

Summary of Significant Changes to the NIH GPS for October 2018 Version
(Guide Notices Issued Before October 1, 2018)

The revised NIH Grants Policy Statement (NIHGPS, rev. 10/01/2018) represents an update to the October 2017 version and is applicable to all NIH grants and cooperative agreements beginning on or after October 1, 2018. 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 October 2017. The 10/01/2018 revision supersedes, in its entirety, the NIH Grants Policy Statement (October 2017) 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 2017, and listed at [Grants Policy & Guidance](#).

Section	Significant Changes	Reason
PART 1: NIH Grants – General Information Chapter 1 – Glossary	Micro-purchase Threshold definition – updated micro-purchase threshold to \$10,000	As directed by OMB Memo M-18-18 issued June 20, 2018. Announced in NOT-OD-18-219
PART II: Terms and Conditions of NIH Grant Awards Chapter 4 – Public Policy Requirements, Objectives and Other Appropriation Mandates	Section 4.1.15.11, NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research, added.	Implements the NIH Policy on the Use of a Single Institutional Review Board, effective for applications submitted on or after January 25, 2018. Per NOT-OD-16-094 , NOT-OD-17-076 , NOT-OD-18-003
	4.1.15.7 Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects. Policy has been updated to state that individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them.	Per NOT-OD-18-116 .

	4.1.15.8 Inclusion of Women and Minorities as Subjects in Clinical Research and Reporting Sex/Gender, Racial, and Ethnic Participation. Updated to include a requirement that recipients conducting applicable NIH-defined Phase III clinical trials ensure results of valid analyses by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov .	Per NOT-OD-18-014 .
	4.1.34 Federal Awardee Performance and Integrity Information System (FAPIIS), and 4.1.35 Mandatory Disclosures. Updated to more clearly state the requirements of 45 CFR 75.113 for disclosing data to the HHS Office of Inspector General.	Clarifies the implementation of regulation 45 CFR 75.113.
Chapter 7 – Cost Consideration	7.4 Reimbursement of Facilities and Administrative Costs. Updated to more clearly state the existing requirement that if a consortium is with a for-profit entity, such as a small business, the organization must have a an established F&A cost rate before they can charge F&A costs.	Incorporates language previous provided in OER guidance , to more clearly outline this requirement.
Chapter 8 – Administrative Requirements	8.1.2.11 Provide Subawards Based on Fixed Amounts. Updated to note the distinction between fixed amount subawards and fixed rate agreements.	Per NOT-OD-18-222
	8.2.4 Inventions and Patents. Updates language to implement the new regulatory requirements.	Implements changes to 37 C.F.R. 401 made on April 14, 2018. Per NOT-OD-18-233 .
	8.3.4.2 Approval Requirements. Update Simplified Acquisition Threshold to \$250,000.	As directed by OMB Memo M-18-18 issued June 20, 2018. Announced in NOT-OD-18-219
	8.4.1.1 Non-Competing Continuation Progress Reports. Updated previous references to the Inclusion Management System to reflect use of new Human Subjects System (HSS), effective June 9, 2018.	Per NOT-OD-18-179

	8.6.4 Submission of Closeout Documents. Updated to outline current requirements for electronic submission.	Per NOT-OD-17-022 .
Chapter 11 - Ruth L. Kirschstein National Research Service Awards	11.3.3.4 Recruitment Plan to Enhance Diversity. Updated to reflect updated Diversity Statement.	Per NOT-OD-18-210 .
	11.3.6.2 Trainees. Updated to state that request for part-time training must be signed by the trainee, the AOR and the training grant PD/PI. The request for part-time training must provide a justification of the need for a reduced level of effort and the expected duration of the period of part-time training.	Per NOT-OD-18-154 .