

Additional Change to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials

Notice Number: NOT-OD-17-066

Key Dates

Release Date: May 30, 2017

Implementation Date: Applications submitted for due dates on or after September 25, 2017

Related Announcements

[NOT-OD-12-111](#)

[NOT-OD-12-141](#)

Issued by

National Institutes of Health ([NIH](#))

Agency for Healthcare Research and Quality (AHRQ)

National Institute for Occupational Safety and Health (NIOSH)

Purpose

This Notice updates and replaces the NIH, AHRQ, and NIOSH policy for post-submission materials for applications submitted for due dates on or after September 25, 2017. It expands that policy to include citations to issued patents as allowable post-submission materials. Post-submission materials are those submitted after submission of the grant application but prior to initial peer review. They are not intended to correct oversights or errors discovered after submission of the application, but rather allow applicants the opportunity to respond to unforeseen events.

Policy

What Will Change

For grant applications submitted for due dates on or after September 25, 2017, citations of issued patents will be accepted as post-submission materials. Eligible patents must be publicly available on the United States Patent and Trademark Office website ([United States Patent and Trademark Office](#)). Citations of foreign patents are also acceptable, so long as the granted patent number and date when the patent was granted are provided, and the issued patent is publicly available and accessible in English.

A citation of a patent must include the names of the inventors, patent title, issued patent number (including country designation, e.g, US for USA), filing date, and the date the patent was issued:

Smith, Samuel S., and John J. Jones. Method of citing issued patents. US Patent #,###,###, filed December 31, 2015, and issued December 27, 2016.

Copies of patent applications or patents, or any other materials related to a patent application or granted patent will not be accepted as post-submission materials, unless specified in the Funding

Opportunity Announcement (FOA) for which the application was submitted or in a special Guide Notice.

Citations should be sent to the Scientific Review Officer by secure e-mail or as a PDF. They must also meet the other requirements outlined at the end of this Notice, including concurrence from the Authorized Organization Representative (AOR).

What Will Not Change

The information below was published previously and has NOT changed.

Other types of post-submission materials not listed below are not likely to be accepted.

Allowable Post-Submission Materials for All Applications

- Citations of issued patents
- 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)

Additional Materials for Certain Applications

Institutional Training and Training-related Grants (e.g., T32, T34, T35, T90, TU2, T15, D43, K12, KM1, UR2)

In addition to the materials for All Applications above, news (since the training grant application was submitted) of:

- a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- a faculty member's promotion, funding, or publications; and
- the addition or removal of any faculty member who will be involved in the training program (mentors or senior/key persons).

Individual Fellowships (F-Series) and Individual Career Development Awards (K-series)

In addition to the materials for All Applications listed above, news (since the F or K application was submitted) of:

- New funding for the Sponsor/Mentor, limited to the project title, funding source (e.g., NIH/AHRQ/NIOSH grant number), a brief description of specific aims, and relevance to the fellowship or career development application under review.
- Change in Mentor(s) or other Senior/Key Persons specified in the original application.

Applications submitted to Requests for Applications (RFAs): the same post-submission materials as other applications (see "All Applications" above), for all due dates in the RFA.

Conference grants (R13, U13): a one-page explanation of all speakers who accepted invitations to participate in the proposed conference after the application was submitted, plus a one-page explanation of all speakers who declined such invitations after the application was submitted. Alternatively, the PD/PI may consider submitting a one-page explanation for each plenary slot on the agenda.

Instructions for Submitting Post-Submission Materials Other Than Citations

All post-submission materials (other than citations) must conform to NIH/AHRQ/NIOSH policies on font size, margins, and paper size as referenced in the applicable application instructions. Any specified formats (e.g., budgets, biographical sketches) and page limits referenced in the applicable application instructions apply.

If post-submission material is not required on a specific format page and/or does not have a specified page limit, each explanation, letter, etc. is limited to one page.

Deadlines

Post-submission materials must be received by the Scientific Review Officer (SRO) no later than 30 calendar days prior to the peer review meeting. Post-submission materials will not be accepted after this time, unless specifically allowed in the FOA for which the application was submitted or in a special Guide Notice.

AOR concurrence

Post-submission materials require concurrence from the Authorized Organization Representative (AOR) of the applicant organization. Although the post-submission materials may originate from the PD/PI, Contact PD/PI, or organizational officials, the AOR must send the materials directly to the SRO or must send his/her concurrence to the PD/PI who will forward the materials

and concurrence to the SRO. A communication from the PD/PI only or with a "cc" to the AOR will not be accepted.

Format instructions

Post-submission materials (other than citations) **can only** be submitted as a PDF attachment. The SRO is responsible for uploading acceptable materials into the official electronic grant file maintained in the eRA Commons. The PD/PI can check his/her application via the Commons to see these materials in the section titled "Additions for Review". This procedure provides the information to reviewers in a secure manner.

Inquiries

Please direct all inquiries to:

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