UCI Office of Research
News & Announcements

An update to the NIH Policy for the *Management of Genomics Summary Results Access* NOT-OD-19-023

The National Institutes of Health (NIH) has updated the policy for the ***Management of Genomic Summary Results (GSR) Access***.

The key updates to the policy are described below. *Please read the full policy, as it includes important details.*

- **Designation of "sensitive" studies and access to "sensitive" studies' genomic summary results**
  - NIH has retained the original proposal to have the submitting institutions for every incoming and already submitted study determine if a dataset should be designated as "sensitive" and the GSR made accessible only through submission of a standard data access request for the full study dataset.

- **Rapid-access tier for GSR**
  - The GDS Policy access model has been updated to allow access to GSR through the unrestricted access tier.

- **Additional resources that have been updated**
  - Points to Consider for Institutions and Institutional Review Boards in the Submission and Secondary Use of Human Genomic Data under the NIH Genomic Data Sharing Policy
  - Informed Consent Resource for Genomic Research

- **Other updates**
  - Data management procedures under the GDP Policy is updated to allow unrestricted access to GSR from most NIH-supported studies for health or research purposes.
  - Institutions submitting datasets to NIH-designated data repositories should indicate in the genomic data sharing plan and the Institutional Certification if GSR from incoming studies should be provided only through controlled-access data access request and review procedures.

- **Informed Consent**
  - Consent forms and the informed consent process for human genomic studies should clearly state the access plans for data and other information generated through the study, including GSR:
    - Informed Consent Resource
    - NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy

There are key elements in the implementation of the GDS GSR Access policy update.

- Investigators proposing to conduct *GDS Policy applicable research* need to indicate in their genomic data sharing plan if a study should be designated as "sensitive" for the purposes of access to GSR.

- **For studies submitted to NIH prior to November 1, 2018**, institutions will have **6 months** to indicate if GSR should be maintained in controlled-access due to concerns about the sensitivity of study information, otherwise the GSR from those studies may be provided through unrestricted access.

Any "sensitive" designations for studies should be made by submitting an updated Institutional Certification to the GPA for the funding Institute or Center, with a copy to the NIH GDS mailbox (gds@mail.nih.gov) and the study's Program Officer, **by May 1, 2019**. It is possible to request additional time by sending an email to the NIH contact; in such cases, the GSR for that study will remain in controlled-access until a final determination is received by the appropriate NIH Institute or Center.

If a submitting institution that has already submitted an Institutional Certification to NIH wishes to confirm to NIH the appropriateness of unrestricted access to GSR from a particular study prior to the end of the six-month period, this can be indicated through the submission of a new Institutional Certification using the updated Institutional Certification template.

For full details, please review the **November 1, 2018 *NIH Notice NOT-OD-19-023***.