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:

2021:
January, February

2020:
January, February, March, April, May, June, July, August, September, October, November, December

2019:
January, February, March, April, May, June, July, August, September, October, November, December

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

February 2021

POLICY ON PROTECTING LIFE IN GLOBAL HEALTH ASSISTANCE IS REVOKED: NOT-OD-21-063 rescinds previously issued notices concerning NIH’s implementation of the requirements for Protecting Life in Global Health Assistance (PLGHA) policy (NOT-OD-17-083 and NOT-OD-19-079).

On January 28, 2021, President Biden issued a Presidential Memorandum (Memorandum on Protecting Women's Health at Home and Abroad?) revoking the Protecting Life in Global Health Assistance? (PLGHA) policy.
Effective immediately, implementation and enforcement of the PLGHA standard provisions are waived for all current National Institutes of Health grant and cooperative agreement awards.

Please direct inquiries to: GrantsCompliance@od.nih.gov

NOTICE OF CHANGES IN THE REVIEW CRITERIA FOR APPLICATIONS SUBMITTED FOR NIH SUPPORT FOR SCIENTIFIC CONFERENCES (R13/U13): NOT-OD-21-055

announces changes to the review criteria for applications submitted for NIH support of Scientific Conferences (R13 and U13) related to the implementation of guidelines announced in NOT-OD-21-053. All changes take effect for R13/U13 applications submitted for the April 12, 2021 application due date and subsequent receipt dates.

- Applications are required to include a Diversity Plan, which reviewers will evaluate plan demonstrate efforts to enhance diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in the planning and implementation, and participation in the proposed conference. The Diversity Plan will be considered in determining the scientific and technical merit of the application, and in providing an overall impact score.
- Applicants should describe past experiences with enhancing diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in biomedical sciences when preparing the Personal Statement of their Biographical Sketches. Reviewers will evaluate if the applicant and key personnel are suited to fulfill the goals of the conference and qualified to perform their roles in the conference.

Please direct inquiries to: ReviewPolicyOfficer@mail.nih.gov.

REQUESTING EXTENSIONS FOR EARLY CAREER SCIENTISTS WHOSE CAREER TRAJECTORIES HAVE BEEN SIGNIFICANTLY IMPACTED BY COVID-19: NOT-OD-21-052

informs recipients of NIH individual fellowships (F series) and NIH career development awards (K series) that NIH is providing an opportunity to request extensions to those whose career tracks have been impacted by COVID-19.

No-Cost Extension

Most NIH award recipient may extend the final budget period up to 12 months without prior approval. Recipients of individual fellowships and some career development awards, e.g. K99 may submit requests for extension. Recipients may also submit prior approval requests for a second no-cost extension. Requests will be considered by ICs on a case-by-case bases. Recipients should work with their OSR Staff.

Funded Extension
Requests for funded extensions from recipients of individual fellowships (F) and career development awards (K) will be considered on a case-by-case basis by each IC. Recipients should work with their OSR Staff.

All requests must include a justification outlining the impact of COVID-19 on the recipient’s training or career development activities.

See the Notice for details and where to send inquiries.

January 2021


The Notice summarizes Fiscal Policies instituted in FY 2021, listed below:

- FY 2021 Funding Levels
- Ruth L. Kirschstein National Research Service Awards (NRSA) ? NOT-OD-21-049 information on campus implementation to follow in an OSR Announcement
- Next Generation Researchers Initiative Policy ? NOT-OD-17-101
- Salary Limits ? NOT-OD-21-057 information on campus implementation to follow in an OSR Announcement
- Other Legislative Mandates ? NOT-OD-21-056

Please direct inquiries to: GrantsPolicy@nih.gov

NOTICE OF LEGISLATIVE MANDATES IN EFFECT FOR FY 2021: NOT-OD-21-056 provides the current statutory provision that limits or conditions the use of funds on NIH grants, cooperative agreements, and contract awards for FY 2021.

FY 2021 Mandates

- Salary Limitation
- Gun Control
- Anti-Lobbying
- Acknowledgement of Federal Funding
- Restriction on Abortions
- Exceptions to Restriction on Abortions
- Ban on Funding Human Embryo Research
- Limitation on Use of Funds for Promotion of Legalization of Controlled Substances
- Restriction on Disclosure of Political Affiliation for Federal Scientific Advisory Committee Candidates
- Dissemination of False or Misleading Information
- Restriction of Pornography on Computer Networks
- Restriction on Distribution of Sterile Needles
Please see NOT-OD-21-056 for details in each area.

**GUIDANCE ON SALARY LIMITATION FOR GRANTS AND COOPERATIVE AGREEMENTS FY 2021:** NOT-OD-21-057 provides information regarding the salary limitation for NIH grant and cooperative agreement awards and extramural research and development contract awards.

Effective January 3, 2021, the salary limitation for Executive Level II is $199,300.

Information on campus implementation will follow in an OSR Announcement.

For a historical record of the salary cap, including effective dates see: https://grants.nih.gov/grants/policy/salcap_summary.htm

**RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARD (NRSA) STIPENDS, TUITION/FEES AND OTHER BUDGETARY LEVELS EFFECTIVE FOR FISCAL YEAR 2021:** NOT-OD-21-049 supersedes NOT-OD-20-070 and provides the FY 2021 stipend levels for Kirschstein NRSA awards for undergraduate, predoctoral, and postdoctoral trainees/fellows, effective for awards made on or after October 1, 2020.

- Calculation of tuition and fees remains unchanged.
- Training Related Expenses on Institutional Training Grants remains unchanged
- Institutional Allowance for Individual Fellows remains unchanged

Information on campus implementation to follow in an OSR Announcement.

**FDA GRANTS/COOPERATIVE AGREEMENTS ? CLINICAL TRIAL INSURANCE REQUIREMENTS:** NOT-FDA-21-005 notifies the FDA applicants and recipients of the requirement to acquire Clinical Trial Insurance on FDA grants/cooperative agreements involving clinical trials.

Clinical Trial liability insurance should cover all liabilities, damages, losses, injuries, complaints and/or claims arising from the trial, including but not limited to malpractice and/or negligence.

Applicants should include the cost of this insurance in the budget and will be responsible for maintaining a certificate of insurance that satisfies relevant regulations/guidance/policies including local requirements.

Please direct inquiries to: OAGSGrantsPolicy@fda.hhs.gov

**UPDATED GUIDELINES FOR ENHANCING DIVERSITY AND CREATING SAFE ENVIRONMENT IN CONFERENCES SUPPORTED BY NIH GRANTS AND COOPERATIVE AGREEMENTS:** NOT-OD-21-053 updates the guidance on enhancing the diversity of
conferences supported by NIH under R13 and U13 activity codes and replaces guidance in NOT-OD-03-066.

The Notice updates the policy for NIH-supported conferences/scientific meetings to include:

- Plans to enhance Diversity are included in the application (see NOT-OD-20-031 NIH Interest in Diversity)
- Strategies that seek to prevent or mitigate the effects of discrimination and harassment, sexual and otherwise (see NOT-OD-15-152 Civil Rights Protections)

Please see NOT-OD-21-053 for details in each area.

FDA-MANDATORY SUBMISSION OF THE FEDERAL FINANCIAL REPORT (FFR) IN THE PAYMENT MANAGEMENT SYSTEM BEGINNING JANUARY 1, 2021: NOT-FD-21-004 announces that in alignment with HHS, the Food and Drug Administration (FDA) is implementing the requirement to submit Federal Financial Reports (FFRs) using the Payment Management System (PMS) effective January 1, 2021.

This change will not affect the FFR submission timeline. FFR due dates outlined in the Notice of Award remain unchanged.

December 2020

REMINDER-MANDATORY SUBMISSION OF THE FEDERAL FINANCIAL REPORT (FFR) IN THE PAYMENT MANAGEMENT SYSTEM BEGINNING JANUARY 1, 2021: NOT-OD-21-046 reminds NIH award recipients that Federal Financial Reports (FFRs) submitted on or after January 1, 2021 must be submitted in the Payment Management System (PMS).

The Notice provides implementation details (e.g. direct access to the PMS using the new Manage FFR button in the eRA Commons) and system changes resulting from the transition to PMS (e.g. Indirect Expense Section 11 of the FFR form is now limited to ten F&A rates).

Training sessions offered by PMS for recipients will be posted at this link as they become available: https://pms.psc.gov/training/gr-ffr-training.html.

Please direct all systems policy inquiries to:

NIH Office of Policy for Extramural Research Administration (OPERA)
Systems Policy Branch
Email: OPERAsystemspolicy@nih.gov

Please direct all eRA systems-related inquiries to:

eRA Service Desk
REQUIRED USE OF TWO-FACTOR AUTHENTICATION USING LOGIN.GOV FOR ERA's MODULES IN 2021: NOT-OD-21-040 informs the research community that by September 15, 2021, NIH eRA users will be required to use Login.gov to access external eRA modules, e.g. Commons, Commons Mobile, Internet Assisted Review (IAR) and ASSIST. Login.gov is a shared service, 2-factor authentication provider managed by General Services Administration (GSA).

eRA will rollout the requirement to associate eRA accounts to Login.gov stating with users of the IAR module. The new requirement will be phased in for reviewers meeting by meeting starting with the February 1, 2021 meeting and forward.

eRA Commons and ASSIST users should plan to associate their eRA Commons and Login.gov accounts any time before the mandatory implementation deadline of September 15, 2021.

Users can only have one eRA account associated to one Login.gov account. If you have more than one eRA account please consult the FAQs: https://era.nih.gov/faqs.htm#XXIV11

Once a user has transitioned to Login.gov, they should not use their eRA credentials and password to access NIH eRA modules.

See step-by-step instructions, FAQs, video tutorials and more at: https://era.nih.gov/register-accounts/access-era-modules-via-login-gov.htm

Direct all inquiries to the eRA Service Desk: https://grants.nih.gov/support/index.html

REMINDER - EXPIRING FUNDS ALERT TO AHRQ GRANT RECIPIENTS WHO RECEIVED MULTI-YEAR-FUNDED AWARDS: NOT-HS-21-004 reminds recipients of AHRQ multi-year-funded (MYF) or awards funded by fixed year appropriations in Fiscal Year 2016, that the 2016 fixed appropriations will expire on September 30, 2021 Upon expiration, funds will no longer be available to the grantee or AHRQ.

The deadline to drawdown funds is generally a few days before September 30. Please check the Program Support Center (PSC) Payment Management System (PMS) website for information regarding the last day to draw funds:https://pms.psc.gov/grant-recipients/cancelled-awards.html.
UPDATED INSTRUCTIONS ON INTERIM REPORTING AND CARRYOVER FOR RADx-UP RECIPIENTS: NOT-OD-21-038 updates the terms and conditions of award for recipients of competitive revisions under the RADx Underserved Populations (RADx-UP) initiative. This Notice applies only to awards for the following NOSIs:

- NOT-OD-20-121 NOSI: Limited Competition for Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing Among Underserved and/or Vulnerable Populations
- NOT-OD-20-120 NOSI: Emergency Competitive Revisions for Community-Engaged Research on COVID-19 Testing Among Underserved and/or Vulnerable Populations
- NOT-OD-20-119 NOSI: Emergency Competitive Revisions for Social, Ethical, and Behavioral Implications (SEBI) Research on COVID-19 Testing Among Underserved and/or Vulnerable Populations

Multiple PD/PI Requirements

Competitive revisions to parent awards with multiple PD/PIs (MPIs) must align with PD/PIs on the parent. Members may be added to the leadership team to provide expertise for the supplement; however, the contact PD/PI and MPIs may not differ for the parent award. Any changes to contact and MPIs must be submitted in a prior approval request with an updated leadership plan.

