

Investigator Responsibilities to the Clinical Data Science Institutional Review Board

1. 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.
2. 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](#)
3. 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.
4. No research related procedures may begin until both IRB and DAC approvals are in place.
5. 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.
6. Each institution seeking CDS-IRB review must have a reliance agreement in place with the NHLBI IRB for Extramural Research Program or through the SMART IRB prior to CDS-IRB review.
7. The email addresses for all key research personnel must reflect the institution to which they are listed.
8. 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.*
9. Results/GSR data can only be shared with collaborators as described in this application and only after the IRB and DAC has granted approval.
10. It is the responsibility of the relying institutions and principal investigators (PI) to provide information of all applicable local, state, or tribal laws and regulations, and to maintain compliance with these laws and regulations.
11. The NHLBI DAC approves the access to data in one-year increments. Per NIH and NHLBI DAC policy, IRB review is required annually for all projects that will continue longer than one year. Please keep this in mind as you prepare your submissions for the IRB and DAC. Submit your data access request (DAR) to the DAC promptly after IRB approval is granted and *at least* 90 days prior to the IRB approval expiration.