NIH Updates

The NIH Guide for Grants and Contracts is the official publication for NIH medical and behavioral research Grant Policies, Guidelines and Funding Opportunities.

In an effort to provide a mechanism to locate specific NIH guide notices that are relevant to UCSF faculty and staff, this page was developed with a library of current relevant NIH policy and guide notices that can be located by searching for key words/topic. While on the page strike CTRL-F and enter a key word or topic of the Notice. Each month the page will be updated. If a notice is not listed that you would like to keep for reference, please email a request to post the guide notice (NOT-OD-18-XXX) on the OSR NIH UPDATES page.

Below is a list of Notices that are relevant to UCSF faculty and staff:

2018: June, July, September, October, November, December,

2019: January,

January 2019

NIH IMPLEMENTATION OF THE FINAL RULE ON THE FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS (COMMON RULE): NOT-OD-19-050 announces the NIH implementation of the Final Rule amending the Federal Policy for the Protection of Human Subjects (Common Rule). Several provisions in the Revised Common Rule resulted in changes to NIH policies and procedures. From an application submission perspective, the most notable changes are: 1.) Changes to categories of research qualifying for exemptions (FAQs) and 2.) Use of new exemptions 7 and 8, when applicable.

UCSF HRPP is hosting two Town Hall meetings to discuss the changes to the federal policy for research involving Human Subjects on:

- Monday, January 14, 2019, 10-11 AM, Mission Bay Rock Hall 102 (Auditorium)
- Tuesday, January 15, 2019, 3-4 PM, Parnassus Nursing N-225

Sessions will be live streamed and recorded. Go to the IRB website on the Town Hall days to link to the live stream.

NIH POLICY FOR REVIEW AND RESUBMISSION OF NEW INVESTIGATOR R01 APPLICATIONS: NOT-OD-19-053 provides an update of review and resubmission of New
Investigator (NI) R01 applications, commencing with R01 applications submitted for due dates on or after January 25, 2019. NIH has prioritized funding of meritorious R01 applications (NOT-OD-17-101) and will continue to make a special accommodation for NI R01 applications by retaining clustered review and preferential release of summary statements. The special NI deadline for next round resubmission of A1 R01 applications will be eliminated.

REMOVAL OF REQUIREMENT FOR IRB REVIEW OF NIH GRANT APPLICATIONS & CONTRACT PROPOSALS: NOT-OD-19-055 provides guidance on the implementation of revisions to the Final Rule on the Federal policy for the Protection of Human Subjects (Common Rule). Effective January 21, 2019 and forward, NIH will no longer require IRB review of the entire grant application or contract proposal. NIH will continue to require certification that all NIH-supported, non-exempt human subjects research protocols have been reviewed and approved by an IRB and the date of final IRB approval provided at Just-In-Time. The notice further provides a reminder that any changes to peer reviewed protocols or the addition of new study protocols require NIH prior approval (NIH GPS 8.1.2.5).

CLARIFICATION REGARDING HARASSMENT AND DISCRIMINATION PROTECTIONS IN NIH TRAINING (T) APPLICATIONS: NOT-OD-19-056 provides clarification that this policy requires a single letter, on institutional letterhead, signed by a key institutional leader with institution-wide responsibilities. The letter provides the institution’s commitment to prevent discriminatory harassment and other discriminatory practices through proper policies, procedures, and oversight; appropriately responding to such allegations; and following NIH prior approval procedures if there is a change in the status of NIH-supported Senior/Key Personnel as a result. This Letter of Support is posted on the OSR webpage for Regulatory/Compliance Requirements and should be included as part of the Letters of Support on the PHS 398 Research Training Program Plan form for T applications due on or after January 25, 2019.

December 2018

REVISION: NIH POLICY AND GUIDELINES ON INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN IN RESEARCH INVOLVING HUMAN SUBJECTS: NOT-OD-18-116 replaces NOT-98-024 revising the NIH Policy and Guidelines on the Inclusion of Children. Now individuals of all ages are expected to be included in all NIH-defined clinical research unless there are scientific or ethical reasons not to include them. Applications for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the Inclusion of Women, Minorities, and Children section of the proposed research project.

