

GENERAL OPERATING PROCEDURES FOR THE NATIONAL ADVISORY COUNCIL FOR NURSING RESEARCH

May 2020

Each Council at the National Institutes of Health (NIH) is required to establish operating procedures for the review of grant applications. These procedures must be in writing and are reviewed each year. The National Advisory Council for Nursing Research (NACNR) advises the Director of the National Institute of Nursing Research (NINR) on research activities and policies. The NACNR provides the second-level peer review of all applications for research grants, training grants, and career development awards. The NACNR also provides advice to the NINR Director on a wide range of areas, including: concepts for research initiatives; the development, recommendation, and setting of NINR policy and research priorities; and workgroup reports. For the second-level peer review, after reviewing applications assigned to NINR, 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 NINR Director or staff. Finally, the Council has designated procedures to delegate selected authorities to NINR staff.

The operating procedures are represented in this document.

SECOND-LEVEL PEER REVIEW

Applications that do not require special Council consideration will be included in the *en bloc* voting process. NIH and/or NINR policy requires that the following types of applications be brought to the attention of council:

1. Any application with a concern identified by an initial review group in any of the following areas:
 - animal welfare
 - human welfare
 - ethical issues
 - potential biohazard
 - gender inclusion
 - minority inclusion
 - inclusion of children
2. Any application from a foreign institution for which an award may be made;
3. Any research application recommended at a fiscal commitment of \$350,000 or more direct costs in any year for which an award may be made, excluding applications submitted to RFAs, NIH Small Business Innovation Research (**SBIR**) and Small Business Technology Transfer (**STTR**) Programs. If a reduction in the direct cost amount has been made by NINR staff that brings the direct cost amount below \$350,000, the application will be presented to Council for information only;

4. Any application identified by NINR staff as requiring special consideration by Council, including applications that are being recommended out of score order based on programmatic priorities;
5. Any application from principal investigators who have \$1 million or more in direct costs from active NIH Research Project Grants (RPGs) in accordance with the NIH policy (<https://grants.nih.gov/grants/guide/notice-files/not-od-12-140.html>) which requires Special Council Review;
6. Any application a council member would like to be brought up for discussion at the Council meeting.

The Council Executive Secretary will designate two council members to review each application for special consideration. Materials for applications requiring special consideration will be made available in the NIH Electronic Council Book (ECB) at least two weeks prior to the council meeting and can be accessed by all members not in conflict with the application.

PRE-MEETING REVIEW

Research applications recommended at a fiscal commitment of \$350,000 or more in any year for which an award may be made are considered high budget based on NINR policy. These applications will be reviewed by Council members during a process identified as “Pre-Meeting Review”. Two council members will be designated to review each application. Concurrently, all other members are alerted to which applications are undergoing high budget review and when this process begins. This process allows for council review and recommendations to be provided, informed by initial review group and internal NINR recommendations, prior to the council meeting, reserving time at the meeting for Council members to focus on other applications that require active Council consideration. This process will be completed through the ECB. If there are any applications that Council members wish to defer to the meeting for discussion, these will be noted and brought up at the Council meeting. Results of the pre-meeting review will remain available in the ECB until the council meeting, at which time the full Council will be asked to provide *en bloc* concurrence on the applications and recommendations listed within the pre-meeting review tab of the ECB.

EXPEDITED REVIEW

Staff may request expedited electronic review for eligible applications. All Council members will be asked to participate in the expedited review and will be notified of the applications under consideration. Expedited review may be designated for, but not limited to:

- Applications that require the availability of time-limited, unique resources;
- Applications that were administratively deferred or re-reviewed due to a successful appeal;
- Applications received in response to Request for Applications (RFAs).

DELEGATION OF AUTHORITY

The Director, National Institute of Nursing Research (NINR), has delegated authority from the Secretary, Department of Health and Human Services, to make awards for grants and cooperative agreements for applications that have been (1) assigned a priority rating after technical and scientific peer review and (2) given a favorable recommendation by the National Advisory Council for Nursing Research. All peer-reviewed research grants (and cooperative agreements) with primary or secondary assignment to the NINR require Council review. NINR staff analyze and review all applications, i.e., non-competing continuation and competing applications [new, competing continuation (renewal), or supplemental] before issuing a grant award. Special note is made of any items requiring adjustment of budget amounts or other terms and conditions. Staff will negotiate any identified adjustments to reduce the budget beyond the Scientific Review Group (SRG) recommended amount. All adjustments reflect the latest determination of actual or estimated needs of the project using Council recommendations, program relevance, and current policies as guides.

The following actions do not require Council review or advice and need not be reported to the Council: change of institution, change of principal investigator, administrative supplements, awards for orderly phase-out or interim support, or additional support either to meet the increased cost of maintaining the level of research previously recommended, or to accommodate activities judged by staff to be within the scope of the previously peer reviewed research.

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 potential solicitation of grants and/or contracts. The concept may be developed into a variety of Funding Opportunity Announcements (FOAs) or Requests for Proposals (RFPs).

Concepts originate from NINR staff and may have input from the scientific community, constituency organizations, or Congress. NINR staff prepares 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 FOAs and RFPs. However, there is no requirement for ICs to develop an approved concept into an FOA or RFP.