Interim Reports

In addition to the annual RPPR, an interim progress report is due every six months for each competitive revision supplement outlining key milestones that have been met. **Due Dates: for awards issued September 2020 interim reports are due March 31, 2021; for awards issued November 2020, interim reports are due May 31, 2021**

Beginning March 31, 2021 interim reports must be uploaded using the Additional Materials (AM) tool in the eRA Commons. The AOR will be required to submit reports to the GMO named on the NoA.

The interim progress report must outline:

- A brief summary of major activities, significant results, and key outcomes or other achievements for each specific aim.
- Funds obligated how much are unliquidated obligations and how much are unobligated.
- If recipient is on track to meet the 75% milestone, if not, provide a justification.

Annual Reports

Competitive revision supplement information will be reported in the annual RPPR, Section G.1 as directed in the current term of award and must include updates to the information provided in the interim report. For parent awards in an extension, recipients must upload the annual
report including budget information for the next year using the AM tool in the eRA Commons.

**Carryover**

Recipients of competitive revision supplements are expected to complete 75% of their milestones along with the accompanying budget within the first 12 months of the project. Recipients maintain authority for automatic carryover of unobligated balances; however, NIH staff will monitor drawdowns in the PMS for large unobligated balances. NIH may offset where performance and expenditure milestones have not been met.

Please direct inquiries to grantspolicy@nih.gov.

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**November 2020**

**ROLLOUT OF REDESIGNED eRA COMMONS HOME AND LANDING SCREENS IN JANUARY 2021:** NOT-0D-21-028 announces the redesign of the home screen (log-in screen) and the landing screen (screen once logged in). A significant change will be that once logged in, the eRA modules will be accessed through an application menu that will be located at the top-left of the screen.

eRA has posted a Take A Peak webpage where users can preview the new home screen and landing screen.

**EXTENDED GUIDANCE FOR APPLICANTS PREPARING APPLICATIONS DURING THE COVID-19 PANDEMIC:** NOT-OD-21-026 informs NIH applicants that the guidance for applicants preparing applications during the COVID-19 pandemic (NOT-OD-20-122) is extended until further notice.

NIH grant applications should not include contingency plans outlining steps needed to recover from temporary, emergency situations, or institutional return-to-the-workplace plans, resulting from the COVID-19 pandemic?. Such contingency plans will not be reviewed during the peer review process. If necessary, NIH staff will review the requested COVID-19 contingency plans carefully before funding.

Temporary, emergency situations due to the COVID-19 Pandemic will not affect review scores. Example situations include, but are not limited to:

- Temporary declines in productivity
- Availability of key personnel
- Proposed patient populations
- Animal facility shutdowns

Please direct all inquiries to: ReviewPolicyOfficer@mail.nih.gov

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**AHRQ GUIDE NOTICE ON EXCEPTION TO THE USE OF THE SINGLE IRB REVIEW REQUIREMENTS DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY:**
NOT-HS-21-002 provides information regarding the Agency for Healthcare Research and Quality (AHRQ)’s implementation of the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) determination of Exception to the Single IRB Review Requirements for Certain HHS-conducted or Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

This exception represents an effort to prioritize the health and safety of both research subjects and investigators, and provides flexibility to institutions in seeking IRB review due to the unique challenges created by the COVID-19 outbreak and is appropriate for cooperative research:

1. That is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency, as declared by the Secretary of Health and Human Services at [https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx](https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx);
2. Where reliance on a single IRB would not be practical; and
3. For which the HHS division supporting or conducting the research approves of the use of this exception.

**AHRQ Exception Request Content Requirements**

- Justification as to why the study meets the exception criteria defined by OHRP
- Include the name of the site(s) for which an IRB other than the single IRB of record is proposed to review the study for the site(s)

**Pre-Award Exception Requests** (for Federal Contracts follow instruction outlined in the RFP)

- Provide exception request and required justification in Section 3.2 under G 500 - PHS Human Subjects and Clinical Trials Information in the grant application.
- Name the PDF ?SIRBexceptionrequest.pdf? and follow instructions in section 3.2 for AHRQ applicants to submit an exception request, instead of a single IRB plan.
- Proposed budget in the application or contract proposal must reflect all necessary single IRB costs without an approved exception. Applicants and offerors should not assume that an exception will be granted when considering what single IRB costs to include in the budget.

**Post-Award Exception Requests**

- Submit a prior approval request in writing to the Grants Management Officer (GMO) for grants or to the Contracting Officer (CO) for contracts
- Requests must include appropriate justification as to why the study meets the exception criteria defined by OHRP
- Requests must be submitted no later than 30 days prior to the proposed change
- Requests must be signed by the Authorized Organization Representative (AOR), please work with your assigned OSR Staff to expedite these requests

Please direct all inquiries to: HopeHongzhu.He@ahrq.hhs.gov

**NOTICE OF OFFICE OF LABORATORY ANIMAL WELFARE STATEMENT ON OVERSIGHT OF NIH-OWNED CHIMPANZEES: NOT-OD-21-022**
announces a statement from the Director, Office of Laboratory Animal Welfare (OLAW) regarding the restricted transportation of significantly compromised NIH-owned chimpanzees.

Summary:

All facilities that house, care for, or are engaged in the transport of NIH-owned chimpanzees are subject to the Animal Welfare Act (AWA) and implementing regulations and policies.

The Alamogordo Primate Facility is a government-owned, contractor-operated federal facility, conducting non-invasive sample collection and observational behavioral studies. In the case of Federal research facilities, the head of the Federal agency conducting the research shall be responsible for all corrective action to be taken at the facility and the granting of all exceptions to inspection protocols.

Animal Welfare Regulations prohibit a research facility, including a Federal research facility, from delivering a nonhuman primate to any intermediate handler or carrier for transportation unless the nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian, certifying the nonhuman primate [must have] appeared to be free of any infectious disease or physical abnormality that would endanger the animal(s) or other animals or endanger public health. Further, if a nonhuman primate is obviously ill, injured, or in physical distress, it must not be transported and in doing so would be a violation of AWA regulations and PHS Policy.

It is the OLAW Director’s determination that the frailest chimpanzees must remain in their current location in keeping with the regulatory requirements.

Please see the Notice for the complete statement and details and direct all inquiries to olaw@mail.nih.gov

October 2020

NOTICE OF CLARIFICATION: POLICY FOR MANAGING CONFLICT OF INTEREST IN NIH PEER REVIEW: NOT-OD-21-019 clarifies Section IIB.4 “Professional Associates (NOT-OD-13-010); Section IIB.2 “May Serve with a Waiver” (NOT-OD-14-069); and NOT-OD-18-115 “Maintaining Integrity in NIH Peer Review Responsibilities and Consequences.”

Policy: NIH considers involvement in the preparation of an NIH grant application/contract proposal as a professional association that creates a conflict of interest with any other individual with a major professional role on that application, whether:

- The application is funded
- The individual involved in the preparation was listed as having a major professional role
- Compensation was provided to the individual involved in the preparation of the application/proposal

Management of such conflicts is outlined in NOT-OD-13-010 and NOT-OD-14-069.
Failure of a Scientific Review Group member to declare any conflict of interests, known to the reviewer, is considered a breach in the integrity of the NIH peer review process. Applicable consequences are outlined in NOT-OD-18-115.

Please refer to the Notices for full details and direct inquiries to: ReviewPolicyOfficer@mail.nih.gov.

**NOTICE OF POLICY REVISION: MANAGING CONFLICTS OF INTEREST FOR REQUESTS FOR APPLICATIONS:** NOT-OD-21-005 removes Section II.B.5 (entirely) from policy notice NOT-OD-13-010 Advance Notice: Revised Policy for Managing Conflict of Interest in the initial Peer Review of NIH Grant and Cooperative Agreement

**NIH OPERATES UNDER A CONTINUING RESOLUTION:** NOT-OD-21-009 announces that the Department of Health and Human Services (HHS), including NIH, operates under the Continuing Appropriations Act, 2021 and Other Extensions Act (PL 116-159) signed on October 1, 2020, which continues government operations through December 11, 2020.

NIH will continue procedures outlined in NOT-OD-20-068 and issue non-competing research awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments will be considered after FY 2021 appropriations are enacted. All legislative mandates in effect for FY 2020 (NOT-OD-20-066) remain in effect, as well as salary the salary limitation (NOT-OD-20-065) and Kirschstein-NRSA pre- and postdoctoral stipend levels (NOT-OD-20-070)

Please direct inquiries to the Grants Management Specialist identified in the Notice of Award.

**EXCEPTIONS TO THE USE OF A SINGLE IRB DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY:** NOT-OD-21-006 provides information regarding NIH implementation of the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) determination of Exception to the Single IRB Review Requirements for Certain HHS-conducted or Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

This exception represents an effort to prioritize the health and safety of both research subjects and investigators, and provides flexibility to institutions in seeking IRB review due to the unique challenges created by the COVID-19 outbreak.

Such an exception is appropriate for cooperative research:

1. That is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency as declared by the Secretary of Health and Human Services at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx
2. Where reliance on a single IRB would not be practical* and
3. For which the HHS division supporting or conducting the research approves of the use of this exception

*Scenarios for which OHRP anticipates it may not be practical to rely on use of a single IRB for multi-site, cooperative research trials during the ongoing COVID-19 pandemic include (but are not limited to):

1. Trials for which timely administration of an intervention for the rapidly emerging COVID-19 outbreak is paramount, but:
   1. research sites cannot be identified in advance due to the unpredictable nature of the exact location of the outbreak and patients cannot be moved to an existing trial site or to a newly established site without further increasing public health exposure risks; or
   2. institutions lacking existing reliance agreements, especially those in underserved or under-resourced areas, may face delays in starting the trial and in administration of the intervention while reliance agreements are negotiated.
2. Trials leveraging existing federally-supported trial networks to maximize access to appropriate patients, but where each network is operating under a different single IRB of record and negotiating reliance agreements between the networks and single IRBs could reduce the ability of qualified sites to access appropriate patients at the correct stage of disease.
3. Trials in which a federal research agency wishes to participate as a research site with non-federal (but federally-supported) sites but is legally prohibited from agreeing to certain terms in reliance agreements required by the non-federal sites.
4. A cooperative research study supporting the response to the COVID-19 outbreak in which the lead site is engaged in administration of an intervention and in addition is receiving study-wide identifiable samples and/or data for the purposes of determining risk factors linked to COVID-19 disease susceptibility, severity, outcome, or for developing potential diagnostics or therapeutics. The sites that would be engaged in the research may include institutions that do not have standing reliance agreements within a research network and establishing new reliance agreements would cause unacceptable delays as well as result in a lost opportunity to collect critical COVID-19 samples and data.
5. Trials in which the lead site or IRB is unable to provide oversight due to disruption in operations caused by the COVID-19 public health emergency, but other sites can continue, and selecting another site as the IRB of record would require renegotiation of reliance agreements with a new IRB of record, and the study would otherwise be required to halt until such agreements were in place.

Note that this exception determination is only made for purposes of section 46.114(b)(2)(ii) - namely, for determining whether certain cooperative research may be excepted from the single IRB mandate. This exception determination does not prevent, nor should it be viewed as discouraging, the voluntary use of a single IRB in cooperative research subject to the 2018 Requirements that would fall into the above category. HHS fully expects use of single IRB where possible even during the COVID-19 public health emergency. Approved use of the flexibilities provided under this exception do not change any other obligations under the 2018 Requirements.
NIH Exception Request Content Requirements

- Justification as to why the study meets the exception criteria defined by OHRP
- Include the name of the site(s) for which an IRB other than the single IRB of record is proposed to review the study for the site(s).

