**Request for Consent Form Review and Data Use Limitation (DUL) Letter**

* Title of Specimen Collection Protocol:
* Protocol Number:
* Consent Form Title:
* Principal Investigator Listed on Consent Form:

Dear Institutional Review Board (IRB)/Ethics Committee (EC) Administrator:

Icahn School of Medicine at Mount Sinai (ISMMS) plans to deposit de-identified genomic data generated from biospecimens collected in the above-referenced protocol into a controlled-access data repository. Most often this data is deposited into the National Institute of Health’s (NIH) Database of Genotypes and Phenotypes, but other similarly protected repositories may also be used.

In order to be responsible stewards of this data, ISMMS routinely requests agreement by the IRB/EC that originally granted approval for the biospecimen collection that 1) data deposition is permissible, and 2) what, if any, restrictions should be placed on future use of the data based on the informed consent signed by participants. **Please note that even if your institution granted permission to deposit data into a repository as part of its original approval process, we are still required to solicit the specific restrictions (if any) that apply to future use of the data.**

We are providing you with one or more standardized forms to document permissibility of data sharing and any use restrictions.

In order to accommodate the NIH’s Genomic Data Sharing (GDS) Policy (for more information, please visit gds.nih.gov), we have created separate forms for biospecimens collected before and after the policy went into effect on January 25, 2015. If a particular dataset originates from specimens collected both before and after the effective date of the policy, we will provide you with both forms to complete, as the required consent language is different for each.

Likewise, if a biospecimen collection study has been underway for a long time, it may involve more than a single version of the same consent form. In such cases, separate DUL forms may need to be completed for different versions of the consent form if the use limitations described in the consent form became either more or less restrictive.

We appreciate your cooperation and understand this is a complex process. If you have any questions regarding these forms or data deposition, please contact the PPHS office at IRB@mssm.edu.