Summary of Significant Changes to the NIH GPS for November 2016 Version
(Guide Notices Issued Before October 1, 2016)

The revised NIH Grants Policy Statement (NIHGPS, rev. 10/01/2016) represents an update to the October/November 2015 version and is applicable to all NIH grants and cooperative agreements beginning on or after October 1, 2016. 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/November 2015. The 10/01/2016 revision supersedes, in its entirety, the NIH Grants Policy Statement (October/November 2015) 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 April 2015, 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. 2.3.6 Legal Implications of Applications: Specifies that all forms and documentation submitted to the NIH must reflect the name of the individual, electronic or otherwise, with the appropriate institutional authority to submit such information; generic departmental signatures unacceptable. Corresponding change made to Secs. 2.3.7.6, 2.5.3, and 4.1.	Implements provisions announced in NOT-OD-16-071.
	Sec. 2.3.7.7 Post-Submission Grant Application Materials: Consolidates previous NIH policy concerning materials submitted after submission of the grant application but prior to the initial peer review.	Implements provisions announced in NOT-OD-16-130.

	Sec. 2.5.3 Determining Applicant Organization Eligibility: Streamline registration requirements and reduces administrative burden by identifying eligibility assessment questions used.	Implements provisions announced in NOT-OD-16-057.
PART II: Terms and Conditions of NIH Grant Awards **Chapter 4 – Public Policy Requirements, Objectives and Other Appropriation Mandates**		
	Sec. 4.1.13.1Effective September 23, 2015, NIH will not fund any new or competing grant applications or contract proposals for research in which human pluripotent cells are introduced into non-human vertebrate animal pre-gastrulation stage embryos while the NIH considers a possible policy revision in this area.	Implements provisions announced in NOT-OD-15-158
	Sec. 4.1.14 Human Fetal Tissue: Expands current policy by specifying NIH expects grantees to maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection when obtaining primary human fetal tissue for research purposes.	Implements provisions announced in NOT-OD-15-143 and NOT-OD-16-033.
	Sec. 4.1.34 Federal Awardee Performance and Integrity Information System: Requires that recipients with a cumulative total support from Federal agencies greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final	Implements provisions announced in NOT-OD-16-019 and NOT-OD-16-067.

	disposition within the most recent five-year period; the recipient must also make semiannual disclosures regarding such proceedings.	
	Sec. 4.1.24.3 Agents Regulated Under the Chemical Weapons Convention (CWC): Adds a subsection informing recipients that the United States is one of 175 States Parties to the CWC and potential declarations, reports, and/or inspections they may be subject to if engaged in activities involving certain chemicals even if the production, processing, consumption, or trade of related chemicals is for peaceful purposes.	Clarifies that NIH researchers engaged in activities involving these chemicals, especially Schedule 1 chemicals (including, but not limited to, the toxic chemicals sarin, soman, tabun, VX, sulfur mustards, Lewisites, saxitoxin, ricin, and nitrogen mustards), may be required to submit declarations and/or reports to the Bureau of Industry and Security (BIS) and may be subject to inspection by the Organization for the Prohibition of Chemical Weapons, which administers the CWC.
Chapter 8 – Administrative Requirements	Sec. 8.1.2.11 Provide Subawards Based on Fixed Amounts: Requires NIH prior approval for a pass-through entity to provide subawards based on fixed amounts when the subawards meet the requirements for fixed amount awards in 45 CFR 75.201(b).	Implements provisions found in 45 CFR 75.353.
	Sec. 8.4.1.6 Invention Reporting: Requires electronic reporting through an Internet-based system, Interagency Edison (http://iEdison.gov)	Implements provisions announced in NOT-OD-15-004 and NOT-OD-16-066.
Chapter 11 – Ruth L. Kirschstein National Research Service Awards	Sec. 11.2.13.1 Revised NIH Parental Leave Policy for NRSA awards: Clarifies that Trainees may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) of parental leave per year for the adoption or the birth of each child. Either parent is eligible for parental leave. Kirschstein-NRSA trainees and fellows must provide advanced notification to the grantee institution prior to taking parental leave. Notification of supervisors and others	Implements provisions announced in NOT-OD-16-105.

	about plans to use leave must be consistent with the organization's policy and must be consistently applied regardless of the source of funds. Corresponding change made to Sec. 11.3.16.1.	
Chapter 12 – Research Career Development ("K") Awards	12.2.3.2.1 K99/R00 Eligibility: Restricts eligibility to no more than 4 years of postdoctoral research training as of the relevant application due date regardless of whether it is a new or resubmission application. 12.2.3.2.2 K99 Phase: Establishes expectation that K99 awardees will receive at least 12 months of career development support from the award before transitioning to the R00 phase. If an applicant achieves independence prior to initiating the K99 phase, neither the K99 nor the R00 phase will be awarded. States that no-cost extensions for K99 awards are not automatic and require prior approval by the NIH. Carryover from the K99 phase to the R00 phase may be allowed provided the K99 phase was funded by extramural support.	Implements provisions announced in NOT-OD-15-153. Implements provisions announced in NOT-OD-16-092.
Chapter 15 – Consortium Agreements	15.2.3 Allowable and Unallowable Costs: Clarifies that when the subrecipient is a commercial organization, the recipient must use either a rate it has negotiated with the subrecipient or a de minimis indirect cost rate of 10 percent of modified total direct costs (MTDC) if the subrecipient has never received a negotiated indirect cost rate from the Federal Government, except under SBIR/STTR awards.	Editing for clarity in response to user input.
Chapter 18 – Grants to For-Profit Organizations	Sec. 18.5 Clarifies that small business concerns (SBCs) eligible to submit Phase II	Implements provisions announced in NOT-OD-16-052.

	applications for projects that were supported with a Phase I SBIR or STTR award from NIH or any other agency are expected to submit the regular Phase II application through SBIR/STTR solicitations as "Renewal" applications based on the awarded Phase I SBIR or STTR project. Only one Phase II application may be awarded for a specific project supported by a Phase I award. NIH policies regarding overlapping applications still apply. A Phase II awardee may receive one additional, sequential Phase II award (called the NIH Phase IIB) to continue the work of an initial Phase II award.	