CHANGES TO NIH ACADEMIC RESEARCH ENHANCEMENT AWARD R15 PROGRAM: NOT-OD-19-015 announces the rebranding of the "NIH Research Enhancement Award." The R15 activity code will include two programs: 1.) Academic Research Enhancement Award (AREA) for Undergraduate-Focused institutions and 2.) Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools. The ineligible institution list will no longer be maintained, instead an institution letter verifying eligibility is required with criteria listed in the funding opportunity announcement.

ADVANCE NOTICE-STREAMLINING THE CERTIFICATIONS AND REPRESENTATIONS PROCESS AND PHASING OUT THE SF-424B: NOT-OD-19-043 announces that effective
January 1, 2020, the System for Award Management (SAM) will become the central repository for common government-wide certifications and representations (assurances) required by NIH. This action will reduce the duplicative practice of Federal-awarding agencies requesting these assurances with the submission of each Federal financial assistance application and will phase-out the use of the SF-424B.

November 2018

UPDATE TO NIH MANAGEMENT OF GENOMIC SUMMARY RESULTS (GSR) ACCESS: NOT-OD-19-023 provides an update to the NIH Genomic Data Sharing (GDS) Policy, which implements data management procedures for GSR access. Investigators proposing to conduct GDS Policy applicable research will be expected to indicate in their genomic data sharing plans (in grant or contract proposals) if a study should be designated as "sensitive" for the purposes of access to GSR.

HARASSMENT AND DISCRIMINATION PROTECTIONS IN NIH TRAINING APPLICATIONS: NOT-OD-19-029 announces that NIH training (T) applications due on and after January 25, 2019 will require an additional letter of support describing the institutional commitment to prevent discriminatory harassment and other discriminatory practices. NOTE: Resources and guidance are under development for the January 25, 2019 due date.

LEGISLATIVE MANDATES IN EFFECT FOR FY 2019: NOT-OD-19-030 provides current requirements that limit or conditions the use of funds on NIH grant, cooperative agreement, and contract awards for FY 2019, under the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 (Public Law 115-245), signed into law on September 28, 2018.

NOTICE OF FISCAL POLICIES IN EFFECT FOR FY 2019: NOT-OD-19-031 summarizes NIH fiscal policies instituted in FY 2019:

- FY 2019 Funding Levels - non-competing continuation awards will generally be issued at the commitment level indicated in the Notice of Award. Out-year commitments for continuation awards remain unchanged. NIH awarding ICs will post their individual fiscal policies here.
- Kirschstein-NRSA - stipends will increase by approximately 2% on average (see NOT-OD-19-036).
- Next Generation Researchers Initiative Policy - NIH will prioritize meritorious R01 - equivalent applications for Early Stage Investigators (ESI) per the policy established in FY 2017 (see NOT-OD-17-101).
- Salary Limits - salaries paid through extramural mechanisms (e.g. grants) shall not exceed Executive Level II, currently $189,600.
- Other Legislative Mandates - other statutory requirements are described in more detail in NOT-OD-19-030.
- Additional Information - details on Fiscal Operations and IC-specific funding strategies will be posted here.

establishes stipend levels for fiscal year (FY) 2019 Kirschstein-NRSA awards for predoctoral and postdoctoral trainees and fellows. Budgetary categories described in this notice apply only to Kirschstein-NRSA awards made on or after October 1, 2018 with FY 2019 funds. All FY 2019 awards previously issued using budgetary levels published in NOT-OD-18-175 will be revised to adjust funding to the FY 2019 levels.

NOTE: Additional information regarding UC scale from HR is forthcoming. OSR to concurrently release additional guidance.

