Human Genomic Data Sharing Certificate

This is how a Principal Investigator (PI) will acquire an Institutional Genomic Data Sharing Certificate for human large scale genomic data generating studies, in order to remain in compliance with the **NIH Genomic Data Sharing Policy**

Pre-requisites:

- IRB protocol approved
- IRB has reviewed the grant application, including the Genomic Data Sharing Plan
- Just-In-Time paperwork requesting a Genomic Data Sharing Certificate
    - Ensure the Grants Management Specialist has identified the appropriate Genomic Program Administrator (GPA) to whom the GDS Certificate must be addressed

Applicability:

A Certificate is needed for any NIH-Funded research project that generates large-scale human genomic data that utilizes: Genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, or genome sequence, transciptomic, metagenomics, epigenomic, or gene expression date.
NOTE: Studies that generate Large-scale non-human genomic data ARE required to comply with the NIH Genomic Date Sharing Policy, including uploading the data to a publicly accessible repository, but they DO NOT require an institutional certificate. More information regarding Genomic Data Certifications can be found here.

Process:

(**Note:** This will be required for any grant that proposes Human Genomic Level Data Collection)

1. Just in Time (JIT) paperwork is issued, requiring a Genomic Data Sharing Certificate.
2. Grants and Contracts will issue the Certificate form to the PI:
    a. This form for studies where data is generated after January 25, 2015
    b. This form for studies where data is generated before January 25, 2015 WITHOUT Consent
    c. This form for studies where data is generated before January 25, 2015 WITH Consent
3. PI will complete the form as appropriate for their study.
4. PI will upload the completed and signed form AND IRB Approval Letter to Sparta (via Email My Team function to medrespre)
    a. NOTE: PI is also responsible for securing the above forms for each participating site in multisite studies where, along with proof of IRB approval where CWRU is the Prime Grantee. PI will need to provide this form to the Prime Grantee upon request where CWRU is a sub-recipient/participating site in a multisite study.
5. CWRU Signing Official [School of Medicine Grants & Contracts Office (SOM G&CO)], if the IRB approval letter is present, signs the document and provides to the Grants Management Specialist at the time of JIT.

If an IRB is not approved for the study:

NIH allows for provisional certification of compliance with the genomic data sharing requirements. This Provisional Certification LINKED HERE can be utilized until IRB approval has been secured and shared with the NIH Grants Management Specialist at the time of JIT.

Additional Information:

If there are any question about this practice:

- SOM researchers can contact Matt DeVries- matthew.devries@case.edu
- Researchers at other Schools can contact Kim Volarcik at kav6@case.edu