

	SOP: NIH Genomic Data Sharing (GDS) Institutional Certification		
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1 PURPOSE

- 1.1 This SOP 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/HRPP 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 Revised from the 5/30/2017 version.

3 SOP Statement

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

4 RESPONSIBILITIES

- 4.1 The HRPP Director, IRB Chair or designee verifies for the Institutional Official or designee 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 an NIH-designated data repository.
- 5.2 Populate the applicable NIH Extramural Institutional Certification form.
- 5.3 Pass the certification letter to the Institutional Official or designee for review and certification.
 - 5.3.1 Provide [NIH Provisional Institutional Certification](#) when required by investigators prior to IRB review of the data sharing plan.
- 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.
- 5.5 A copy of the signed certification letter may be kept in the study files.

6 MATERIALS

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

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://osp.od.nih.gov/wp-content/uploads/PTC_for_IRBs_and_Institutions.pdf
- 7.3 NIH Institutional Certification Forms (<https://osp.od.nih.gov/scientific-sharing/institutional-certifications/>)
- 7.4 Provisional Institutional Certification (https://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification.pdf)