SOP: NIH Genomic Data Sharing (GDS) Institutional Certification			
NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-064	Executive Director, IRB Office Northwestern University	10/25/2021	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 the IRB Analyst has communicated to the investigator.

2 PREVIOUS VERSION

2.1 Revised from previous version dated 11/22/2018

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 Pass the applicable NIH Extramural Institutional Certificate form to the Institutional Official or designee for review and certification. Obtain the IRB Office Executive Director's signature on the NIH certification form.

5.3 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 form for the investigator to forward to the NIH.

6 MATERIALS

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

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)

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)