramural Institutional Certification Form or 3.301 (HRP-528) - LETTER - NIH GDS Institutional Certification with submission-specific information. Pass the Form or letter to the IO or designee for review and certification.
- 5.3 Save a copy of the signed form/letter in eIRB+.
- 5.4 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification Form/letter for the investigator to forward to the NIH.

6 MATERIALS

- 6.1 3.214 (HRP-332) - WORKSHEET - NIH GDS Institutional Certification.
- 6.2 3.301 (HRP-528) - LETTER - NIH GDS Institutional Certification.

7 REFERENCES

- 7.1 [National Institutes of Health Final Genomic Data Sharing Policy](#) .
- 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 \(GWAS\)](#) .
- 7.3 [NIH Extramural Institutional Certification Forms](#) .