Summary of Significant Changes to the NIH GPS for October 2017 Version
(Guide Notices Issued Before October 1, 2017)

The revised NIH Grants Policy Statement (NIHGPS, rev. 10/01/2017) represents an update to the November 2016 version and is applicable to all NIH grants and cooperative agreements beginning on or after October 1, 2017. While the update does not introduce any new material for the first time, 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 November 2016. The 10/01/2017 revision supersedes, in its entirety, the NIH Grants Policy Statement (November 2016) as a standard term and condition of the award.

Notable Policy Changes: Implements new policies and clarification of existing policies announced in the NIH Guide since October 2016, and listed at Grants Policy & Guidance.

Section	Significant Changes	Reason
PART 1: NIH Grants – General Information **Chapter 2 – The National Institutes of Health as a Grant-Making Organization**	Sec. 2.3.5 Types of Funding Opportunity Announcements: Specifies that NIH will require that all applications involving one or more clinical trials be submitted through a FOA specifically designed for clinical trials effective for applications with receipt dates on or after January 25, 2018.	Implements provisions announced in NOT-OD-16-147 and NOT-OD-17-043
PART II: Terms and Conditions of NIH Grant Awards **Chapter 3 – Overview of Terms and Conditions**	Sec. 3.1 Federalwide Standard Terms and Conditions for Research Grants: While the language of this section has not changed, the Federalwide Research Terms and Conditions have been updated, effective April 3, 2017. Recipients are encouraged to review the updated documents at http://www.nsf.gov/bfa/dias/policy/rtc/index.jsp. NIH implementation of these Federalwide research terms and conditions has no significant change in the requirements or terms and conditions for NIH awardees.	As published in the Federal Register (82 FR 13660), the Federal-wide Research Terms and Conditions were updated effective April 3, 2017.

Chapter 4 – Public Policy Requirements, Objectives and Other Appropriation Mandates	Sec. 4.1.3 ClinicalTrials.gov and Dissemination of NIH-Funded Clinical Trial Information Requirements: This policy applies to applications submitted on or after January 18, 2017, requesting support for the conduct of a clinical trial to be initiated on or after January 18, 2017. NIH expects all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, ensure that their NIH-funded clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting. As part of their applications, applicants seeking NIH funding will be required to submit a plan for the dissemination of NIH-funded clinical trial information that will address how the expectations of this policy will be met. NIH-funded awardees and investigators conducting clinical trials funded in whole or in part by the NIH will be required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.	Implements provisions announced in NOT-OD-16-149.
	Sec. 4.1.4.1 Certificates of Confidentiality: Section 301(d) of the PHS Act, as amended by Section 2012 of the 21 Section 2012 of the 21st Century Cures Act, P.L. 114-255, states that the Secretary shall issue Certificates of Confidentiality (Certificates) to investigators or institutions engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. All recipients covered by this policy are deemed to be issued a Certificate, and are therefore required to protect the privacy of individuals who are subjects of such research. NIH will no longer accept applications or issue paper certificates for NIH-funded research	Implements provisions announced in NOT-OD-17-109.

	collecting "covered information," as defined in the policy.	
	Sec. 4.1.15.10 NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials: Establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2).	Implements provisions announced in NOT-OD-16-148.
	Sec. 4.2.2 Certification of Filing and Payment of Taxes has been removed. This statutory requirement is no longer in place.	Clarifies legislative mandates in effect as outlined in NOT-OD-17-075
Chapter 8 – Administrative Requirements	Sec. 8.1.2.5 Change in Scope: The prior approval requirement for changes from "No Clinical Trial" to "Includes Clinical Trial" has changed. This project change now requires submission of a competitive revision application, to a FOA which accepts clinical trials.	Implements provisions announced in NOT-OD-16-147 and NOT-OD-17-043
	Sec. 8.2.5 Interim Research Products: This section outlines reporting instructions to allow investigators to cite their interim research products and claim them as products of NIH funding.	Implements provisions announced in NOT-OD-17-50
	8.4.1.4 Final Research Performance Progress Report: Effective January 1, 2017 (June 30, 2017, for SBIR/STTR awards) the Final RPPR has replaced the final progress report for closeout. NIH is no longer accepting Final Progress Reports. This section has been updated to provide guidance on the submission of Final and Interim RPPRs. Corresponding changes made to: 8.6, 11.3.13.4, 18.5.5.5	Implements provisions announced in NOT-OD-17-022, NOT-OD-17-037 and NOT-OD-17-085.

	Sec. 8.6.2 Final Research Performance Progress Report: Removes previous NIH Type 2 policy, which allowed progress reports submitted in Type 2 applications to serve in lieu of a separate final progress report. NIH now requires that organizations submit an "interim-RPPR" while their renewal (Type 2) application is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPR.	Implements provisions announced in NOT-OD-17-022, and NOT-OD-17-037.
Chapter 11 - Ruth L. Kirschstein National Research Service Awards	Sections 11.2 and 11.3 Individual Fellowships and Institutional Research Training Grants: Updated language to clarify part-time work requirements for trainees and fellows. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part time research, teaching, or clinical employment, so long as those activities do not interfere with, or lengthen, the duration of their NRSA training.	Implements provisions announced in NOT-OD-17-095
Chapter 12 – Research Career Development ("K") Awards	Sec 12.8.1 Salaries and Fringe Benefits: Update language to implement new guidance regarding non-career development award (CDA) effort. For effort not directly committed to the mentored CDA, CDA recipients may devote effort, with compensation, on Federal or non-Federal sources as the Program Director/Principal Investigator (PD/PI) or in another role (e.g., co-Investigator), as long the specific aims of the other supporting grant(s) differ from those of the CDA. Corresponding change made to: 12.3.6.3	Implements provisions announced in NOT-OD-17-094

Chapter 16 – Grants to Foreign Organizations, and Domestic Grants with Foreign Components	Sec. 16.6 Allowable and Unallowable Costs: Update the language regarding allowable F&A costs, to reflect changes to 45 CFR 75 implemented on January 11, 2017. F&A costs under grants to foreign and international organizations will be funded at a fixed rate of 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements. Awards to domestic organizations with a foreign or international consortium participant may include 8 percent of modified total direct costs, exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. These funds are paid to support the costs of compliance with federal requirements.	Implements changes to 45 CFR 75.414(ii), effective January 11, 2017 (81 FR 89393).
Chapter 17 – Grants to Federal Institutions and Payments to Federal Employees Under Grants	Section 17.5 Payment: NIH Office of Financial Management will continue payments of grants and cooperative agreements to Federal departments and agencies through the Interagency Payment and Collection method (IPAC) rather than through the Payment Management System. Federal recipients are not required to complete the Federal cash transactions section of the Federal Financial Report (FFR). Corresponding change made to: 17.7.4.	Implements provisions announced in NOT-OD-17-052.