

OER Policy Announcement 2018-02

Urgent Awards

MEMO

Date: June 19, 2018
To: All Extramural Staff
From: Mike Lauer, M.D., NIH Deputy Director for Extramural Research
Subject: Notification of Changes to NIH Urgent Award Policy

Purpose: This announcement serves as notification to the NIH extramural staff of the policy and procedures governing the use of Competitive Revisions for making awards in response to immediate needs to help address specific, public health crises in a timely manner. This announcement incorporates the lessons learned from NIH's response to previous public health crises and thus establishes the framework for responding to urgent "now or never" needs and provides clarification to the existing policy framework for IC use of Competitive Revisions and Administrative Supplements to address urgent needs.

Applicability: This announcement is applicable to all National Institutes of Health (NIH) Institutes and Centers (ICs) that engage in scientific peer review of grant and cooperative agreement applications.

The policies and procedures outlined in this announcement serve as broad guidelines for Urgent Competitive Revisions, and each IC is authorized to adapt these policies and develop internal guidance to implement them. While this Policy Announcement focuses on the use of Competitive Revisions, it does not affect or restrict existing NIH policies or procedures governing ICs' use of Administrative Supplements. The policy requirements surrounding the use of administrative supplements does not change when used for issuing administrative supplements for urgent awards.

Definitions:

1. **Maximum competition:** all eligible entities may apply for funds under a particular financial assistance program. Eligibility may be restricted to a certain class of entities by the program's appropriation or authorizing legislation, congressional committee reports, regulation, or the funding announcement.
2. **Limited competition:** occurs when there are administrative requirements which place limitations on (1) the eligibility of entities or type of entities which may apply; (2) the geographic location of the project; or (3) time available for review and award. Unlike single source awards, limited competition allows for more than one eligible entity to apply for funding. Examples include programs that restrict applicants to those currently receiving funding, or that have justifiable program priorities established and published under a funding announcement. This has the effect of restricting competition to that which is less than full and open. However, in accordance with NIH policy, limited competition does not apply to administrative supplements that by definition are neither competitive nor open to applicants beyond current recipients.
3. **Emergency application/award:** an application(s) submitted or an award(s) made based on a presidentially declared disaster under the Stafford Act, a public health emergency declared by the Secretary, HHS, or other local, regional or national disaster. The term includes, but is not

limited to, an application/award for a replacement grant for continuation of health services in a community or to a specified population because of termination of an existing award.

4. **Objective Review:** a process that (1) involves the thorough and consistent examination of applications based on standard criteria and an unbiased evaluation of scientific or technical merit or other relevant aspects of the applications, (2) is performed by persons expert in the field of endeavor for which support is requested, and (3) is intended to provide advice to the individuals responsible for making award decisions.
5. **Urgent Guide Notice:** a guide notice issued by an IC (or ICs) in response to a specific public health or safety crisis. The Urgent Guide Notice provides details on the specific, urgent need, justification for the announcement, and any other specific guidance or requirements.
6. **Urgent Competitive Revision:** an application or award resulting from a competitive process for which the award must be expedited so that the project's potential for success is not jeopardized. With this announcement, emergency applications/awards, are distinguished from urgent applications/awards.
7. **Urgent Administrative Supplement:** a request or award of additional funds during a current project period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project.

Policy:

NIH may issue Urgent Guide Notices in support of competitive revisions to meet immediate needs to help address a specific and urgent public health crisis in a timely manner, but that was unforeseen when the new or renewal application or grant progress report for non-competing continuation support was submitted. A Guide Notice soliciting competitive revisions augments the information contained in the Urgent Competitive Revision Supplements to Existing NIH Grants and Cooperative Agreements (Parent Urgent Supplement) FOA.

Solicitations for such Urgent Competitive Revisions must adhere to the following guidelines:

1. Urgent Competitive Revisions and Administrative Supplements must be used for:
 - a. Addressing an immediate need to help address a specific, public health crisis in a timely manner
 - b. Supplementing active awards, which already have researchers and facilities, to meet such an immediate need that expands the scope of the parent award (e.g., Urgent Competitive Revision). If the scope is not expanding the immediate need may be addressed by issuing administrative supplements.
2. Urgent Competitive Revisions and Administrative Supplements shall **not** be used for:
 - a. Emergency Awards;
 - b. Expediting funding of grant projects that can succeed if held for the next applicable review cycle;
 - c. Making awards prior to the expiration of an appropriation or FOA;
 - d. Applicant organizations that failed to submit applications in a timely manner;
 - e. Accelerating funding (e.g., "new" funding mechanisms, IC initiatives or priorities, etc.).

3. Urgent Guide Notices will include, at a minimum, the justification for the urgent announcement, specific research aims and objectives, submission deadlines (generally, rolling submission), and any special submission requirements, review criteria, reporting requirements and other specific award conditions.
4. Because these awards are high-risk, the justification for announcing urgent awards will require approval from the Director, OPERA and Deputy Director, OER prior to issuance of an Urgent Guide Notice.
5. Urgent Competitive Revision applications must be reviewed by an ad hoc objective review panel convened by the IC if there is not sufficient time to review applications under normal review procedures due to time constraints. A determination to fund a project using the Urgent Competitive Revision process does not circumvent the requirement for Council approval.

Responsibilities:

1. **Chief GMO (CGMO), or other Designated IC Official(s):** The CGMO, or other officials designated in the IC's internal procedures for Urgent Competitive Revisions, shall:
 - a. Develop and maintain implementing procedures for Urgent Competitive Revisions that align with the NIH OER policy. These procedures should include, at a minimum:
 1. Guidance for identifying urgent needs that are identified.
 2. Procedures for developing Urgent Guide Notices and requesting OER approval.All Urgent Guide Notices will need to include:
 1. Link to the Urgent Parent FOA
 2. Basis for urgent announcement
 3. Specific research aims/objectives
 4. Submission deadlines (e.g., rolling submission)
 5. Special review criteria (if applicable)
 6. Any other submission requirements
 7. Reporting Requirements and any other Special Award Conditions
 3. Establishing IC internal ad hoc objective review panels for reviewing applications for Urgent Competitive Revisions, including managing potential conflicts of interest to ensure panel participants are free of bias.
 4. Obtaining Council concurrence, and expedited council review for recommended Urgent Competitive Revisions.
 5. Document how approved applications address the basis for the guide notice.
 6. Ensure that any scope changes align with the basis for the guide notice.
 7. Ensure oversight on awarded Urgent Competitive Revisions.
 - b. Submit all Urgent Guide Notices to the Director, OPERA for OER approval.
 - c. Maintain records in accordance with [NIH Manual Chapter 1743](#) – “Keeping and Destroying Records.”
2. **Director, OPERA:** The Director, OPERA shall:
 - a. Review all Urgent Guide Notices for compliance with NIH policy.
 - b. Recommend approval or disapproval to the Deputy Director, OER
3. **Deputy Director OER:** The Deputy Director, OER shall
 - a. Review and approve/disapprove proposed Urgent Guide Notices prior to IC issuance.

Effective Date: Effective immediately with the issuance of this policy announcement.

Please direct all inquiries regarding the changes to this policy to the Division of Grants Policy, OPERA at: grantspolicy@od.nih.gov.