Pre-award Exception Requests (for Federal Contracts follow instruction outlined in the RFP)

- Provide exception request and required justification in the Other Attachments section of the Research & Related Other Project Information form in the grant application
- Name the PDF document ?SIRBexceptionrequest.pdf and follow instruction in the NIH Application Guide
- Proposed budget in the application or contract proposal should reflect all necessary single IRB costs. Applicants and offerors should not assume that an exception will be granted when considering costs to include in the budget

Post-Award Exception Requests

- Submit a prior approval request in writing to the Grants Management Officer (GMO) for grants or to the Contracting Officer (CO) for contracts
- Requests must include appropriate justification as to why the study meets the exception criteria defined by OHRP
- Requests must be submitted no later than 30 days prior to the proposed change
- Requests must be signed by the Authorized Organization Representative (AOR), please work with your assigned OSR Staff to expedite these requests

Please direct all inquiries to: SingleIRBPolicy@mail.nih.gov

NOTICE OF TEMPORARY EXTENSION OF ELIGIBILITY FOR THE BRAIN INITIATIVE DIVERSITY K99/R00 CAREER TRANSITION AWARD DURING THE COVID-19 PANDEMIC: NOT-NS-21-004 announces that the BRAIN Initiative will be providing up to a two-receipt cycle extension of the eligibility for prospective applicants that meet the requirements to apply for the BRAIN Initiative Advanced Postdoctoral Career Transition Award to Promote Diversity (K99/R00).

- For individuals whose eligibility would normally end with the October/November due dates, the temporary extension would allow them to apply in February/March 2021 or June/July 2021.
- For individuals whose eligibility would normally end with the February/March 2021 due dates, the temporary extension would allow them to apply in June/July 2021 or October/November 2021.

NIH, AHRQ, and NIOSH will accept a one-page update with preliminary data as post-submission materials for applications submitted under all activity codes, ONLY if the FOA used for submission allowed preliminary data in the application.

Contacts for inquiries are listed in NOT-OD-20-179.

REQUIREMENT FOR TRAINEE DIVERSITY REPORT TO BE SUBMITTED ELECTRONICALLY FOR INSTITUTIONAL RESEARCH TRAINING, CAREER DEVELOPMENT, AND RESEARCH EDUCATION AWARDS BEGINNING IN EARLY FY 2021: NOT-OD-20-178 announces the requirement for recipients of institutional research training, career development, and research education awards to submit the Trainee Diversity Report, required with the Research Performance Progress Report (RPPR), Interim Final RPPR, and Final RPPR, electronically using a new option that will be available in the xTrain module beginning October 30, 2020.

NIH will integrate the Trainee Diversity Report form into the xTrain module of the eRA Commons. The electronically generated report will leverage demographic data from appointed trainees? Personal Profiles in the eRA Commons, minimizing the need for manual data entry.

Beginning October 30, 2020, the following activity codes will require an electronically generated Trainee Diversity Report with the RPPR, I-RPPR, and F-RPPR submission:

T15, T32, T34, T35, T37, T42, T90, TL1, TL4, TU2, K12/KL2, KM1, R25, R38, R90, RL5, RL9

For the specified activity codes, eRA will check RPPRs for an electronically generated Trainee Diversity Report. If the electronically generated report is missing, the RPPR will not be accepted. Please see NOT-OD-20-178 for special provision for K12/KL2, R25, KM1 and R90 activity codes.

September 2020

REMEMBER: NIH POLICY ON USE OF HYPERTEXT IN NIH GRANT APPLICATIONS: NOT-OD-20-174 reminds the NIH applicants about the guidance that restricts the use of hypertext (e.g. hyperlinks and URLs) in NIH grant applications.
Use of unallowable hyperlinks and URLs raise the following concerns:

- **Reviewer Confidentiality:** Sophisticated web-based tracking systems may allow identification of reviewers who attempt to access the link.
- **Overstuffing:** All materials required for review must be contained within the page limits of the application. Linking out to additional information may exceed the content limitations of the application.
- **Review Consistency:** Some reviewers may consider hyperlinked materials while others may not, which may create inconsistency among reviewers.
- **Malware:** The possibility exists for malware or other breaches to occur on the reviewer’s computer and/or system.

Applicants are reminded of the guidance in the SF424 (R&R) Application Guide:

- Hyperlinks and URLs are only allowed if specified in the funding opportunity announcement (FOA) and form field instructions where it is typically limited to citing relevant publications in biosketches and publication lists.
- It is highly unlikely for a FOA to allow links in Specific Aims, Research Strategy, and other page-limited attachments.
- Hyperlinks and URLs may not be used to provide information necessary to application review.
- Reviewers are instructed against viewing linked sites and are cautioned that they should not directly access a website unless the link was specifically requested in the application instructions.
- When allowed, the actual URL text should appear on the page rather than being hidden behind a word or phrase.
- Applications that do not follow this guidance may be withdrawn from review and funding consideration.

Direct inquiries to GrantsPolicy@od.nih.gov.

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**NOTICE OF LIMITED AVAILABILITY OF RESEARCH NON-HUMAN PRIMATES:** NOT-OD-20-173 informs researchers who are conducting or planning to conduct COVID-19 studies involving non-human primates (NHPs), housed at the National Primate Research Centers (P51) or P40 facilities supported by ORIP, that access to and availability of NHPs will be limited and that specific programmatic priority settings will be implemented to minimize impact of the shortage.

All requestors seeking to utilize National Primate Research Center (NPRC) or ORIP-supported resources for COVID-19 studies must submit the information requested in the COVID-19 NHP Study Information Portal so that the urgency of the proposed research and its timeline for potential impact on public health can be assessed by the NIH COVID-19 Expert Panel (the ?Expert Panel?). The Expert Panel will make recommendations on the urgency for a study to be conducted and the timeline for public health impact, which will be conveyed to the Research Advisory Committee at each NPRC or the NHP Facility Director.

All information submitted via the portal will be treated as confidential and proprietary to the
submitter and will not be shared outside of NIH. NIH is only collecting information on studies that have secured funding, whether from government, private, or other sources.

Please see NOT-OD-20-173 for complete details.

Please direct all inquiries to: COVID19.NHPstudies@nih.gov

NOTICE OF CHANGE TO THE ELIGIBILITY OF PRINCIPAL INVESTIGATORS IN PAR-20-042: NCMRR EARLY CAREER RESEARCH AWARD (R03 CLINICAL TRIAL OPTIONAL):
NOT-HD-20-030 announces NICHD changes to the eligibility limit in PAR-20-042 to acknowledge productivity delays due to the COVID-19 pandemic and mitigation efforts.

Original eligibility limit states that the PD/PI must be no more than 7 years beyond the date that the first professional, advanced professional, or terminal academic degree was awarded, whichever is most recent. **This limit had been increased to 8 years.**

Please direct inquiries to Theresa Hayes Cruz, PhD at cruzth@mail.nih.gov.

August 2020

NOTICE TO EXTEND ELIGIBILITY FOR SUBMISSION OF NIAID K99/R00 PATHWAY TO INDEPENDENCE AWARD APPLICATIONS (AND PHYSICIAN SCIENTIST K99/R00) DUE TO COVID-RELATED DISRUPTIONS: NOT-AI-20-068 announces that the National Institute of Allergy and Infectious Diseases (NIAID) will extend the 48-month eligibility requirement for submission of K99/R00 applications due to COVID-related disruptions.

Subject to future updates, NIAID will provide a 2-receipt cycle extension (roughly 8 additional months) of eligibility for individuals who were eligible to apply for the K99/R00, under normal eligibility rules, between June/July 2020 and February/March 2021 (inclusive of these dates). In addition, those who normally would have been eligible to apply for the June/July 2021 receipt date will have a 1-receipt cycle (roughly 4 months) extension.

**Examples:**

- Individuals whose eligibility ended with the June/July 12, 2020 submission dates, the extension would allow them to apply for the K99/R00 in October/November 2020 or February/March 2021.
- Individuals whose eligibility would normally end with the February/March 12, 2021 due date, the extension would allow them to apply through the October/November 2021 due dates.
- Individuals whose eligibility would normally end with June/July 12, 2021 due date, the extension would allow them to apply through the October/November 2021 due dates.

**Please Note:**

- If the final due date at which an individual could apply was for the February/March 12, 2020 due dates, this individual is **no longer eligible** for the K99/R00.
• If an individual’s eligibility is good through the June/July 2020 due dates and the review of their February/March submission was not completed in time to be resubmitted at the June/July 2020 due date, the individual is **no longer eligible** to apply for the K99/R00 and may not receive an extension.

• An individual who has applied twice for the K99/R00 is **not eligible** for an extension.

**Reminder:**

• K99 applicants who wish to receive non-COVID-related extensions, (e.g. for childbirth, adoption, family leave, etc.) must continue to provide relevant documentation.

Please direct inquiries to the AITrainingHelpDesk@niaid.nih.gov

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**NOTICE OF TEMPORARY EXTENSION OF ELIGIBILITY FOR THE NIDCR DUAL DEGREE DENTIST SCIENTIST PATHWAY TO INDEPENDENCE AWARD (K99/R00):** NOT-DE-20-031 announces that the National Institute of Dental and Craniofacial Research (NIDCR) will provide up to a two-receipt cycle extension (roughly 8 months) of eligibility to applicants for the Dual Degree Dentist Scientist Pathway to Independence Award (K99/R00) due to disruptions caused by the COVID-19 pandemic.

Applicants must have both a clinical dental (DDS/DMD) and research (PhD) degree and no more than 4 years of postdoctoral research experience since their most recent doctoral degree to meet submission requirements for this award during the period covered by the June/July 2020 due dates through the February/March 2021 due dates.

**Examples:**

• If an individual’s eligibility ended with the June/July 12, 2020 due dates, the extension would allow them to submit for the October/November 2020 or February/March 2021 due dates.

• If an individual’s eligibility ends with the October/November 12, 2020 due dates, the extension will allow them to apply for the February/March 2021 or the June/July 2021 due dates.

• If an individual’s eligibility will end with the February/March 12, 2021 due dates the extension will allow them to apply in June/July 2021 or October/November 2021.

**Reminders:**

• Individuals applying for the NIH Pathway to Independence (Parent K99/R00) should refer to NOT-OD-20-158.

• K99 applicants who wish to receive non-COVID-related extensions, (e.g. for childbirth, adoption, family leave, etc.) must continue to provide relevant documentation.

Please direct inquiries to Leslie A. Frieden, PhD at leslie.frieden@nih.gov.

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**EXTENDING THE SPECIAL EXCEPTION TO THE NIH/AHRQ/NIOSH POST-SUBMISSION MATERIAL POLICY DURING THE COVID-19 PANDEMIC:** NOT-OD-20-163 extends the special exception for post-submission materials announced in NOT-OD-20-123, for the May
2021 Council round. Beginning with applications submitted for the September 25, 2020 due date. NIH, AHRQ, and NIOSH will accept a one-page update with preliminary data for applications under all activity codes, ONLY if the Funding Opportunity Announcement (FOA) used for the submission allowed for preliminary data in the application.

All materials listed as acceptable in NOT-OD-19-083 and any preliminary data (per this exception) must be submitted no later than 30 days prior to the study section meeting.

Post-submission materials will not be accepted for those applications that undergo expedited review, such as emergency competitive revisions and urgent competitive revisions.

Please see NOT-OD-20-163 for details and where to direct inquiries.

TEMPORARY EXTENSION OF ELIGIBILITY FOR THE NIH K99/R00 PATHWAY TO INDEPENDENCE AWARD DURING THE COVID-19 PANDEMIC: NOT-OD-20-158 announces that NIH will be providing up to a two-receipt cycle extension (roughly eight additional months) of eligibility for prospective K99/R00 applicants who have/will reach the 4 year eligibility threshold while experiencing delays in submitting an application due to disruptions caused by the COVID-19 pandemic. The extension will apply only to eligible applicants submitting new and resubmission K99/R00 applications under parent announcements PA-20-187, PA-20-188, and PA-20-189, which will be automatically accepted by NIH. This extension is temporary and subject to change.

