Summary of Upcoming Significant Changes to the NIH Grants Policy Statement

The revised NIH Grants Policy Statement (NIHGPS, rev. 11/2015) will represent an update to the 03/31/2015 version and will be applicable to all NIH grants and cooperative agreements beginning on or after the revision date. It incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated 03/31/2015. When issued, the revised NIHGPS will supersede, in its entirety, the NIH Grants Policy Statement (03/31/2015) as a standard term and condition of the award. Please note that this document is for information only and that these changes will not be effective until the revised NIHGPS is issued by NIH in November.

Section	Significant Changes	Reason
PART 1: NIH Grants – General Information **Chapter 2 – The National Institutes of Health as a Grant-Making Organization**	Sec. 2.3.7.10 NIH Genomic Data Sharing: Requires that applications proposing to generate large-scale human and/or non-human genomic data are expected to include a genomic data sharing plan; requires that applicants who wish to use controlled-access human genomic data from NIH-designated data repositories briefly address their plans for requesting access to the data in the application, and state their intention to abide by the NIH Genomic Data User Code of Conduct.	Implements provisions announced in NOT-OD-15-083 and NOT-OD-15-086.
	Sec. 2.3.9.5 Application Non-compliance: Reminds applicants that NIH may withdraw any application identified during the receipt, referral and review process that is not compliant with the instructions in the SF424 (R&R) Application Guide, the Funding Opportunity Announcement, and relevant NIH Guide Notices. Subsequent subsections renumbered.	Implements provisions announced in NOT-OD-15-095.

PART II: Terms and Conditions of NIH Grant Awards **Chapter 4 – Public Policy Requirements, Objectives and Other Appropriation Mandates**	4.1.3 ClinicalTrials.gov Requirement Text added to clarify that results reporting is still required after the period of performance has ended.	To clarify FDAAA requirement.
	Sec. 4.1.15.9 Informed Consent for Research on Dried Blood Spots Obtained Through Newborn Screening:	Implements provisions announced in NOT-OD-15-127.
	Sec. 4.1.14 Human Fetal Tissue Research The language is changed from "guidance" to "regulatory requirements".	To highlight this is a regulatory requirement.
Chapter 8 – Administrative Requirements	Sec. 8.1.1.3 Extension of Final Budget Period of a Previously Approved Project Period without Additional NIH Funds	To reduce administrative burden, NIH will allow our recipients to reduce effort during a NCE without prior approval.
	Sec. 8.1.2.5 Change in Scope: Expands the description of Changes from the Approved Involvement of Human Subjects Requiring Prior NIH Approval	Implements provisions announced in NOT-OD-15-128 and NOT-OD-15-129.
	Sec. 8.2.3.3 Genomic Data Sharing (GDS) Policy: Allows investigators to request permission to transfer controlled-access genomic and associated phenotypic data obtained from NIH-designated data repositories that are under the auspices of the NIH GDS Policy to public or private cloud systems for data storage and analysis.	Implements provisions announced in NOT-OD-15-086.
	Sec. 8.2.4 Inventions and Patents: Requires recipients to report inventions subject to Bayh-Dole regulation electronically to NIH through iEdison (http://iEdison.gov).	Implements provisions announced in NOT-OD-15-080.