National Institute of General Medical Sciences

NIH Policy Updates

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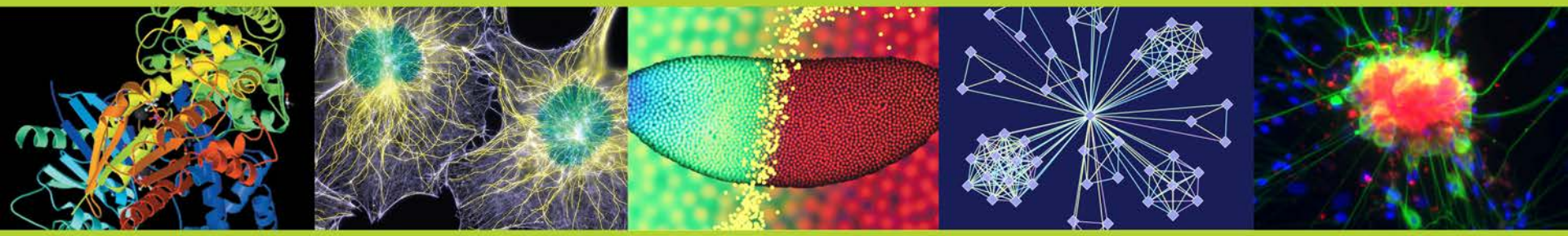

Grant Closeout Requirements

NIH GPS 8.6 Closeout: Recipients must submit the all closeout documents within 120 calendar days of the end of the period of performance (project period)

- Final Research Performance Progress Report (F-RPPR)
- Final Invention Statement and Certification (FIS)
- Final Federal Financial Report (FFR) – must ensure that there are no discrepancies between the final FFR expenditure data (in eRA Commons) and the FCTR in the PMS

Grant Closeout Requirements

- HHS policy requires NIH to initiate unilateral closeout procedures within 180 days of the period of performance end date if any of the closeout reports are not timely and acceptable

- Sanctions may include, but are not limited to, corrective actions, removal of authorities, and/or delay or withholding of further awards

Interim and Final Progress Reports

- NOT-OD-17-022: The Final Research Performance Progress Report (F-RPPR) has replaced the Final Progress Report (FPR) for closeout
  - The general format is the same as the interim/annual RPPR
  - Recipients are required to report on Project Outcomes
  - Due dates have not changed
- NOT-OD-17-037: Implementation of the Interim-RPPR while a Renewal Application is Under Consideration - Effective 02/09/2017
  - ~~*Old policy - whether funded or not, the progress report contained in the renewal (Type 2) application may serve in lieu of a separate final progress report*~~
  - If the recipient organization has submitted a renewal application on or before the date by which a Final-RPPR would be required for the current competitive segment, then submission of an Interim-RPPR via eRA Commons is required no later than 120 calendar days from the period of performance end date
    - If the renewal application is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment.
    - If the renewal application is not funded, the Interim-RPPR will be treated by NIH staff as the institution's Final-RPPR.

Human Subjects System (HSS)

- NOT-OD-18-179: Transition from Inclusion Management System to New Human Subjects System (HSS) as of June 9, 2018
- Consolidates human subjects and clinical trial information in one place
- NIH migrated enrollment records previously in IMS to HSS
- PIs and SOs can access HSS via a *Human Subjects* link in the *Status* section of eRA Commons and via a *Human Subjects* link in the *RPPR* section of eRA Commons
- https://era.nih.gov/hss_overview.cfm

Human Subjects System (HSS)

- The HSS will allow recipients to:
  - Add/update study information
  - Create new enrollment reports or view/edit/update existing enrollment data
  - Make off-cycle corrections or updates after application or Research Performance Progress Report (RPPR) submission
  - Convert a delayed onset study to a full study record, once detailed study information is available
  - Access and update all human subject and clinical trial data associated with their applications or grants in one place

Clinical Trials

- NOT-OD-16-148: Expects 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) – Effective 01/01/2017
- NOT-OD-16-149: Expects 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 01/18/2017
- NOT-OD-17-043: All grant applications with plans to conduct clinical trials must be submitted in response to an FOA which specifically states that clinical trials are allowed – Effective 01/25/2018
- NOT-OD-17-114: Active FOAs with due dates on or after 01/25/2018 were updated to state whether clinical trial are or are not allowed

Clinical Trials

- If there is a research or pilot project on an IDeA award, additional information and documentation will be required when it is submitted for prior approval to NIGMS

- Terms specific to each clinical trial will be included in SECTION IV – GM Special Terms and Conditions on the NoA

NIH Forms

NOT-OD-17-119: New NIH "FORMS-E" Grant Application Instructions Available for Due Dates On or After January 25, 2018

- Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
- Expansion and use of discrete form fields for clinical trial information
- Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms

- Make sure you are using the current forms for all applications and prior approval requests

Questions?

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