Examples:

- Individuals whose eligibility ended with the June/July 12, 2020 due dates, the temporary extension would allow them to apply for the K99/R00 in October/November 2020 or February/March 2021.
- Individuals whose eligibility would normally end with October/November 12, 2020 due dates, the temporary extension would allow them to apply in February/March 2021 or June/July 2021.
- Individuals whose eligibility would normally end with February/March 12, 2021 due dates, the temporary extension would allow them to apply in June/July 2021 or October/November 2021.

K99 applicants who wish to receive non-COVID-related extensions, (e.g. for childbirth, adoption, family leave, etc.) must continue to provide relevant documentation.

Please direct inquiries to NIHTrain@mail.nih.gov.

NEW ONLINE TRAINING MODULE FOR THE VERTEBRATE ANIMALS SECTION (VAS) OF NIH APPLICATIONS: NOT-OD-16-006 announced and described the changes implemented to simplify and remove redundancies in the Vertebrate Animals Section (VAS) for NIH grant, cooperative agreement, and contract applications. The Office of Laboratory Animal Welfare (OLAW) recently released an online training module for the VAS that can be completed in 20-30 minutes. The module provides:

- An overview of the requirements
A checklist for applicants and reviewers
Detailed instructions

The VAS Training Module and more details can be found on the OLAW webpage for the Vertebrate Animals Section (VAS).

Please direct inquiries to OSRInfo.ucsf.edu.

July 2020

UPCOMING CHANGES TO THE NOTICE OF AWARD (NoA) BEGINNING OCTOBER 1, 2020: NOT-OD-20-155 announces the upcoming changes to the format of the NIH Notice of Award (NoA). The Department of Health and Human Services (HHS) has developed a standard Page One to be used across HHS effective October 1, 2020.

The majority of the change will affect the appearance of Page One of the NoA. There will be four sections (see the NOT-OD-20-155 for details):

- Award Data
- Recipient Information
- Federal Agency Information
- Federal Award Information

NIH NoAs will continue to use the following sections, following Page One:

- Section I ? Award Data
- Section II ? Payment Information
- Section III/IV ? Terms and Conditions of Award

In the coming weeks, additional information and samples will be posted on the View Notice of Award webpage.

Please direct inquiries to OSRInfo.ucsf.edu.


After October 1, 2020, grant applications and contract proposals must be consistent with the 2020 Guidelines. Grant applications must continue to follow application form instructions in the How to Apply ? Application Guide (see the Notice for complete details).

Please direct inquiries to: OLAW@mail.nih.gov.
GUIDANCE FOR APPLICANTS PREPARING APPLICATIONS FOR THE FALL 2020 DUE DATES DURING THE COVID-19 PANDEMIC: NOT-OD-20-122 provides guidance for investigators and institutions preparing NIH grant applications for the May 2021 Council round, beginning with applications for the September 25, 2020 due date.

- NIH grant applications should not include contingency plans that outline steps needed to recover from temporary emergency situations or institutional return-to-the-workplace plans resulting from the COVID-19 pandemic.
- Contingency plans will not be considered in peer review.
- Reviewers will be instructed to disregard situations due to the COVID-19 pandemic, e.g. temporary declines in productivity, availability of key personnel, proposed patient populations, animal facility shutdowns, etc.
- Reviewers will continue to assume that temporary emergency problems arising from the COVID-19 pandemic will be resolved and complications related to COVID-19 should not affect their scores.

If needed, COVID-19 contingency plans will be requested and carefully considered by NIH staff before funding.

Please direct inquiries to ReviewPolicyOfficer@mail.nih.gov.

NIH EXTRAMURAL LOAN REPAYMENT PROGRAMS - 2020:
The NIH Loan Repayment Programs (LRPs) are a set of programs established by Congress and designed to recruit and retain highly qualified health professionals into biomedical or biobehavioral research careers. LRP repays up to $50,000 annually of a researcher’s qualified educational debt in return for a commitment to engage in NIH mission-relevant research at a domestic, non-profit, or government entity. LRP applications are accepted annually from September 1 through November 20. LRP applications are not grant applications and can be submitted by the applicant’s department. Below are LRP application requests released this week:

- NOT-OD-20-133 Extramural Loan Repayment Program for Clinical Researchers (LRP-CR)
- NOT-OD-20-134 Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (LRP-IDB)
- NOT-OD-20-135 Extramural Loan Repayment Program for Contraception and Infertility Research (LRP-CIR)
- NOT-OD-20-136 Extramural Loan Repayment Program for Pediatric Research (LRP-PR)
- NOT-OD-20-137 Extramural Loan Repayment Program for Health Disparities Research (LRP-HDR)

NOTICE OF REQUIREMENT FOR ELECTRONIC SUBMISSION OF ALL ADMINISTRATIVE SUPPLEMENTS: NOT-OD-20-128
announces three updates to NIH administrative supplement submission policies.

1. Effective immediately, NIH will begin accepting administrative supplement applications for multi-project awards electronically using the single-project application form package for research grants and cooperative agreements (e.g. Competition ID = FORMS-F-ADMSUPP-RESEARCH).

2. Effective July 25, 2020, the streamlined submission method through the eRA Commons will be discontinued.

3. Effective July 25, 2020, all supplement applications to existing single and multi-project awards must be submitted electronically through Grants.gov using NIH ASSIST, Grants.gov Workspace, or institutional system-to-system (S2S) solutions (e.g. eProposal).

NIH will reissue parent administrative supplement announcements PA-18-591 and PA-18-592. Any in-progress applications submitted through Grants.gov using these announcements must be completed by July 24, 2020. Applications submitted on or after July 25, 2020 must use the reissued announcements.

See the Notice for complete details.

UPCOMING MANDATORY SUBMISSION OF THE FEDERAL FINANCIAL REPORT (FFR) IN THE PAYMENT MANAGEMENT SYSTEM BEGINNING JANUARY 1, 2021: NOT-OD-20-127 informs NIH recipients that beginning January 1, 2021, they will be required to submit the SF-425 Federal Financial Report (FFR) in the Payment Management System (PMS) as opposed to the eRA Commons/FFR Module.

FFRs submitted prior to January 1, 2021 will use the eRA Commons/FFR Module based on the previous requirements set forth by the agency (NIH Grants Policy Statement 8.4.1.5.2).

This change will not affect FFR due dates as outlined in the NIH Grants Policy Statement 8.4.1.5.2 and 8.6.1.

Please see the Notice for complete details.

GUIDANCE REGARDING CHANGE IN STATUS, INCLUDING ABSENCE OF PD/PI AND OTHER KEY PERSONNEL NAMED IN THE NOTICE OF AWARD: NOT-OD-20-124 serves to clarify NIH expectations regarding administrative requirements for change in status and change of recipient organization.

- NIH recipients are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research and
- Prior approval requests regarding change in the status, of the PD/PI and Key Personnel named in the Notice of Award (NoA), and change of recipient organization should include mention as to whether the change is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions)
Requests for prior approval of any additional or substitute PD/Pis or Senior/Key Personnel named in the NoA, or change from a multiple PD/PI model to a single PD/PI model, must be submitted promptly, and must be accompanied by a strong scientific justification related to the scientific project, including:
- Any proposed changes in scope
- The biographical sketch of any new individuals proposed and other sources of support
- Any budget changes resulting from the proposed change.
- A new or revised Leadership Plan is required if the request is to change from a single PD/PI model to a multiple PD/PI model, or to change the number or makeup of the PD/Pis on a multiple PD/PI award.
- The Commons ID must be provided for any new PD/Pis.

NIH expects both relinquishing and applicant organizations to disclose whether a Change of Recipient Organization is occurring within the context of an ongoing or recent investigation of misconduct of any kind, including but not limited to professional misconduct or research misconduct.

Affected sections of the Grants Policy Statement are 8.1.2.6 Change in Status and 8.1.2.7 Change of Recipient Organization.

Please direct inquiries to GrantsPolicy@nih.gov.

SPECIAL EXCEPTION TO THE NIH/AHRQ/NIOSH POST-SUBMISSION MATERIAL POLICY DURING THE COVID-19 PANDEMIC: NOT-OD-20-123 announces that NIH, AHRQ, and NIOSH understand that the emergency declaration related to Coronavirus Disease 2019 (COVID-19) can adversely affect the ability of many applicants to generate preliminary data in time for the submission of their grant applications.

This Notice provides an exception to the policy for post-submission materials (NOT-OD-19-083 ) for applications submitted for the January 2021 council (beginning with applications submitted for the May 25, 2020 due date for Fall 2020 review meetings). NIH, AHRQ, and NIOSH will accept a one-page update with preliminary data as post-submission materials for applications submitted under all activity codes, ONLY if the Funding Opportunity Announcement (FOA) used for submission allowed preliminary data in the application. One page of preliminary data will be accepted for single component applications or for each component of a multi-component application.

Please see the Notice for complete details and where to submit inquiries.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY DATA MANAGEMENT PLAN POLICY: NOT-HS-20-011 announces that effective immediately all new competing grants and research contract proposals to the Agency for Healthcare Research and Quality (AHRQ) are required to include a Data Management Plan (DMP) for managing, storing and disseminating primary data, samples, physical collections, and other supporting materials created or gathered in the course of research funded by AHRQ. This policy applies to AHRQ intramural
researchers and extramural recipients of AHRQ grants and research contracts unless otherwise specified in the funding opportunity announcement (FOA) or request for proposals (RFP).

The DMP should be submitted under the Resource Sharing Plan section of a grant application or as an appendix for a research contract proposal. The plan will not count toward the page limit for grant applications or contract proposals.

AHRQ recognizes the time and costs required to prepare data for sharing. AHRQ will allow the inclusion of appropriate costs for data management and access in grant applications and research contract proposals. The appropriateness of requested funding levels for DMPs will be assessed on a case-by-case basis through scientific peer review and by program and grants or contracts management staff. Requests can be made only for costs that will be incurred while the award is active. Applicants must categorize these costs as either direct costs or as indirect costs as appropriate in accordance with federal and institutional policy.

Award recipients are expected to include updates on publicly released data in digital format resulting from their research in quarterly reports (if applicable), annual progress reports, and final reports, and will develop mechanisms to monitor such compliance.

- Annual or quarterly reports should provide information on the progress of data management and public release of research products (could include citations of relevant publications, conference proceedings, and descriptions of other types of data sharing and dissemination).
- Final reports are required to include a discussion on execution and any updating of the original DMP included in the original grant applications or research contract proposals.

Please see the Notice for complete details.

May 2020

COVID-related notices or communications have been posted on the OSR COVID-19 webpages.

April 2020

FLEXIBILITIES AVAILABLE TO AHRQ APPLICANTS AND RECIPIENTS IMPACTED BY COVID-19: NOT-HS-20-010 announces flexibilities allowed by the Agency for Healthcare Research & Quality (AHRQ) to applicants and recipients impacted by COVID-19 due to loss of operation. A summary of flexibilities in the following areas are posted on the OSR COVID-19 webpage under Sponsor Specific Guidance:

- Late Application Submission Policy
- Pre-award Costs
- No-cost Extension
- Delays in Research Progress/Reporting
Expenditures of Award Funds for Salaries, Stipends, and Other Project Activities
Travel Costs

As the COVID-19 national emergency continues, recipients may identify the need for other cost related flexibilities. AHRQ will consider such requests on a case-by-case basis. Please work with your OSR Staff to contact the Grants Management Specialist named on the most recent Notice of Award.

Please direct inquiries to OSRInfo@ucsf.edu.

