DEPARTMENT OF CONTRACTS & GRANTS
YOUR PARTNER IN RESEARCH ADMINISTRATION

NewsFlash!

Announcement: The National Institutes of Health (NIH) has released a notice summarizing the significant changes (see below) that will be incorporated into the revised FY 2016 NIH Grants Policy Statement (NIHGPS). It is anticipated that the FY 2016 NIHGPS will be available in November, but NIH is making the Significant Changes document immediately available to keep applicants and recipients informed of upcoming policy changes and clarifications.

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	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.

and Other Appropriation Mandates		
	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 BayhDole regulation electronically to NIH through iEdison.	Implements provisions announced in NOT-OD-15-080.

If you have any questions about the changes, please contact your DCG Officer.