

EXHIBIT 51

Research General Terms and Conditions
Agency Specific Requirements for the National Institutes of Health (NIH)
(April 8, 2021)

NIH Home Page: <http://www.nih.gov/>

NIH Office of Extramural Research Home Page: <http://grants.nih.gov/grants/oer.htm>

NIH Grants Policy Statement: <http://grants.nih.gov/grants/policy/policy.htm>

NIH Forms and Applications: <http://grants.nih.gov/grants/forms.htm>

I. NIH Implementation of the Research General Terms and Conditions

- A. The Research General Terms and Conditions apply to all NIH grants and cooperative agreements with the exception of the automatic carryover provision found in 2 CFR § 200.308(c)(3). Automatic carryover authority will be indicated on the Notice of Award (NoA) (See II.d below).
- B. NIH Implementation of the Research General Terms and Conditions includes: 1) The Uniform Guidance as codified in 2 CFR §200; 2) conditions on activities and expenditure of funds in statutory requirements, such as those included in appropriations acts detailed at: http://grants.nih.gov/grants/policy/appropriations_info.htm; and 3) the [NIH Grants Policy Statement](#).
- C. For certain funding mechanisms, NIH implements streamlined requirements for progress report submission, the Notice of Award (NoA), and financial reporting. Known as the Streamlined Noncompeting Award Process (SNAP), NIH routinely applies SNAP to most Research Project (R-series) awards (except R35s, R41s, and R43s), and Career Development Awards (K-series). NIH grantees are expected to follow the SNAP process for those awards that are issued under the SNAP, as indicated on the NoA. Agency-specific requirements listed below will indicate where differences exist between SNAP and non-SNAP grants. Additional information on SNAP can be found in the NIHGPS, at 8.4.1.2, “Streamlined Noncompeting Award Process”.

II. Prior Approval Requirements Not Included in or Modified from the Research General Terms & Conditions

- a. Transfer of funds budgeted for participant support costs to other categories of expense (200.308(c)(5)): Waived, unless change in scope. For the purposes of Kirschstein NRSA programs, this term does not apply. NIH will continue to use the terms trainees, trainee-related expenses, and trainee travel in accordance with NRSA Regulations. Participant support costs are only allowable when identified in specific FOAs.
- b. Subawarding, transferring or contracting out any work under a Federal award (200.308(c)(6)): NIH prior approval is required for the transfer of a significant part of the research or substantive programmatic effort only when the transfer represents a change of scope unless the transfer is to a foreign entity. If the transfer is to a foreign entity, prior approval must be obtained in order to complete the appropriate administrative assurances.

- c. Initiate a one-time extension of the period of performance by up to 12 months (200.308(e)(2)): Recipients are required to notify NIH of their initiation of a one-time no-cost extension. Recipients are encouraged to use the No-Cost Extension Notification feature in the eRA Commons and can submit notifications up to the last day of the current end date, essentially waiving the 10-day requirement.
- d. Carry forward unobligated balances to subsequent periods of performance (200.308(e)(3)): NIH prior approval may be required for carryover of unobligated balances on all P mechanisms except P01s; cooperative agreements (U's); Institutional National Research Service Awards (T's); Phase I SBIR & STTR (R43, R41); clinical trials (regardless of mechanism) and awards to individuals. The NIH Notice of Award will state whether prior approval is or is not required for carry over.
- e. Subawards based on fixed amounts at any dollar amount, provided the subawards meet the requirements for fixed amount awards in 200.201(200.333): NIH prior approval is required in order for recipients to provide subawards based on fixed amounts (as defined in 2 CFR 200.45) to which the conditions in 2 CFR 200.201 apply.
- f. Direct charge the salaries of administrative and clerical staff (200.413(c)(1)): NIH prior approval is not required to rebudget funds to direct charge the salaries of administrative and clerical staff if the following conditions are met: administrative or clerical services are integral to the project or activity; individuals involved can be specifically identified with the project or activity; the costs are not also recovered as indirect costs. The only time a prior approval request would need to be submitted is when additional funds are requested for such a position or the incurrence of such costs constitutes a change of scope.
- g. Direct charge special arrangements and alterations costs incurred specifically for a Federal award (200.462(a)): NIH prior approval is required for Alterations and Renovations that exceed \$500,000.

III. Allowable Direct Costs Aside from Those in 2 CFR 200

- a. The allowability of direct costs not specifically covered by the provisions of 2 CFR 200, Subpart E shall be in accordance with the NIHGPS or the NIH Funding Opportunity Announcement published in the NIH Guide for Grants and Contracts, if more current.

IV. Non-Adoption of 2 CFR 200.240(a)(2) Termination Clause

- a. NIH does not adopt 2 CFR § 200.240(a)(2), stating that the Federal awarding agency may terminate a Federal award if the award no longer effectuates the program goals or agency priorities. NIH derives and exercises discretionary decision-making related to program goals and priorities, separate and distinct from non-compliance, as described within the [NIH GPS Section 2.4.4 Disposition of Applications](#).