REMINDER ? CHANGES TO FORMS & INSTRUCTIONS FOR RESEARCH TRAINING, FELLOWSHIP, & CAREER DEVELOPMENT AWARD APPLICATIONS DUE ON OR AFTER MAY 25, 2020: NOT-OD-20-090 reminds the biomedical and health services research communities of changes to application forms and instructions for research training, fellowship, and career development award applications due on or after May 25, 2020. Changes to the following areas are described for:

- Training in techniques for rigorous and reproducible research
- Training in relevant quantitative and data science approaches
- Training data tables
- Progress reporting for renewal applications
- Required letters for applications to selected programs

Applicants are urged to consult FORMS-F Application Guides for detailed guidance. Research training data table modifications are expected to be incorporated into the xTRACT system on April 24, 2020. Users who have prepared data tables in xTRACT will need to update selected data entry fields prior to finalizing their research training datasets.

Please direct inquiries to NIHTrain@mail.nih.gov.

March 2020

REMINDER: FORMS-F GRANT APPLICATION FORMS & INSTRUCTIONS MUST BE USED FOR DUE DATES ON OR AFTER MAY 25, 2020 ? NEW GRANT APPLICATION INSTRUCTIONS NOW AVAILABLE: NOT-OD-20-077 reminds NIH and AHRQ applicants that FORMS-F application packages must be used for due dates on or after May 25, 2020 and FORMS-E application packages for due dates on or before May 24, 2020.

Applicants are encouraged to submit early to work through any unforeseen issues. Applications submitted using the incorrect application package for their due date may be withdrawn and removed from funding consideration.

The notice also provides the following updates:

- FORMS-F instructions are now posted on the How to Apply ? Application Guide page
- Significant changes to forms and instructions are listed at https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.120-significant-changes.htm
FORMS-F application packages are being posted to active Funding Opportunity Announcements (expected completion by March 25, 2020)

Parent announcements will be reissued with FORMS-F for due dates on or after May 25, 2020 (FORMS-F application packages will not be added to existing parent applications)

Please send questions and concerns to the NIH Office of Policy for Extramural Research Administration (OPERA) Systems Policy Branch at OPERAsystemspolicy@nih.gov

NIH LATE APPLICATION POLICY DUE TO PUBLIC HEALTH EMERGENCY FOR U.S. FOR 2019 NOVEL CORONAVIRUS (COVID-19): NOT-OD-20-082 reiterates the late application policy that NIH will consider accepting late applications on a case by case basis when delays occur because the applicant or recipient organization is officially closed or unable to submit grant applications due to the effects of COVIS-19, in accordance with NIH Grants Policy Statement, Section 2.3.9, under the following circumstances:

- Institutions must submit applications or reports as soon as possible after reopening or resuming operations so that the time to submit does not exceed the number of days the institution was officially closed or unable to submit
- A cover letter must accompany the application with enough detail about the delay so that NIH staff can make a determination whether circumstances justify accepting the application late.
- Institutions need not request advance permission to submit late due to this declared emergency

Please see NIH Grants Policy Statement, Section 2.3.9 for the complete policy on late application submission.

GENERAL FREQUENTLY ASKED QUESTIONS (FAQs) FOR PROPOSAL SUBMISSION & AWARD MANAGEMENT RELATED TO COVID-19: NOT-OD-20-083 provides high-level questions associated with proposal submission and award management that may arise in relation to COVID-19. As COVID-19 and associated impacts continue to evolve, applicants and award recipients are encouraged to monitor NIH weekly notices.

FLEXIBILITIES AVAILABLE TO APPLICANTS AND RECIPIENTS OF FEDERAL FINANCIAL ASSISTANCE AFFECTED BY COVID-19: NOT-OD-20-086 informs the research community of short-term administrative flexibilities identified that apply to NIH applicants and recipients conducting research activities related to or affected by COVID-19.

Some of the flexibilities include, but are not limited to:

- Pre-award costs
- Prior approvals waived for carryover of unobligated funds, no-cost extension of the final year up to 12 months, and rebudgeting
- Salaries
- Travel
- Delays in reporting (will still delay awards)
Extension of closeout

Please see NOT-OD-20-086 for the complete list and details.

GUIDANCE FOR NIH-FUNDED CLINICAL TRIALS AND HUMAN SUBJECTS STUDIES AFFECTED BY COVID-19: NOT-OD-20-087 provides guidance outlining flexibilities available to recipients conducting NIH-funded clinical trials and human subject studies that are impacted by the declared public health emergency for COVID-19.

At this time, NIH is encouraging recipients to consult with their IRBs about potential measures to protect participants and research staff. For example:

- Limit study visits to those needed for participant safety or coincident with clinical care
- Virtual study visits
- Flexibility for laboratory tests or imaging needed for safety monitoring to occur at local laboratories or clinics
- Canceling large gatherings of 50 or more
- Limiting or suspending unnecessary travel

Delays to ongoing research due to the effects of COVID-19:

- Recipients may submit late financial and progress reports
- Recipients may carryover unobligated balances on active grants without prior approval

Delays in research progress on NIH-funded clinical trials & human subjects research due to COVID-19:

- Recipients may extend the final budget period of approved projects on active grants one time for up to 12 months without prior approval (NIH GPS 8.1.1.3).
- Recipients should contact awarding Institute or Center (IC) and provide details on the effect of COVID-19 to request additional extensions including mid-project period extensions.
- NIH will allow clinical trial and other human subjects research to extend beyond the typical 7-year timeframe for extensions related to COVID-19.

Unanticipated costs incurred as a result of COVID-19:

- If unobligated balances are not available to rebudget, recipients may request administrative supplements from the awarding IC (PA-18-591). ICs will make funding decisions on a case by case basis to support the safety and welfare of participants and sustain research during delays.
- Examples of unanticipated costs:
  - Arrangements for participants to receive care at local sites or virtually, rather than at the study site
  - Supply chain disruptions
  - Personnel disruptions due to illness or closure of facilities
  - Additional lab testing (e.g. for COVID-19)
  - Increased transportation costs
Additional NIH resources are posted on the COVID-19 Information for NIH Applicants and Recipients webpage.

UPDATE: NIH LATE APPLICATION POLICY DUE TO PUBLIC HEALTH EMERGENCY FOR U.S. FOR COVID-19: NOT-OD-20-091 informs the research community that NIH will accommodate late applications (prior permission and cover letter not required) for due dates between March 9, 2020 and May 1 through May 1, 2020. Due dates after May 1, including the May 7, 2020 AIDS and AIDS-Related Research due dates will remain as posted and follow the usual late application policies and will require a cover letter.

- This applies to all relevant FOAs including those that indicate no late applications will be accepted and pertains to applications reviewed by CSR.
- This does not supersede the IC’s discretion or authorities to make decisions on a case-by-case basis.

NIH will extend the expiration date of FOAs that expire prior to May 1 for 90 days to accommodate submission of late applications. Grants.gov will be adjusted to allow NIH to receive these applications.

- Reference letters for Fellowships and Career Development Award applications submitted during this interval will be accepted through May 1, 2020.
- Non-AIDS applications eligible for continuous submission will also be accepted through May 1, 2020.
- Some IC reviewed FOAs with due dates during this time may accept applications beyond the May 1, 2020 deadline. Applicants must first contact the IC to confirm that a later deadline is possible.

NIH cannot guarantee that all late applications submitted through May 1, 2020 will be reviewed in the council round to which they were submitted (e.g. August or October 2020). Further extension of this flexibility creates multiple challenges for conducting review and applications submitted after May 1, 2020 may not be reviewed until meetings for the January 2021 council round (e.g. October-November 2020).

February 2020

UPDATED GUIDANCE FOR VIDEOS SUBMITTED AS NIH APPLICATION MATERIALS: NOT-OD-20-061 provides an update of the video format instructions to maintain compatibility with NIH information systems.

Effective immediately, post-submission videos do not need to be embedded in PDF files. Acceptable formats are .mp4, .mov, .avi, and .wmv. File size limit remains at 25 MB.

Please remember that videos may only be submitted as post-submission materials and not embedded or linked from the application materials unless expressly instructed to do so in the FOA. The application cover letter must include information about the intent to submit the video as post submission materials. If this is not done the video will not be accepted (SF 424 R&R Application Instructions, Cover Letter Attachment).

If multiple videos are submitted for the same application the aggregate length cannot exceed
2 minutes for single-project applications and 5 minutes for multi-component applications.

See details and references in NOT-OD-20-061.

GUIDANCE ON SALARY LIMITATION FOR GRANTS AND COOPERATIVE AGREEMENTS FY20: NOT-OD-20-065 announces that effective January 5, 2020, the salary limitation for Executive Level II increased from $192,300 to $197,300. The salary limitation applies to NIH grants, cooperative agreements and extramural research and development contract awards.

The Office of Sponsored Research implemented the new higher cap on all new, renewal, and revision applications effective January 10, 2020. Existing awards may adopt the new salary cap through rebudgeting; however, no additional funds will be provided by the sponsor. For a historical record of the salary cap including effective dates, see the NIH Salary Cap Summary page.

University-specific guidance is available from Contracts and Grants Accounting.

NOTICE OF LEGISLATIVE MANDATES IN EFFECT FOR FY 2020: NOT-OD-20-066 provides the current requirements that limit or conditions the use of funds on NIH grants, cooperative agreements and contract awards for FY 2020. The following mandates remain in effect for FY 2020:

Division A, Title II ? Department of Health and Human Services

1. Salary Limitation
2. Gun Control
3. Anti-Lobbying
4. Acknowledgement of Federal Funding
5. Restriction on Abortions
6. Exceptions to Restrictions on Abortions
7. Ban on Funding Human Embryo Research
8. Limitation on Use of Funds for Promotion of Legalization of Controlled Substances
9. Restriction on Disclosure of Political Affiliation for Federal Scientific Advisory Committee Candidates
10. Dissemination of False or Misleading Information
11. Restriction of Pornography on Computer Networks
12. Restriction on Distribution of Sterile Needles

Please see NOT-OD-20-066 for complete details.
Ruth L. Kirschstein National Research Service Award (NRSA) Stipend, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2020: NOT-OD-20-070 establishes the stipend and other budgetary levels for FY 2020 Kirschstein-NRSA awards for undergraduate, predoc toral and postdoctoral trainees and fellows made on or after October 1, 2019, and supersedes NOT-OD-19-036.

Current stipend levels are to be used in the preparation of future competing and non-competing NRSA institutional training grant and individual fellowship applications. They will be administratively applied to all applications currently in the review process.

NRSA support is limited to 5 years (aggregate) for predoctoral trainees (6 years for dual-degree training) and 3 years (aggregate) for postdoctoral fellows. NIH provides 8 levels of postdoctoral stipends to accommodate individuals who complete other forms of health-related training prior to accepting a Kirschstein-NRSA supported position. Please note that the presence of 8 discrete levels of experience does not constitute an endorsement of extended periods of postdoctoral research training.

Other NIH Budgetary Notes:

1. FY 2020 Stipend for Predoctoral Fellows is $25,320.
2. Please see NOT-OD-20-070 for FY 2020 stipend levels for Postdoctoral trainees and fellows.
3. Calculation and thresholds for Tuition and Fees for all educational levels remain unchanged.
4. Training-related Expenses and Institutional Allowance for Postdoctoral trainees and fellows have been increased by $1,000 from $10,850 to $11,850.
5. Training-related Expenses and Institutional Allowance for Predoctoral trainees remain unchanged.

Please see NOT-OD-20-070 for complete details. University-specific guidance is forthcoming from UCSF Human Resources.

