



October 20, 2017

Via: <https://osp.od.nih.gov/gsr-rfi/>

Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750,
Bethesda, MD 20892

Re: Proposed Update to the NIH Genomic Data Sharing Policy's Access Model for Genomic Summary Results

The Association of American Universities, the Association of Public and Land-grant Universities and the Council on Governmental Relations appreciate the opportunity to comment on NOT-OD-17-110, Proposed Update to the NIH Genomic Data Sharing Policy's Access Model for Genomic Summary Results. Our associations endorse the agency's efforts to improve access to, and promote broad sharing of, aggregate genomic data held in NIH repositories (e.g., the Database for Genotypes and Phenotypes), in a manner that is proportional to the risks and benefits posed. We further support the use of a "rapid access" tier that requires users to affirm agreement with a statement regarding responsible use of the information. With respect to "potentially stigmatizing traits" and "increased privacy risk or heightened risk of group harm" the nature of the data should largely preclude such risks. However, we support the approach of providing institutions submitting data sets the option to indicate, as part of their Genomic Data Sharing Plan and Institutional Certification, that summary results should be provided only through controlled access as appropriate.

We would suggest that the implementation plan with respect to datasets submitted to or accessible through designated repositories prior to the effective date include a common process for notifying funding Institutes or Centers if summary data should be maintained in controlled access, and that the process not require re-certification of the submitted or currently accessible data. We also request that NIH clarify that the consent requirements detailed in the notice are limited to prospective collections.

Thank you again for the opportunity to comment.

About the Signatory Associations

The Association of American Universities is an association of 60 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities. The Association of Public and Land-grant Universities (APLU) is a research, policy, and advocacy organization with a membership of 235 public research universities, land-grant institutions, state university systems, and affiliated organizations in the U.S., Canada, and Mexico, that is dedicated to strengthening and advancing the work of public universities. The Council on Governmental Relations (COGR) is an association of over 190 leading research universities and affiliated academic medical centers and independent research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.