V. Contact Information

a. Contact Information for Technical Matters

The NIH Scientific Program Official as identified on the Notice of Award is responsible for the scientific monitoring of the research.

b. Contact Information for Administrative Matters

The NIH Grants Management Officers/Specialist as identified on the Notice of Award is the official to be notified when required by the General Terms and Conditions.

c. Contact Information for Intellectual Property Matters

The NIH point of contact for intellectual property matters is:

Division of Extramural Inventions and Technology Resources
Office of Policy for Extramural Research Administration, NIH
6705 Rockledge Dr., Rm. 1136, MSC 7980
Bethesda, MD 20892-7980
Telephone: 301/435-1986

Inventions should be reported using Interagency Edison (located at <http://www.iedison.gov/>).

The Office of Policy for Extramural Research Administration (OPERA) is responsible for developing and maintaining the NIH GPS. Interim changes to NIH grants policy will be published in the NIH Guide for Grants and Contracts. Each change will be described, including its applicability and effective date.

VI. Agency-Specific Requirements Related to Articles in The Research General Terms And Conditions

Part II Subpart B of the NIHGPS includes additional policy guidance as well as terms and conditions that vary from standard terms and conditions because of the type of grant, grantee, or grant-supported activity. These terms and conditions may apply in addition to or in lieu of those in the Research General Terms and Conditions. Each section of Part II Subpart B of the NIHGPS specifies how the coverage relates to Section II Subpart A of the NIHGPS, and consequently to the Research General Terms and Conditions.

Part II Subpart B includes:

- Multiple Program Director/Principal Investigator Applications and Awards
- Construction, Modernization, or Major Alteration and Renovation of Research Facilities
- Ruth L. Kirschstein National Research Service Awards

- Research Career Development Awards
- Modular Applications and Awards
- Support of Scientific Meetings (Conference Grants)
- Consortium Agreements
- Grants to Foreign Institutions, International Organizations, and Domestic Grants with
- Foreign Components
- Grants to Federal Institutions and Payments to Federal Employees Under Grants
- Grants to For-Profit Organizations
- Research Patient Care Costs

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VII. Revised Budget Requirements

- a. While a modified, streamlined, progress report is still a feature of grants awarded under the Streamlined Non-competing Award Process (SNAP) authorities, a streamlined version of the RPPR has replaced the eSNAP module in the eRA Commons. For all SNAP awards, the progress report is submitted using this streamlined version of the RPPR that does not include detailed budget information.
- b. For non-SNAP awards, revised budget information should be submitted according to the instructions in Section H of the [RPPR Instruction Guide](#).

VIII. Technical Reporting

NIH requires grantees to report on scientific progress using the Research Performance Progress Report (RPPR) module in eRA Commons. Annual progress reports submitted in any format other than the RPPR will not be processed by the NIH and will require resubmission through the RPPR.

As of January 1, 2017, NIH has replaced the Final Progress Report with the Final RPPR (F-RPPR). Generally, the format will be the same as the annual RPPR, making it easier for recipients to navigate through the F-RPPR based on familiarity with the existing format of the annual RPPR. Effective February 9, 2017, if the recipient organization has submitted a renewal application on or before the date by which an F-RPPR would be required for the current competitive segment, then submission of an "Interim-RPPR" via eRA Commons is now required. Based on this requirement, NIH has discontinued the policy for renewal applications whereby, "whether funded or not," the progress report contained in the renewal application may serve in lieu of a separate final progress report.

IX. Financial Reporting

- a. Generally, for SNAP awards, a Federal Financial Report (FFR) is required at the end of a competitive segment only. It must be submitted within 120 days after the end of the competitive segment and must report the cumulative support awarded for the entire competitive segment. An FFR must be submitted at this time whether or not a competing continuation award is made.
- b. For non-SNAP awards, the FFR is required annually. The report must be submitted for each budget period, no later than 90 days after the end of the calendar quarter in which the budget period ends. The report must also cover any authorized extension in time of the budget period. For non-SNAP awards, the final FFR must be submitted within 120 days after the end of the competitive segment.
- c. For grants eligible for automatic carryover, the FFR must specify the amount to be carried over to the next budget period. The notification must be provided under item 12, "Remarks," on the FFR.
- d. If more frequent reporting is required, the NoA will specify both the frequency and due date.

FFRs must be submitted electronically to NIH using the FFR system located in the eRA Commons. Questions concerning specific financial matters should be directed to the Government Accounting Branch, 301-451-9210, or visit the Government Accounting web-page at <https://ofm.od.nih.gov/Pages/Government-Accounts-Branch.aspx>.

X. Incremental Funding Actions

A. SNAP:

1. Instructions for submitting SNAP progress reports are included in the [RPPR Instruction Guide](#).
2. Career Development Awards that are issued under SNAP are to follow the RPPR instructions for SNAP and the CDA instructions of the RPPR at Section 7.1.
3. NIH will use the quarterly FFR cash transaction data submitted to the Payment Management System (PMS) to monitor the financial aspects of SNAP awards. Final FFR expenditure data is required to be submitted to NIH within 120 days of the end of a competitive segment (see 200.344).

B. Non-SNAP

1. Instructions for submitting non-SNAP progress reports are included in the [RPPR Instruction Guide](#).
2. Institutional Research Training Grant, Including Ruth L. Kirschstein National Research Service Awards are to follow the specific training grant instructions of the RPPR at Section 7.4.

3. A FFR is required to be reported annually to NIH for non-SNAP awards. Final FFR expenditure data is required to be submitted to NIH within 120 days of the end of a competitive segment (see 200.344).