

NIGMS Council Operating Procedures - 2025

Each Council at the National Institutes of Health (NIH) is required to establish operating procedures for the review of grant and cooperative agreement applications. These procedures must be in writing and are reviewed each year.

The National Advisory General Medical Sciences Council (NAGMSC) advises the Director of the National Institute of General Medical Sciences (NIGMS) on research activities and policies. The NAGSMC provides the second-level peer review of all applications for research grants and cooperative agreements, training grants, and career development awards. The NAGSMC also provides advice to the NIGMS Director on a wide range of areas including concept clearance for proposed research initiatives; the development, recommendation, and setting of NIGMS policy and research priorities; and workgroup reports.

Grants and cooperative agreements with a primary assignment to NIGMS must receive the concurrence of the NAGMSC with the initial review for scientific and technical merit in order to be awarded NIGMS funds. The Council will vote on them as either *en bloc* or individual special actions. In addition, the Council may conduct expedited reviews upon the request of the NIGMS Director or Executive Secretary. Finally, the Council has designated procedures to delegate selected authorities to NIGMS staff. These sets of operating procedures are represented in this document.

Second Level Peer Review

- Applications that are being considered for funding may be presented individually to the Council (during closed session) for special consideration, when:
 - The application is from a foreign institution
 - The applicant has submitted an appeal
 - An applicant would have research support in excess of \$1,500,000 in annual total costs from all sources (“Council Review and Oversight Policy”)
 - The reviews or research proposed has been identified by either Council or staff as being of particular interest or concern.
 - A Council member identifies an application for discussion at the Council meeting
- Applications that **do not** require specific Council consideration will be included in the *en bloc* process.
 - Before the Council meeting, all Council members review Early Concurrence applications in the Electronic Council Book, which contains peer review results for grant applications assigned to NIGMS, that do not have special considerations (outlined above), and that meet certain percentile/score thresholds; based on that review, the members recommend individual or *en bloc* concurrence of peer review results. This Early Concurrence applies to applications meeting certain score thresholds, which vary according to the distribution of scores per round.

- Applications receiving Early Concurrence will be eligible for funding as soon as the Executive Secretary of Council has certified that the review is complete.
- Applications that did not go through the Early Concurrence process will be voted on *en bloc* at the Council meeting.

CONCEPT CLEARANCE

Concept clearance is the process by which ICs receive public advice on the merits of potential initiatives. A concept describes the basic purpose, scope, and objectives of a grant or cooperative agreement program. The concept may be developed into a Notice of Funding Opportunity (NOFO).

Concepts originate from NIGMS staff and may have input from the scientific community, constituency organizations, HHS and other federal agencies, or Congress; NIGMS staff prepare concept summaries for review by Council in open session. Council may recommend approval, modification, deferral, or disapproval of a concept. Approved concepts are the basis for programs initiated through NOFOs. However, there is no requirement for ICs to develop an approved concept into a NOFO.

POLICY AND RESEARCH PRIORITIES

Council members serve as a national resource for advising on institute policy and research priorities. On occasion, special working groups will be formed by or at the request of Council to examine and address critical scientific, programmatic, or policy issues of importance to the Institute and its constituencies.

EMERGENCY PROCEDURES FOR COUNCIL MEETINGS

In the event of an emergency that would preclude the usual Council meeting from occurring, NIGMS staff will consider utilizing one or more of the following procedures:

- Consider only closed-session items, possibly focusing on a selected subset of applications for second-level review;
- Utilize the Electronic Council Book in conjunction with electronic voting/approvals;
- Organize a fully electronic/virtual conference to address necessary business;
- Relocate the meeting to another site and/or date

The NAGMS Council Executive Secretary, in consultation with the Director, NIGMS, and senior NIGMS staff members, will communicate the altered procedures and meeting arrangements to Council members and Institute staff.