MEMORANDUM

To: Clinical Researchers

From: P. Pearl O'Rourke, MD, Director, Human Research Affairs

Date: November 14, 2014

Re: New NIH Policy Regarding Large-scale Genome Research

A new Genome Data Sharing (GDS) Policy for NIH funded large scale (human and non-human) genome research goes into effect January 25, 2015. This memo highlights important aspects of the policy that require a change in current practice.

The new GDS policy expands the existing GWAS policy (http://gds.nih.gov/index.html) with the primary purpose of requiring a data sharing plan for those studies within scope. NIH will continue to update this site as it transitions from the GWAS to the GDS policy. If your research is covered by this policy, you must be aware of these new requirements.

Highlights of the GDS Policy:

Scope: "All NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research." See the attached chart regarding definition of large-scale.

> NOTE: You are strongly encouraged to contact your Program Officer with any questions regarding whether or not your research is covered by this policy.

If your research meets these criteria (NIH-funded and large-scale human or non-human genomic data):

A data sharing plan must be submitted with your grant application. Of note the budget can include costs of a data sharing plan.

If your research meeting these criteria involves non-human large-scale genomic data:

- You must have a data sharing plan that includes submission of data to a publicly accessible data base no later than publication of the data. Of note earlier submission may be requested by the NIH.

If your research meeting these criteria involves human large-scale genomic data:

- You must have a plan that includes timely sharing of
    - de-identified genotype/phenotype data in combination with
    - resources/tools necessary for interpreting the data (e.g., protocol, analysis tools)

- You must obtain institutional certification *prior to receipt of the award* during the 'Just in Time' (JIT) period. NOTE: This is a change from GWAS in which institutional certification is completed at the time of data submission. Please contact the IRB to request the certification as soon as you know that your application scored well and is likely to be funded. *Do not wait until receipt of the JIT notice.*

- You must be aware of new informed consent requirements:

    - Informed consent including future research use and broad sharing is required for:

        - Any specimens used in your research that are collected after January 25, 2015 and

        - Any specimen used to generate a cell line after January 25, 2015.

        This informed consent requirement includes clinical specimens as well as specimens obtained specifically for research – both identifiable as well as de-identified specimens. NOTE: This is a change in that *within this policy*, no longer can de-identified excess clinical specimens be considered non-human subject research and no longer is a waiver of informed consent allowed.

        At this time for research not covered by the GDS policy, de-identified excess clinical specimens will continue to be considered non-human subject research and waivers of consent will continue to be considered.

The IRB and Grants and Contracts will implement changes in processes to maintain compliance with this new policy.

<u>The IRB shall:</u>

- Provide template language that meets the GDS policy. Of note the PHS Biobank informed consent is being amended to meet the criteria of the GDS policy.

- Continue review of elements required for the IO certification, including adequacy of informed consent for the specimens used.

<u>Grants and Contracts shall:</u>
Provide guidance consistent with the NIH GDS policy and Partner's IRB policy on data sharing. NOTE: NIH has not provided guidance on implementation of the new GDS regulations and the GDS continues to state that the information is being prepared. Presumably, guidance will be posted by April 2015 – prior to a request for GDS plans at the JIT stage for proposals submitted in January 2015. Until we have guidance, we can't provide specific information on the process. However, assume that the general process will not change, other than the requirement that it occur earlier.

NIH Genome Data Sharing Policy
Tool for determining large scale genomic status

Type of Data	***From***	***From***
Human		
>300,000 variant sites	Genotyping, methylation, RNA	>1000 individuals
DNA Sequence	> 1 gene or similar region	>1000 individuals
DNA Sequence	>100 genes or regions of similar size	>100 individuals
Sequence	> 100 metagenomes or metatranscriptomes	Human microbiome
Animal		
>100,000 SNPs	Genotyping	>1 model organism species or strain
DNA Sequence	Whole exome or whole genome	>1 model organism species or strain
Gene expression	Transcriptome	1 or more model organism species or strain
Sequence	> 100 metagenomes or metatranscriptomes	Model organism microbiome
Microbial		
Sequence	DNA or RNA	>100 isolates of infectious organisms
Cells		
DNA methylation	Comparison of genomewide methylated sites	>10 cell types
Other		
DNA methylation	Comparison of genomewide differential methylation at single-base resolution	Within an individual or across cell types within the same subject

Note: Investigators are strongly encouraged to contact their NIH Program Officer with any questions.