

The NHLBI Clinical Data Science IRB

Funded by the National Heart, Lung, and Blood Institute

(Agreement Number: OT2 HL 146019-01)

www.nhlbi.nih.gov/review-boards-and-committees/clinical-data-science-irb

Investigator Responsibilities for the Secondary Use of Data:

The Principal Investigator (PI) assumes full responsibility for the research project, including but not limited to, the oversight of all research related activities, training of all research personnel, and protecting participant confidentiality.

- As a condition of gaining access to the data, you understand that you have an ethical and legal responsibility in protecting the data, the latter described in the Data Use Certification (DUC) Agreement and Code of Conduct and taking steps so that your analysis does not cause harm to the original participants or any associated groups or communities.
- You and your research team, to include all collaborating sites and corresponding key research personnel, will adhere to all data access, data use, downloading of any results data or genomic summary results (GSR), and IT security policies, as outlined in the following documents and any additional requirements provided by the Data Access Committee (DAC).
 - [DUC Agreement](#)
 - [Genomic Data Sharing \(GDS\) Policy](#)
 - [Genomic Data User Code of Conduct](#)
 - [Update to NIH Management of Genomic Summary Results \(GSR\) Access \(NOT-OD-19-023\)](#)
 - [NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy](#)
- Additionally, as a condition of gaining access to the data, you ensure that you and your research team will not seek to re-identify individuals.
- No research related procedures may begin until both IRB and DAC approvals are in place.
- Only the analysis of data and/or the triangulation of data with other sources as described in this application and as approved by both the IRB and DAC is permissible. Further research would require a modification or new application.
- If research personnel are affiliated with other institutions or agencies outside the institution they are listed under in this application, no data, analyses, or performance of the research from this project can be shared between those other affiliations, unless:
 - Those affiliations and the roles of that individual are reflected in this application.
 - Each affiliated institution has a reliance agreement in place.
- Results/GSR data can only be shared with collaborators as described in the IRB-approved application and after the DAC has granted approval.
- It is the responsibility of the relying institutions and PIs to provide information of all applicable local, state, or tribal laws and regulations, and to maintain compliance with these laws and regulations.
- The NHLBI DAC approves the access to data in one-year increments. Per NIH and NHLBI DAC policy, IRB review is required annually for many projects that will continue longer than one year. If applicable, please submit your annual review 60 days prior to the IRB expiration.