



## *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

### **Council Member Guidance of Second-Level Review**

In order to assist Council members in the performance of their duties, the following information is presented to clarify the different, but complementary, functions of both the first and second levels of the NIH peer review process. The first level of review is conducted by a Scientific Review Group (SRG) composed primarily of non-federal scientists with expertise in relevant scientific disciplines and current research areas. Each SRG is led by a Scientific Review Officer (SRO) who is an extramural staff scientist and the Designated Federal Official (DFO) responsible for ensuring that each application receives an objective and fair initial peer review and that all applicable laws, regulations, and policies are followed. As such, SRG members focus on the scientific and technical merit of applications with an emphasis on factors such as significance, investigator, innovation, approach, environment, reasonableness of the proposed budget and duration, and other factors such as protection of human subjects, animal welfare, gender and minority representations, inclusion of children, etc. It is important to emphasize that SRG members do not consider factors such as program relevance, policy issues, funding levels, anticipated budget reductions, and comparisons with other applications. All of these factors and issues comprise the first level of review in the NIH peer review process.

The second level of review at NICHD is conducted by members of the National Advisory Child Health and Human Development (NACHHD) Council, which is comprised of senior scientists as well as representatives from the lay public active in health affairs. The second level of review is broader and distinctly different from that of the SRG in the first level of review. NACHHD members are automatically provided summary statements that represent the SRG findings of the scientific and technical merit of applications along with any funding recommendations by extramural staff. Council members do not undertake an in-depth, scientific and technical merit review of applications as that has already taken place in the first level of review. Instead, Council members focus on factors such as oversight of the peer review process, assessment of the quality of SRG review of grant applications, evaluation of program priorities and relevance, evaluation of applications with special considerations (e.g., unresolved Appeals of initial review, requests for co-funding, applications to Foreign organizations, foreign transfers, applications of High Program Priority (HPP) or Low Program Priority (LPP), Method to Extend Research in Time (MERIT) award nominations or extensions, applications submitted in response to Requests for Applications (RFAs), and applications from PIs who receive  $\geq$  \$1.0M/year in direct costs from active NIH awards), and recommendations to institute staff for funding.

When Council members read and reflect on the summary statements from the first level of review, it is important to remember that Council is not a study section. Your charge as Council

members is to ensure that the initial peer review process was conducted fairly and that the conclusions and recommendations of the SRG are supported by the summary statements. It is also important to remember that a review may be appropriate even if the SRG reached a conclusion that differs from one that you, as a Council member, might reach. In conducting your second level of review as a Council member, you should ask yourself questions such as:

- Was this application reviewed by peers? Were the reviewers knowledgeable in the field and did the SRG have the right expertise represented on the committee?
- Are the comments in the critiques appropriate? Does the narrative in the summary statement support the priority score? Did the SRG raise substantive issues or are the comments trivial? Are any identified concerns reasonable?
- Are the recommendations for the budget and length of support reasonable? If changes to the requested budget or duration of support were recommended by the SRG, are the reasons given appropriate?

Remember that the SRG provides technical and scientific merit evaluation of grant applications to guide NIH staff in making funding decisions and it is within the purview of Council members to question items in the summary statement that appear incongruous with the assessment of the scientific or technical merit and the priority score.

To assist you, Council members are automatically provided access to summary statements and staff recommendations through the [NICHD Council Member Website](#) in order to carry out the second level of review. Council members will also be provided with electronic access to individual grant applications in situations involving unresolved Appeals by applicants of the initial SRG review. For those rare occasions when a Council member feels that the summary statement alone is insufficient to make a reasoned determination of the appropriateness of the initial SRG review or to make a funding recommendation, the Council member should bring this to the attention of the appropriate Program staff contact to determine whether a copy of the grant application is also needed. If you have any questions about your duties as a Council member or about any of the information above, please contact your Program “Council Buddy” or staff of the Office of Extramural Policy (OEP) for further assistance.