January 2020

NOTICE OF INFORMATION: NATIONAL DEATH INDEX LINKAGE ACCESS FOR NIH-SUPPORTED INVESTIGATORS: NOT-OD-20-057 announces that effective January 1, 2020 through an agreement between the National Institutes of Health (NIH) and the Centers for Disease Control (CDC) National Center for Health Statistics (NCHS), NIH-supported investigators, who are actively funded to conduct research that requires their research data be linked to the National Death Index (NDI), will be able to do so at no cost. To be covered by this agreement:

- NIH-supported investigators will continue to submit applications for NDI linkage per current NDI procedures
- NDI will review and approve or disapprove these applications
- The NIH-supported investigator must be the owner or steward of the research data to be linked to the NDI data file
- Investigators are limited to no more than 4 linkage requests in a calendar year
- Any linkages exceeding $100,000 will require NIH prior approval
ADDITIONAL GUIDANCE ON THE NIH POLICY ON THE USE OF A SINGLE INSTITUTIONAL REVIEW BOARD FOR MULTI-SITE RESEARCH: NOT-OD-20-058 informs the research community that effective January 20, 2020, Career Development (K) and Fellowship (F) awards that obtain initial IRB approval on or after January 20, 2020 are subject to the sIRB policy.

- Not included are studies for which NIH approved an exception from the sIRB policy before January 20, 2020. Exempted studies conducted under ongoing, non-competing awards (with receipt dates prior to January 25, 2018) that received an initial IRB approval before January 20, 2020 will continue to use multiple IRBs for the duration of the exemption but no later than the next competing award.
- K and F applications submitted on or after January 20, 2020 must follow revised instructions to complete the PHS Human Subjects and Clinical Trials Information form, Section 3.2 is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one site?
- K and F applications with studies approved on or after January 20, 2020 must select either ?Yes? or ?No? to indicate if it is a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site. ?N/A? may not be used.

Please direct questions regarding the additional policy guidance to the Office of Policy for Extramural Research Administration at grantscompliance@mail.nih.gov.

Questions regarding application forms and instructions should be directed to OPERAsystemspolicy@nih.gov.

UPDATE OF NIH CONTINUOUS SUBMISSION POLICY: CHANGE IN SUBMISSION DEADLINES AND END OF RECENT SUBSTANTIAL SERVICE OPTION: NOT-OD-20-060 supersedes NOT-OD-17-042 and NOT-OD-18-178 and alerts the research community of plans to discontinue the practice of granting one-year continuous submission status to reviewers with recent substantial review service. This change will be implemented as follows:

- Reviewers who are currently eligible for continuous submission through Recent Substantial Service will remain eligible through the end of their term on September 30, 2020
- Reviewers who earn eligibility for continuous submission through Recent Substantial Service during the period January 1, 2019 through June 30, 2020 will be eligible from August 1, 2020 through September 30, 2021
- No reviewers will subsequently earn or be granted continuous submission eligibility due to Recent Substantial Service

Effective February 8, 2020, the continuous submission deadlines for assignment to each council round have been moved back approximately one week (see Table 1 of NOT-OD-20-060). Continuous submission eligibility for appointed members of NIH committees and other terms/requirements of the overall policy have not changed with the exception of the deadlines.
for assignment to a given council round.

December 2019

NIH/AHRQ CHANGES TO POLICIES, INSTRUCTIONS, & FORMS FOR RESEARCH TRAINING GRANT, FELLOWSHIP, & CAREER DEVELOPMENT APPLICATIONS: NOT-OD-20-033 provides additional information on the planned changes to forms and instructions affecting research training grant, fellowship, and career development applications as announced in NOT-OD-20-026.

Planned changes will affect the following areas:

- Training in techniques for rigorous and reproducible research
- Training in relevant quantitative and data science approaches
- Progress reporting for renewal applications
- Research training data tables
- Extending requirements for rigor and transparency to fellowship research projects
- Required letters for applications to diversity-related programs

Please see NOT-OD-20-033 for a detailed listing of the changes.


Significant changes include, but are not limited to:

Section 2.3.5 Types of Funding Opportunity Announcements ? introduction of Notices of Special Interest (NOSI), which highlights a specific topic of interest and directs applicants to one or more active FOAs (usually a parent announcement) to apply for the initiative described.

Sections 2.3.7.11 and 4.1.14.2 Human Fetal Tissue from Elective Abortions (HFT) ? requires applicants proposing use of HFT to provide justification for the use of HFT, details regarding procurement and costs, and information about how HFT will be used. Reiteration of Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) specific requirements and prohibitions on research involving human fetal tissue and how HHS Regulations for Protection of Human Subjects 45 CFR 46.204 and 46.206 may be specifically relevant to such research. The requirement expects grantees and contractors to maintain appropriate documentation and required informed consent and acknowledgement that human fetal tissue was not received or transferred for valuable consideration.

Section 4.1.3.1 Policy on Dissemination of NIH-Funded Clinical Trial Information ? additional language requiring recipients of NIH funding who conduct non-exempt human subjects research that is subject to the revised Common Rule and is a clinical trial, as defined in 45
CFR 46.102(b), be aware that for each trial one IRB-approved consent form must be posted on a designated public federal website in accordance with 45 CFR 46.116(h) after recruitment closes and no later than 60 days after the last study visit by any subject as required by the protocol.

Section 4.1.27 Research Misconduct ? clarifies institution?s responsibilities in handling suspected or confirmed research misconduct in NIH-funded research and requirement for recipient and subrecipient institutions (foreign or domestic) to hold assurances with the HHS Office of Research Integrity (ORI) and follow procedures to communicate matters related to research misconduct proceedings to the NIH and ORI.

Section 4.2.1-12 Appropriations Mandates ? updated per 2019 Appropriations.

Section 11.3.13.1 Statement of Appointment ? the requirement of the Open Researcher and Contributor Identifiers (ORCID) is added to the appointment process for trainees, scholars, and participants supported by institutional research training, career development, and research education awards that require appointments through the xTrain system, including: T03, T15, T32, T34, T37, T42, T90/R90, TL1, TL4, TU2, K12/KL2, R25, R38, RL5, and RL9. Appointments will not be accepted unless an ORCID is linked to an individual?s Personal Profile in the eRA Commons.

Section 12.4.1 Application ? beginning with receipt dates on or after January 25, 2020, the requirement for an ORCID will be enforced at the time of application for individual fellowship (F series) and career development (K series) awards. eRA system validations will check for ORCIDs and applications will not be accepted unless an ORCID is linked to the PD/PI?s eRA Commons Personal Profile.

NIH will continue to publish interim grants policy changes, each change will be described including applicability, effective date and language to implement any changes as a term or condition of awards. Check back for future NIH UPDATES or the NEWS page for highlights on Notices that announce the implementation of future policy changes.

NIH OPERATES UNDER A CONTINUING RESOLUTION: NOT-OD-20-046 announces that the Department of Health and Human Services (HHS), including NIH, operates under the "Continuing Appropriations Act, 2020 and Health Extenders Act of 2019" (Public Law 116-69) signed by President Trump on November 21, 2019. The Continuing Resolution continues government operations through December 20, 2019 at 99.3209% of the FY 2019 enacted level.

Continuing the procedures under NOT-OD-19-131 and consistent with NIH practices during the Continuing Resolutions of FY 2006-2019, NIH will issue non-competing research awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments will be considered after FY 2020 appropriations are enacted.

All FY 2019 legislative mandates (NOT-OD-19-030), salary cap (NOT-OD-19-099), and predoctoral and postdoctoral stipend levels and tuition and fees (NOT-OD-19-036) remain in effect under this Continuing Resolution.
NEW NIH FORMS-F GRANT APPLICATION FORMS AND INSTRUCTIONS FOR APPLICATIONS DUE ON OR AFTER MAY 25, 2020: NOT-OD-20-026 announces NIH's plan to implement FORMS-F for grant applications due on or after May 25, 2020. Significant changes, e.g. new, deleted, or modified fields, will be made to the following application forms:

- PHS 398 Career Development Award Supplemental form
- PHS 398 Cover Page Supplement
- PHS Assignment Request form
- PHS Fellowship Supplemental form
- PHS Human Subjects and Clinical Trials Information
- SBIR/STTR Information

The Notice provides a High-level Summary of form changes and plan to transition from FORMS-E to FORMS-F (see NOT-OD-20-026 for details).

- FORMS-F will be available in new Funding Opportunity Announcement (FOA) application packages beginning February 25, 2020.
- New FOAs published prior to February 25, 2020 with initial due dates on or after May 25, 2020, will be posted without application forms until the updated forms become available. Application packages will be added to these FOAs by March 25, 2020.
- Previously issued active FOAs with submission due dates on or after May 25, 2020 (except Parent FOAs for administrative supplements, change of institution, and successor-in-interest), will be updated to add FORMS-F between February 25, 2020 and March 25, 2020.
- Administrative supplements, change of institution, and successor-in-interest parent announcements will be reissued with new FOA numbers and FORMS-F application packages and instructions on May 25, 2020. Applications started on or after May 25, must use the FORMS-F parent FOA. FORMS-E parent applications will remain available until June 25, 2020 allowing applicants one month to complete applications initiated using FORMS-E.
- Applications with due dates on or before May 24, 2020 must use FORMS-E
- Applications submitted under the NIH Late Policy 2-week consideration window that were submitted on or before May 24, 2020 must use FORMS-E
- Applications submitted by June 7, 2020 under the NIH Continuous Submission Policy for the May 7, 2020 AIDS due date must use FORMS-E

NIH plans to provide additional guidance and confirmation of implementation plans in early 2020.

NOTICE OF NIH’S INTEREST IN DIVERSITY: NOT-OD-20-031 supersedes NOT-OD-18-210 and provides updated diversity language for existing Funding Opportunity Announcements (FOAs) effective immediately. A noted significant change is the increase of criterion describing Disadvantaged Backgrouns. Please see the NOT-OD-20-031 for the current
Diversity Statement and updated criterion for Disadvantaged Backgrounds.

October 2019

NIH OPERATES UNDER A CONTINUING RESOLUTION: NOT-OD-20-003 announces that the Department of Health and Human Services (HHS), including NIH, operates under the "Continuing Appropriations Act, 2020 and Health Extenders Act of 2019" (Public Law 116-59) signed by President Trump on September 27, 2019. The Continuing Resolution continues government operations through November 21, 2019 at 99.3209% of the FY 2019 enacted level.

Continuing the procedures under NOT-OD-19-131 and consistent with NIH practices during the Continuing Resolutions of FY 2006-2019, NIH will issue non-competing research awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments will be considered after FY 2020 appropriations are enacted.

All FY 2019 legislative mandates (NOT-OD-19-030), salary cap (NOT-OD-19-099), and predoctoral and postdoctoral stipend levels and tuition and fees (NOT-OD-19-036) remain in effect under this Continuing Resolution.

GUIDANCE ON POSTING INFORMED CONSENT FORMS FOR AHRQ-FUNDED CLINICAL TRIALS: NOT-HS-19-023 provides guidance to AHRQ grant applicants on posting clinical trial informed consent forms, as required by the Final Rule. The HHS Office of Human Research Protections (OHRP) has identified ClinicalTrials.gov and Regulations.gov as the publicly available federal websites that will satisfy the consent form posting requirement.

To fulfill the requirement, recipients conducting AHRQ-funded clinical trials must submit one IRB-approved version of a consent form that has been used to enroll participants to either ClinicalTrials.gov or Regulations.gov. AHRQ recipients submitting informed consent forms to Regulations.gov should maintain a copy of their receipt and tracking number. Additional instructions are available at: https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/.

NIH EXTENDS EXLIGIBILITY WINDOW FOR PATHWAY TO INDEPENDENCE AWARDS (K99/R00): NOT-OD-20-011 serves to update the NIH extension policy on the eligibility window for PIs to apply for a K99/R00 Pathway to Independence Award.

