NIH Update

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FY 2017 NIH Grants Policy Statement

The updated NIHGPS will be available on October 31, 2016.

 The revised Grants Policy Statement will be applicable to all NIH grants and cooperative agreements with budget periods beginning on or after <u>October 1, 2016</u>.

Until publication, NIH will continue to publish interim grants policy changes through the issuance of NIH Guide Notices via the NIH Guide for Grants and Contracts.

Stay tuned for additional information!!!



Enhancing Clinical Trial Stewardship & Transparency

NIH invests more than \$3 billion each year to fund clinical trials.

Therefore, in order to improve its stewardship of clinical trials. NIH recently announced the following reforms, which are crucial first steps in achieving its goal:

- Expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials be trained in Good Clinical Practice (GCP). – <u>Effective January 1, 2017</u>
- Expectation that all NIH-funded clinical trials are registered and that results are submitted to ClinicalTrials.gov whether or not subject to FDAAA. – Applies to grants, contracts, and intramural clinical trials submitted on or after January 18, 2017.
- Requires all applications involving one or more clinical trials to be submitted in response to a clinical-trial specific FOA. – Effective for receipt dates on or after <u>September 27, 2017</u>.



Kirschstein National Research Service Awards (NRSA) News

NIH is fully supportive of an increased salary threshold for postdoctoral researchers. Therefore, subject to the availability of a FY17 appropriation, NIH announced the following projected stipend levels for postdoctoral trainees and fellows supported by Kirschstein NRSA awards in FY 2017.

Career Level	Years of Experience	Actual Stipend for FY 2016	Projected Stipend for FY 2017	Monthly Stipend
Postdoctoral	0	\$43,692	\$47,484	\$3,957
	1	\$45,444	\$47,844	\$3,987
	2	\$47,268	\$48,216	\$4,018
	3	\$49,152	\$50,316	\$4,193
	4	\$51,120	\$52,140	\$4,345
	5	\$53,160	\$54,228	\$4,519
	6	\$55,296	\$56,400	\$4,700
	7 or More	\$57,504	\$58,560	\$4,880

Once implemented, this increased support for NRSA stipends in FY17 will ensure that all postdoctoral NRSA recipients are above the \$47,476 exemption threshold established by the DOL's revisions to the rules on paid overtime under the Fair Labor Standards Act (FLSA).



Appendix Policy Change

NIH issues a new policy to eliminate most appendix materials that are submitted with applications. The new policy is effective for application due dates on or after January 25, 2017.

Allowable Appendix Materials are as follows:

For all applications:

- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items
 - Applications submitted without required appendix materials will be considered incomplete and will not be reviewed.

For Clinical Trials (all of the above plus the following):

- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND)

Reminder: Applications will be withdrawn and not reviewed if they are submitted with appendix materials that are not allowed and/or required by the FOA.





Post-Submission Materials for Applications

NIH recently issued Guide Notice <u>NOT-OD-16-130</u>, which simplifies and consolidates the current NIH policy concerning post-submission materials.

The policy change highlights the only post-submission materials that NIH will accept are those resulting from unforeseen events such as the following for example:

- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)

As a reminder, the policy on post-submission application materials is not intended to correct oversights/errors discovered after submission of the application.



Federal-wide Research Updates

NSF and NIH are pleased to announce that both the Research Terms and Conditions (RTCs) and the Final-RPPR have cleared the Subcommittee on Social, Behavioral and Economic Sciences (SBE) and are currently working their way through the Committee on Science (COS) approval process.

Participating research agencies are currently in the process of developing their supporting documents (e.g., Agency Specific Research Terms and Conditions) as well as their agency implementation plans.

Stay tuned for additional information!!



REMINDER Timely Reporting

Annual progress reports must be submitted in the RPPR format.

- Non-SNAP annual progress reports are due the 1st of the month preceding the month in which the budget period ends.
- SNAP progress reports are due the 15th of the month preceding the month in which the budget ends.
- Multi-year funded progress reports due on the anniversary of the budget/project period start date of the award. (electronic submission RPPR only)

Federal Financial Report (FFR)(SF-425) Expenditure Data

- Annual (Non-SNAP Awards)
 - FFR submitted for each budget period no later than 90 days after the end of the calendar quarter (CQ) in which the budget period ended.
 - Budget period ends 1/31/2016 FFR due 6/30/16
 (90 days after the end of the CQ of 3/31/16)
- Final (SNAP and Non-SNAP Awards)
 - FFR submitted within 120 days following the end of the project period.

