Summary of Significant Changes to the NIH GPS for December 2019 Version

(Guide Notices Issued Before October 1, 2019)

The revised NIH Grants Policy Statement (NIHGPS, rev. December 2019) represents an update to the October 2018 version and is applicable to all NIH grants and cooperative agreements beginning on or after October 1, 2019. 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 2018. The December 2019 revision supersedes, in its entirety, the NIH Grants Policy Statement (October 2018) as a standard term and condition of the award.

Section	Significant Changes	Reason
PART II: Terms and Conditions of NIH Grant Awards Chapter 2 – The National Institutes of Health as a Grant-Making Organization	Section 2.3.5 Types of Funding Opportunity Announcements.	Introduction of Non-parent program announcements for Notices of Special Interest (NOSI). Per <u>NOT-OD-19-107</u> .
	Section 2.3.7.8 DUNS Number and SAM Registration Requirements	Addition of SAM and DUNS requirements language. Per <u>NOT-OD-19-</u> 043.
	Section 2.3.7.11 Human Fetal Tissue from elective abortions	Addition of a section on human fetal tissue from elective abortions. Per <u>NOT-OD-19-128</u> and <u>NOT-OD-19-137</u> .
Chapter 4 – Public Policy Requirements, Objectives and Other Appropriation Mandates	Section 4.1.15.2, Certification of IRB Approval.	Removal of the Requirement for Institutional Review Board Review of NIH Grant Applications and Contract Proposals Related to Research. Per <u>NOT- OD-19-055</u> .

Notable Policy Changes: Implements new policies and clarification of existing policies announced in the NIH Guide since October 2018, and listed at Grants Policy & Guidance.

	Section 4.1.3.1 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.	Addition of language related to informed consent. Per <u>NOT-OD-19-050</u> and <u>NOT-OD-19-110</u> .
	Section 4.1.14.2 Human Fetal Tissue from Elective Abortions	Addition of a section on human fetal tissue from elective abortions. Per <u>NOT-OD-19-128</u> and <u>NOT-OD-19-137</u> .
	Section 4.1.27 Research Misconduct.	Updated to clarify issues related to research misconduct. Per <u>NOT-OD-19-020</u> .
	Section 4.2.12 Appropriations Mandates.	Updated per 2019 Appropriation. Per NOT-OD-19-030.
Chapter 11 – Public Policy Requirements and Objectives	Section 11.3.13.1 Statement of Appointment	Addition of language related to ORCID ID requirements. Per <u>NOT-OD-19-109</u> .
Chapter 12 – Application Requirements and Submission	Section 12.4.1 Application	Addition of language related to ORCID ID requirements. Per <u>NOT-OD-19-109</u> .
Chapter 18 – Grants to For-Profit Organizations	Section 18.5 Small Business Innovation Research and Small Business Technology Transfer Programs.	Updated to reflect most recent SBIR/STTR Policy Directive. Per <u>SBIR/STTR 2019 Policy Directive</u> .
	Section 18.5.4.1 Program Levels (Total Costs). Updated numbers for program levels and hard caps.	Per <u>SBIR/STTR 2019 Policy Directive</u> .
	Section 18.5.5.2 Intellectual Property. Updated language to clarify data rights of STTRs as equivalent to SBIRs.	Per <u>SBIR/STTR 2019 Policy Directive</u> .
	Section 18.5.5.4 SBIR Life Cycle Certification. Added language requiring Life Cycle Certification Submissions.	Per <u>SBIR/STTR 2019 Policy Directive</u> .
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