Applicants for the K99 awards listed in the Notice must have no more than 4 years of postdoctoral research experience at the time of application. NIH considers requests for extension of the eligibility window on a case by case basis for reasons including medical concerns, disability, family care, extended periods of clinical training, natural disasters, and active duty military service.

Consistent with the NIH Extension Policy for Early Stage Investigator Status (ESI), effective immediately, NIH will approve an extension of one year for childbirth within the 4 year K99
eligibility window. Applicants must provide the child’s date of birth in the extension request justification submitted to IC program officials and/or scientific/research contacts listed in the FOA at least 12 weeks before submitting an application.

Recommended timeframe to submit extension requests for NIH Standard Due Dates:

- For February 12, requests were due during the week of November 18, 2019
- For March 12, requests should be received on or during the week of December 16, 2019
- For June 12, requests should be received on or during the week of March 16, 2020
- For July 12, requests should be received on or during the week of April 13, 2020
- For November 12, requests should be received on or during the week of August 17, 2020

September 2019

(no policy/procedure changes to post)

August 2019

NIH ANNOUNCES NEW CENTRALIZED NOTIFICATIONS FOR UNFUNDED APPLICATIONS: NOT-OD-19-133 introduces a new centralized, streamlined process for official NIH notification of unfunded applications.

- NIH will begin sending centralized, automated notifications of unfunded applications via the eRA system approximately 14 months after the application’s council date
- Notifications will be sent to the AOR/SO listed in the grant application and to the Notice of Award email address
- PIs and individuals with privileges to view Status will also be able to see if an unfunded application notification has been sent for a specific application in eRA Commons
- Funding decisions are specific to the applications included in the email and have no impact on subsequent submissions/resubmissions. There is no change to NIH’s application submission/resubmission policy as outlined in NOT-OD-18-197
- More information is available in the FAQs and the eRA Online Help webpage.

For technical assistance contact the eRA Service Desk.

Questions regarding this policy should be directed to OPERAsystemspolicy@nih.gov.

REPORT ON REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS: ANIMAL CARE AND USE IN RESEARCH: NOT-OD-19-136 announces the publication of Reducing Administrative Burden for Researchers: Animal Care and Use in Research, a report by NIH, USDA and FDA, resulting from Title II, Section 2034(d) of the 21st Century Cures Act (P.L. 114-255), enacted December 13, 2016. With regard to the regulations and policies for the care and use of laboratory animals in research, the Act instructs NIH to:

1. Seek the input of experts
2. Identify ways to ensure applicable regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative
3. Take steps to eliminate or reduce identified inconsistencies, overlap, or duplication
4. Take other actions, as appropriate to improve the coordination or regulations and policies with respect to research with laboratory animals

Implementation of the planned changes in policies, guidance, or regulations are expected to begin within the next two years to accommodate time needed for the public engagement processes.

**CLARIFYING COMPETING APPLICATION INSTRUCTIONS AND NOTICE OF PUBLICATION OF FAQs REGARDING PROPOSED USE OF HFT IN RESEARCH**: NOT-OD-19-137 provides clarification of competing application instructions referenced in NOT-OD-19-128 and announces the publication of Frequently Asked Questions (FAQs) regarding the proposed use of human fetal tissue from elective abortions in extramural applications for grants, cooperative agreements, and R&D contracts.

Clarifications from this Notice have been incorporated into guidance provided on the Human Fetal Tissue Research (HFT) - NIH Requirements page of the OSR website.

**SEXUAL AND GENDER MINORITY PROPOPULATIONS IN NIH-SUPPORTED RESEARCH**: NOT-OD-10-139 announces the revision of the definition of Sexual and Gender Minority (SGM) populations for research purposes at NIH. NIH is releasing the updated SGM definition to foster and expand inclusion of SGM individuals in health research. Please see the Notice for the full revised definition.

**July 2019**

**REQUIREMENT FOR ORCID iDs FOR INDIVIDUALS SUPPORTED BY RESEARCH TRAINING, FELLOWSHIP, RESEARCH EDUCATION, AND CAREER DEVELOPMENT AWARDS BEGINNING IN FY2020**: NOT-OD-19-109 announces the NIH/AHRQ/CDC requirement that individuals supported by research training, fellowship, research education, and career development awards, have an Open Researcher and Contributor Identifier (ORCID). The requirement will be implemented through the appointment process in the xTrain system commencing October 2019 and through the application process commencing with applications due January 25, 2020. Prospective applicants/appointees should follow the ORCID link from their Personal Profile in the eRA Commons to create and link or link the ORCID profile back to their eRA Commons Personal Profile. Please see NOT-OD-19-109 for details and specific activity codes affected.

**REMINDEERS OF NIH POLICIES ON OTHER SUPPORT AND ON POLICIES RELATED TO FINANCIAL CONFLICTS OF INTEREST AND FOREIGN COMPONENTS**: NOT-OD-19-114 reminds the extramural community of the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest. There is no change to the policies, the notice highlights several points summarized below:
Other Support:

Report all current projects and activities that involve senior/key personnel including all resources, funded or in-kind (e.g. lab space, equipment, supplies, employees) in support of and/or related to all of their research endeavors regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.

Foreign Component:

NIH requires recipients to determine if supported activities include a foreign component, defined as: the existence of any significant scientific element or segment of a project outside of the United States. For example:

- Work performed by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended
- Work performed by a researcher in a foreign location employed or paid for by a foreign organization, whether or not NIH grant funds are expended

Conflict of Interest

FCOI regulation specifies the minimum requirements for investigators to disclose to their institution their significant financial interests including financial interests received from a foreign entity.

For details and FAQs, please refer to NOT-OD-19-114.

NOTICE OF SYSTEM CHANGE AND PROCEDURE FOR REQUESTING AN EXTENSION TO EARLY STAGE INVESTIGATOR (ESI) STATUS: NOT-OD-19-125 serves to inform the extramural community of a change in the procedure for requesting an extension of early stage investigator (ESI) eligibility.

NIH defines ESI as a Program Director/Principal Investigator (PD/PI) who has completed their terminal research degree or post-graduate clinical training within the past 10 years who has not previously competed successfully as PD/PI for a substantial independent NIH research award. Some investigators may experience a lapse in their research/research training or less than full-time effort during the 10 year ESI period. NIH will consider requests for extension the ESI period for reasons such as family care responsibilities, medical concerns, disability, natural disasters, and active duty military service.

Effective August 22, 2019, the ESI Extension request button will be available in the Education section of the PD/PI?s Personal Profile in the eRA Commons. If selected, the system will provide text fields for justification of the extension request and the ability to upload PDFs of supporting documentation. If the request is approved after review by the ESI Extension Committee, a new ESI end date will appear in the Education section of the PD/PI?s Personal Profile. With the introduction of the new ESI Extension process, the prior Extension Request form and portal will be retired.

Note: other aspects of the ESI Extension process remain unchanged. See Early Stage Investigator FAQs
EXTENSION OF CERTAIN FLEXIBILITIES FOR PROSPECTIVE BASIC EXPERIMENTAL STUDIES WITH HUMAN PARTICIPANTS: NOT-OD-19-126 announces the delay of the enforcement of the NIH Policy on the Dissemination of NIH funded clinical trial information for Basic Experimental Studies with Human Subjects (BESH) through September 24, 2019.

Points to be considered:

NIH recognizes that registering and reporting results in ClinicalTrials.gov for BESH studies can pose a challenge

- NIH is extending the delayed enforcement of this reporting requirement originally announced in NOT-OD-18-212 through September 24, 2019
- This delayed enforcement is only applicable to BESH studies submitted to FOAs designated as "basic experimental studies with humans? in the title
- During this time NIH expects registration and results reporting using alternative publicly available platforms
- Plans for meeting NIH reporting expectations using an alternative platform should be described at the time of application in the Dissemination Plan Attachment
- Funded awardees for applications to BESH-specific FOAs who are not using ClinicalTrials.gov, should provide in their annual progress reports the unique identifier assigned by the alternate platform (if available) and a link to the report (e.g. page or record) in the alternate platform

NOTE:

- NIH will not extend leniency for applications submitted to incorrect FOAs based on the study-type designation.
- Commencing with due dates on or after September 25, 2019, applications submitted to an incorrect FOA based on study-type designation (e.g. clinical trial submitted to a "clinical trial not allowed? FOA) may be withdrawn.
- See clinical trial-specific FAQs.

CHANGES TO NIH REQUIREMENTS REGARDING PROPOSED HUMAN FETAL TISSUE RESEARCH: NOT-OD-19-128 announces the upcoming HHS requirements and review considerations for NIH research applications (e.g. grants, cooperative agreements, and R&D contracts) that involve the proposed use of human fetal tissue obtained from elective abortions (HFT). Changes will apply to competing grant applications submitted for due dates on or after September 25, 2019 and in response to R&D contract solicitations published on or after September 25, 2019. Information on the changes are posted on the Human Fetal Tissue Research (HFT) - NIH Requirements page of the OSR website.
NIH EXPANDING USAGE OF NOTICES OF SPECIAL INTEREST: NOT-OD-19-107 alerts the extramural community that NIH has been updating the format of the Weekly NIH Funding Opportunities and Notices to include a special section highlighting Notices of Special Interest (NOSI) since early May.

NOSIs highlight a specific topic of interest, e.g. a specific area of research or program and direct applicants to use one or more active Funding Opportunity Announcements (FOAs), often parent announcements, for submission of applications for the initiative described in the NOSI. These Notices of Special Interest will replace the non-parent announcements (PAs) that have standard submission and review requirements, which will be phased-out to streamline how NIH announces areas of interest.

NIH will continue to post full FOAs for Requests for Applications (RFAs), program announcements with special receipt/referral/review considerations (PARs), and program announcements with set-aside funds (PASs).

Applicants must always follow guidance found in the FOA used for submission and the How to Apply? Application Guide as well as any additional submission guidance described in the NOSI. Applicants are encouraged to contact the Program Official listed on the NOSI for clarification prior the submission. Applicants will be required to include the notice number in the Agency Routing Identifier field (4b) of the SF424 (R&R) form at the time of submission.

For more information, please visit the Applying Electronically FAQs, Section II Funding Opportunities.

NOTICE OF INTENT TO PUBLISH FUNDING OPPORTUNITY ANNOUNCEMENT TO DEVELOP STATE-LEVEL CAPACITY FOR DISSEMINATION AND IMPLEMENTATION OF PATIENT-CENTERED OUTCOMES RESEARCH INTO PRIMARY CARE: NOT-HS-19-019 announces that the Agency for Healthcare Research and Quality (AHRQ) intends to publish a Request for Application (RFA) to disseminate and implement patient-centered outcome research (PCOR) findings into primary care practices, with a focus on improving heart health and developing sustainable, primary care quality improvement (QI) capacity within states.

Additionally, this notice is intended to inform potential applicants of the expectation to establish multi-organizational partnerships that will support AHRQ?s role to disseminate and implement patient-centered outcomes research.

See NOT-HS-19-019 for more information.


NIMH has established an informatics infrastructure to enable responsible sharing and use of data collected from and about human subjects by the research community. This data archive
provides the infrastructure and support to enable mental health researchers to deposit their data and share that data with the research community. Consistent with the authorities under the 21st Century Cures Act, researchers funded by NIMH are required to deposit all raw and analyzed data (including, but not limited to, clinical, genomic, imaging, and phenotypic data) from experiments involving human subjects into this infrastructure.