CORRECTION-KIRSCHSTEIN-NRSA INDIVIDUAL PREDOCTORAL FELLOWSHIP TO PROMOTE DIVERSITY IN HEALTH-RELATED RESEARCH: NOT-OD-19-039 informs prospective applicants that the Certification Letter required in PA-18-666 should avoid revealing sensitive personal information, such as the candidate’s specific racial/ethnic background or type of disability. The certification letter must be on institutional letterhead and scanned so that an institutional official signature is visible. The letter should be uploaded to the "Other Attachments” section in the Research & Related Other Project Information Form.

October 2018:

REINSTATEMENT OF NIH SBIR DIRECT-TO-PHASE II AUTHORITY: NOT-OD-19-019 announces the reinstatement of this NIH SBIR Direct Phase II provision through Fiscal Year 2022. Please refer to the notice for exceptions.

COMMUNICATING RESEARCH MISCONDUCT TO NIH: NOT-OD-19-020 reminds recipient institutions of their responsibilities in handling research misconduct (suspected or confirmed) in NIH-funded research. The notice also clarifies the requirement of recipient and subrecipient institutions (foreign or domestic) to hold assurances with HHS Office of Research Integrity (ORI) and outlines procedures to communicate matters related to research misconduct proceedings to the NIH and ORI.

REVISED NIH GRANTS POLICY STATEMENT (NIHGPS): NOT-OD-19-021 announces publication of the revised NIH Grants Policy Statement (NIHGPS. Rev. October 2018). This revision is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2018 and supersedes, in its entirety, NIHGPS. Rev. October 2017 as a standard term and condition of award.

NEW FUNDING OPPORTUNITY ANNOUNCEMENTS (FOAs) TARGETING BASIC EXPERIMENTAL STUDIES WITH HUMANS: NOT-OD-19-024 announces the intent to publish new R01 Parent Announcements identified as Basic Experimental Studies with Humans, which focus on applications that propose clinical trials that also meet the definition of basic research. Pay close attention to participating Institutes and Centers and any restrictions posted in the Related Notices section of each FOA. Applications proposing basic experimental studies involving humans may also be submitted to opportunities which allow clinical trials.

September 2018:

2018 BAYH-DOLE ACT FINAL RULE: NOT-OD-18-233 implements the new final regulations of the Bayh-Dole Act (rights to Federally-funded inventions and licensing of
government-owned inventions), which applies to all NIH new (including renewals) and continuation awards beginning on or after October 1, 2018.

**FIXED AMOUNT AWARDS**: NOT-OD-18-222 provides clarification of the definition of ?fixed amount? subawards, specifically when used for human subject studies, e.g. clinical trials and other types.

**FELLOWSHIP APPLICATION UPDATES**: NOT-OD-18-227 announces planned updates to the application instructions and review criteria for fellowship grant applications for due dates on or after January 25, 2019.

**RESEARCH APPLICATION UPDATES**: NOT-OD-18-228 announces planned updates to the application instructions and review criteria for research grant applications for due dates on or after January 25, 2019.

**CAREER DEVELOPMENT AWARD APPLICATIONS**: NOT-OD-18-229 announces planned updates to the application instructions and review criteria for career development award applications for due dates on or after January 25, 2019.

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**July 2018:**

**SUBMISSION/RESUBMISSION POLICY**: NOT-OD-18-197 consolidates the policy onto one notice and rescinds prior notices. Use this notice when referring to the policy.

**UPDATES TO RPPR**: NOT-OD-18-202 announces update to the delegation feature of the final and interim RPPR to align with the annual RPPR. Now, PIs can delegate initiation of any RPPR to the ASST role. Also, RPPR forms include decimals in the effort being reported.

**2018 COMMON RULE**: NOT-OD-18-211 announces NIH implementation of the 3 burden reducing provisions during the 6 month delay. UCSF has decided not to implement to provisions and is working on campus-wide training materials for the January 21, 2019 compliance date.

**BASIC SCIENCES HS STUDIES**: NOT-OD-18-212 announces delayed enforcement and short-term flexibilities for some requirements affecting Basic Science Studies with Human Participants.

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**June 2018:**

**CONTINUOUS SUBMISSION**: NOT-OD-18-178 reminds the research community of the application deadlines based on Council Round assignment.