

Pharmacology Pre-award office contact & proposal deadlines for - Spring 2017

Below are our Pre-award office due dates on grant applications & specifically NIH R01/R21 proposal submissions due for this upcoming Cycle II.

And as a reminder, the proposal preparation and submission of your grant applications are handled by our pre-awards office and your fund managers will assist with budget preparations. If you are planning on submitting grant applications, please do notify Ilya ASAP so that we may work with you on compiling your proposals to meet OCGA & Sponsor due-dates. Because each agency has it's own guidelines and policies, to allow us sufficient time to assist you in compiling a complete & error-free application, we encourage you to notify Ilya of (i) your intend to submit ASAP & (ii) to work with our pre-awards office on finalizing each component as you have it instead of waiting until you have all components.

Pre-award Office Contact:

Ilya Kisel (ikisel@mednet.ucla.edu; 310-267-2038)

Due Dates:

All documents (except for the specific aims and research) are due to the pre-award office at **8AM, 7 business days prior to agency deadline.**

The specific aims and research components of your grants are due to the pre-award office at **8AM, 5 business days prior to agency deadline.**

NIH R01 and R21 applications: below are our pre-award office due-dates for NIH's R01/R21 upcoming CYCLE II application round.

<u>Type</u>	<u>Admin Documents</u> <u>Due Date Pre-Award Office</u> 7 business days prior to agency due date (8 AM)	<u>Research Plan</u> <u>Due Date Pre-Award Office</u> 5 business days prior to agency due date (8 AM)	<u>Agency Due Date (5 PM)</u>
R01-New	Wednesday, May 24, 2017	Friday, May 26, 2017	Monday, June 5, 2017
R21-New	Wednesday, June 7, 2017	Friday, June 9, 2017	Friday, June 16, 2017
R01-Renewal, Revision, Resubmission	Friday, June 23, 2017	Tuesday, June 27, 2017	Wednesday, July 5, 2017
R21-Revision, Resubmission	Thursday, July 6, 2017	Monday, July 10, 2017	Monday, July 17, 2017

**NIH policy changes & reminders affecting your 2017 NIH application submissions:

- [New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017: \(NOT-OD-16-129\) & \(NOT-OD-17-035\)](#)

Allowable appendix materials

Beginning with applications submitted to the NIH, AHRQ, or NIOSH for due dates on or after January 25, 2017, the only allowable appendix materials are:

- *For applications proposing clinical trials (unless the FOA provides other instructions for these materials):*
- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND), as appropriate
- *For all applications:*
- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items.
 - If appendix materials are *required* in the FOA, review criteria for that FOA will address those materials, and applications submitted without those appendix materials will be considered incomplete and will not be reviewed.

Consequences for submitting disallowed appendix materials

Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.

2. **[Changes to the NIH/AHRQ Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017: \(NOT-OD-16-130\)](#)**

“Post-submission application materials are those submitted after submission of the grant application but prior to the initial peer review. The policy is based on the principle that, for the majority of applications, the only post-submission materials that these agencies will accept are those resulting from an unforeseen event & is not meant for correcting oversights/errors discovered after submission.” Please refer to this notice (hyperlinked above) for comprehensive list of allowable post-submission materials on all grant types, which **MUST** be submitted to NIH “no later than 30 calendar days prior to peer review meeting” & must have our OCGA (signing official) concurrence.

Allowable Post-Submission Materials for All Applications

- Revised budget page(s) (e.g., due to new funding or institutional acquisition of equipment)
- Biographical sketches (e.g., due to the hiring, replacement, or loss of an investigator)
- Letters of support or collaboration due to the hiring, replacement or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution [e.g., Program Director/Principal Investigator (PD/PI) moves to another university]
- News of professional promotion or positive tenure decision for any PD/PI or Senior/Key Personnel
- Approval by the NIH Stem Cell Registry of a human embryonic cell line(s) after submission of the application (see [NOT-OD-12-111](#))
- Videos, within defined limits, that demonstrate devices and experimental data with a temporal element, which refers to the need to show how something functions or occurs over time, or demonstrates movement or change. Applicants must follow the directions in [NOT-OD-12-141](#) for submitting videos to accompany grant applications
- Other post-submission materials specified in the FOA for which the application was submitted or in a special Guide Notice.
- **News of an article accepted for publication since submission of the application**, which must include *only*:
 - List of authors and institutional affiliations
 - Title of the article
 - Journal or citation (if available)

Copies of articles, links to articles, or any other materials related to an article accepted for publication will not be accepted as post-submission materials, unless specified in the Funding Opportunity Announcement (FOA) for which the application was submitted or a special Guide Notice.

3. **Notice of Extension of Effective Date for Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research, for all applications (new, renewal, revision or resubmission) to September 25, 2017:**

(NOT-OD-16-094) & (NOT-OD-17-027)

For proposals due on or after Sept. 25, 2017, proposing human subject research + to be conducted in multiple domestic (U.S) sites, NIH will require use of Single IRB (sIRB) for multi-site research. Applications will need to include a “plan identifying/describing the use of an sIRB that will be selected to serve as the IRB of record for the study sites; to include a statement confirming that participating sites will adhere to sIRB policy & describe how communications between sites & sIRB will be handled.” On the budget, direct cost funding may be requested to cover additional costs associated with “the establishment & review of the multi-site study by the sIRB, along with the appropriate justification “ (please refer to below NOT-OD-16-109 for further guidance). This policy does not apply to career development, research training or fellowship grants.

Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research: [\(NOT-OD-16-109\)](#)

***if you are working on an NIH application due on or after 9/25/17, which requires use of sIRB (regardless if UCLA will be the lead or will rely), please contact OHRPP (Office of the Human Research Protection Program) for assistance in complying with this NIH policy: irbreliance@research.ucla.edu

****Upcoming NIH policy changes slated to take effect next year, in 2018:**

1. Update on Clinical Trial Funding Opportunity Announcement Policy, taking effect 1/25/2018
(NOT-OD-17-043)

Effective January 25, 2018, all grant applications with plans to conduct clinical trials must be submitted in response to an FOA which specifically states that clinical trials are allowed.

After that date, applications planning a clinical trial that are submitted to a non-clinical trial FOA will be returned without review.