This policy applies to all grant applications that involve human subject research submitted to NIMH and FOAs that NIMH participates in after January 1, 2020. This policy does not apply to the following types of applications:

- Fellowship (F)
- Research Career Development (K)
- Training (T)
- Small Business (SBIR/STTR)
- Small Grants (R03)
- Education (R25)
- Awards related to AIDS applications

The NIMH Data Sharing Policy does not supersede the general NIH Genomic Data Sharing Policy (NOT-OD-14-124); however, it does mandate that the NIMH Data Archive (NDA) serve as the repository for genomic data resulting from NIMH funded research unless NIH agrees to a different data archive during the negotiation of the award terms and conditions. Awardees who are measuring human genomic data will register with dbGaP. After registration, all data (including, but not limited to, clinical, genomic, imaging, and phenotypic data) will be deposited in the NDA and a link to the NDA collection will be added to the dbGaP registration.

Computational credits may be applied for to facilitate the re-analysis of aggregated data in the single cloud based data archive. All data associated with new projects at the NIMH Repository and Genomics Resource will be deposited in the NDA and then appropriate data will be transmitted to the NIMH Repository and Genomics Resource.

See NOT-MH-19-033 for details and additional information concerning Proposal and Post Award requirements.

May 2019

**NIGMS-managed HIV/AIDS RESEARCH PORTFOLIO TRANSITIONING TO NIAID:** NOT-GM-19-039 announces that effective immediately the National Institute of General Medical Sciences (NIGMS) is transferring its HIV/AIDS portfolio and associated funds to the National Institute of Allergy and Infectious Diseases (NIAID). This portfolio is funded from the HIV/AIDS budget, which is separate from the general NIGMS appropriations. The transfer will be coordinated by the NIH Office of AIDS Research (OAR).

Also, effective immediately, HIV/AIDS applications will no longer be accepted by NIGMS. This applies to FOAs issued by NIGMS, FOAs in which NIGMS participates, and NIH Parent Announcements.

Affected grantees will be contacted by NIGMS and NIAID staff with further information including Program Official and Grants Management Specialist assignment.
NOTICE OF INTENT TO PUBLISH A FUNDING OPPORTUNITY ANNOUNCEMENT FOR MAXIMIZING THE SCIENTIFIC VALUE OF EXISTING BIOSPECIMEN COLLECTIONS: NOT-OD-19-100 announces the intent of the NIH Tobacco Regulatory Science Program (TRSP), participating NIH ICs, and FDA Center for Tobacco Products (CTP) to promote a new initiative through an R21 Funding Opportunity Announcement (FOA). The FOA will solicit applications for research that will stimulate exploratory research relevant to the mission of the FDA CTP using existing (publicly available) biospecimen currently stored in repositories in the United States. This will include (but not limited to) collections associated with:

- Population Assessment of Tobacco and Health (PATH) Study
- National Health and Nutrition Examination Survey (NHANES)
- NHLBI Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC)
- Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial

**Short Turnaround:** Estimated FOA publication: August 1, 2019. First estimated Application due date: October 8, 2019.

Please see NOT-OD-19-100 for more information (please note estimated award and start dates).

NOTICE OF INTENT TO PUBLISH A FUNDING OPPORTUNITY ANNOUNCEMENT FOR SECONDARY ANALYSES OF EXISTING DATASETS OF TOBACCO USE AND HEALTH: NOT-OD-19-104 announces the intent of the NIH Tobacco Regulatory Science Program (TRSP), participating NIH ICs, and FDA Center for Tobacco Products (CTP) to promote a new initiative through an R21 Funding Opportunity Announcement (FOA). The FOA will solicit applications for research proposing innovative analysis of existing (publicly available) nationally representative U.S. cross-sectional and longitudinal data to investigate novel scientific ideas and/or to generate new models, systems, tools, methods, or technologies that have the potential for significant impact on biomedical or biobehavioral research in areas relevant to the FDA CTP.

**Short Turnaround:** Estimated FOA publication: August 1, 2019. First estimated Application due date: October 8, 2019.

Please see NOT-OD-19-104 for more information (please note estimated award and start dates).

REQUIRED USE OF THE xTRACT SYSTEM TO PREPARE DATA TABLES FOR TRAINING GRANT RPPRs IN FY 2020: NOT-OD-19-108 announces the requirement to use the xTRACT feature in the eRA Commons to prepare the required data tables for Research Performance Progress Reports (RPPRs) of institutional research training awards (T15, T32, T90/R90, and TL1). Beginning with RPPRs due October 1, 2019, system validations in the RPPR module will check to ensure that the uploaded data tables were created using xTRACT.
This requirement is not mandatory for new and renewal institutional research training awards (T15, T32, T90/R90, and TL1) in FY 2020; however, this may become a requirement in future years.

Other types of predoctoral, postdoctoral, and career-level training, education, and career development awards that currently use training data tables (T37, R25, K12/KL2) will not be required to use xTRACT to prepare tables for RPPRs in FY 2020. Recipients of these awards may wish to wait for future editions of xTRACT, which are expected to include features and instructions tailored to these specific programs.

Please see NOT-OD-19-108 for more information and specific details.

**GUIDANCE ON POSTING INFORMED CONSENT FORMS FOR NIH-FUNDED CLINICAL TRIALS:** NOT-OD-19-110 provides guidance regarding where to post clinical trial informed consent forms, as required by Section 46.116(h) of the Revised Common Rule (Subpart A of 45 CFR 46). The Revised Common Rule requires Federally-supported clinical trial (as defined in 45CFR46.102(b)) recipients to post an IRB-approved consent form on a public federal website designated for posting such consent forms.

NIH-funded recipients should submit IRB-approved English-language informed consent forms to ClinicalTrials.gov, following the instructions. Note: ClinicalTrials.gov does not support non-English documents.

NIH-funded recipients using only non-English informed consent forms to enroll participants should submit IRB-approved informed consent forms to Docket ID: HHS-OPHS-2018-0021 on the Regulations.gov website following the instructions provided by the Office for Human Research Protections.

See NOT-OD-19-110 for specific details.

**April 2019**

**NOTIFICATION OF CHANGE IN FEDERAL-WIDE UNIQUE ENTITY IDENTIFIER REQUIREMENTS:** NOT-OD-19-098 alerts NIH recipients of the Federal-wide transition from the Data Universal Numbering System (DUNS) to a new Government-owned Unique Entity Identifier (UEI). Effective December 2020, the System for Award Management (SAM) will be the central repository for the new SAM Managed Identifier (SAMMI) that will be incorporated into an institution’s SAM registration and will not impact the Institutional Profile File (IPF) generated by the eRA Commons. Details related to full implementation will be provided to agencies by December 2020.

**FY 2019 SALARY LIMITATION FOR GRANTS & COOPERATIVE AGREEMENTS:** NOT-OD-19-099 announces that effective January 6, 2019, the salary limitation for Executive Level II increased from $189,600 to $192,300. The salary limitation applies to NIH grants, cooperative agreements and extramural research and development contract awards. Existing
awards may adopt the new salary cap through rebudgeting; however, no additional funds will be provided by the sponsor. For a historical record of the salary cap including effective dates, see the NIH Salary Cap Summary page.

For University-specific guidance, please see the May 1, 2019 issue of the Controller's Newsletter.

**PUBLICATION OF REVISED NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES:** NOT-OD-19-106 announces the update of the NIH Guidelines to eliminate duplicative review and reporting requirements for human gene transfer protocols and describes NIH’s efforts to refocus the role of the NIH Recombinant DNA Advisory Committee (RAC) to be closer to its original mandate. The RAC has been renamed the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC). Please see the Notice for links to the final revisions.

**IMPORTANT NOTE:** Though NIH is streamlining individual protocol reporting requirements, robust oversight over gene therapy trials will continue as Federal and local oversight must continue to review and approve these trials before any research with human participants can be initiated.

**March 2019**

**NOTICE OF SPECIAL INTEREST: DEVELOPMENT OF CRYOGENIC OR OTHER LONG-TERM PRESERVATION AND REVIVAL METHODS FOR DROSOPHILA AND ZEBRAFISH GENETIC STOCKS:** NOT-OD-19-089 announces that the Office of Research Infrastructure Programs (ORIP) is interested in receiving grant applications for hypothesis-driven research projects through PA-19-056 NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) aimed at developing or improving cryogenic or other long-term preservation and revival methods of either Drosophila or zebrafish genetic stocks. Submission should indicate that they are in response to NOT-OD-19-089 in Field 4.b. on the SF 424 form. Interested Principal Investigators are encouraged to contact scientific contacts listed on the Notice to be advised on the appropriateness of the intended research project, competitiveness of a potential application, and alignment with ORIP’s program priorities. Please see the Notice for areas of high priority.

**CLARIFICATION REGARDING THE SUBMISSION OF BIOSKETCHES FOR PA-18-906:** NOT-OD-19-091 informs potential applicants using the eRA Commons for electronic-based submissions for PA-18-906 ?Research Supplements to Promote Diversity in Health-Related Research (Admin Supp-Clinical Trial Not Allowed)? that biosketch information for the candidate, any mentors, and any senior or key persons directly involved in the activities related to the supplement should be included. Biosketches for mentors and other senior and key persons should provide evidence of past mentoring experience.

**February 2019**

**REVISED GUIDANCE ON PROTECTING LIFE IN GLOBAL HEALTH ASSISTANCE:** NOT-OD-19-079
extends the applicability of the PLGHA policy (see NOT-OD-17-083) to the foreign non-governmental organizations (NGO) who are subrecipients (and their vendors) of US State or local governmental entities including state universities that receive US global health assistance from the President's Emergency Plan for AIDS Relief (PEPFAR). This requirement is effective January 3, 2019 for new awards and contracts and existing awards and contracts when amended to add new funding. The term will appear in Section IV: Special Terms and Conditions of the Notice of Award, below is an example of the term:

In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organizations (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award either as a prime recipient or subrecipient of a US NGO are strictly prohibited regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning or engaging in any activity that promotes abortion as a method of family planning or to provide financial support to any other foreign NGO that conducts such activities. Please refer to the NOT-OD-19-083 for full provisions of the requirement.

UPDATE TO NIH/AHRQ/NIOSH POLICY ON POST-SUBMISSION MATERIALS: NOT-OD-19-083 updates and clarifies the NIH, AHRQ, and NIOSH policy for post-submission materials for applications submitted on or after May 25, 2019.

What will change: for Training Grant (T series) applications submitted on or after May 25, 2019, a list of publications up to 3-pages will be accepted as post-submission materials. This replaces the former 1-page limit.

Clarifications: Preprints and Other Interim Research Products are not accepted as post-submission materials - they do not represent unforeseen events. Missing or corrected materials are not accepted unless specifically listed in this Notice as post-submission materials. Materials resulting from change of institution or change of PD/PI that occurs between application submission and peer review must first be sent to the SRO managing the review with a copy to the Division of Receipt and Referral (csrdrr@mail.nih.gov), and after review materials should be sent to the Grants Management Specialist listed in eRA Commons for that application.

See the Notice for Allowable Post-Submission Materials for All Applications.

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 hosted two Town Hall meetings on January 14-15, 2019, to discuss the changes to the federal policy for research involving Human Subjects. The sessions were live-streamed and recorded. See the HRPP Common Rule webpage for more information and resources.

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 allows for a single letter, on institutional letterhead, signed by a key institutional leader with institution-wide responsibilities. The letter provides the institution’s commitment to the planned program and includes its 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.

Please note, UC has a separate campus-wide Letter of Support for the prevention of harassment and other discriminatory actions. The link to this letter is posted on the OSR webpage for Regulatory/Compliance Requirements. The campus-wide letter and the program specific letter should be included in the single pdf for the Letters of Support on the PHS 398 Research Training Program Plan form for T applications due on or after January 25, 2019. Also, consult specific instructions provided by individual NIH Institutes and Centers.

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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-STREMLINING 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 on the NIH Funding Strategies webpage.
- 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 on the NIH Funding Strategies webpage.

KIRSCHSTEIN-NRSA STIPENDS AND OTHER BUDGETARY LEVELS (FY 2019): NOT-OD-19-036 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 the 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.

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.

June 2018:

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