

Guide to Orientation of National Advisory Councils Reviewing NIH Roadmap Initiatives: Project Team/Lead IC Roles.

Except for the NIH Director's Pioneer Award, all grant applications submitted in response to Roadmap RFAs will receive second level review by the advisory council of the lead IC. The Pioneer Award will receive second level review by the Advisory Council of the Director, NIH. This is a guide for Project Teams and Lead ICs for the management of this second level of review.

It is recognized that each NIH National Advisory Council has an operating plan which has been developed in conjunction with the Institute or Center (IC) it serves. Practices vary among councils with regard to discharging their responsibilities for second level peer review that preclude the establishment of a specific protocol for the reviewing of Roadmap initiatives. Nonetheless, there are certain principles and procedures that apply to all IC councils participating in Roadmap reviews. This document provides general information which may be useful in council orientation procedures and sets out the specific duties of certain staff directly involved in Roadmap activities.

1. The Project Team leadership and the Lead IC senior staff should develop a plan for orientation of Council members to the NIH Roadmap and to the specific initiatives to be reviewed.

The leadership of the Project Team and the senior staff of the lead IC are jointly responsible for providing all of the information, including orientation, required in review of Roadmap initiatives. These plans should be consistent with each lead IC council's procedures for second-level peer review and must involve close cooperation with the council executive secretary. Decisions about how best to inform Council members of particulars regarding which applications are being considered for Roadmap funding will be determined at the local level by agreement of the Project Team and the appropriate lead IC staff members.

2. All Council Members Should be Provided with General Roadmap Background

Since the Council members are acting on behalf of the NIH, not their specific IC, as they provide their review they need to understand the context and intent of the overall Roadmap. This background may be provided in person, in writing or by telephone conference. The following narrative is offered as a brief summary, and should be used in conjunction with the NIH Roadmap website (www.nihroadmap.nih.gov).

Narrative:

Developed with input from more than 300 nationally recognized leaders in academia, industry, government, and the public, the NIH Roadmap provides resources for research that transcends the missions of individual Institutes and Centers and therefore that the NIH as a whole must address. It lays out a vision for a more efficient and productive system of medical research by reducing redundancy and stimulating cooperation.

The Roadmap identifies areas of exceptional research opportunity around three main themes: New Pathways to Discovery, Research Teams of the Future, and Re-engineering the Clinical Research Enterprise. Each is vital to the mission of all Institutes and Centers (I/C's), so the initiatives developed within each theme are cross-cutting in their impact.

For each of the themes, the Roadmap initiatives foster research that is not currently feasible by providing infrastructure, new grant mechanisms, increased opportunities for collaboration, incentives for high risk research, and harmonized regulatory burdens for clinical research. The Roadmap initiatives also provide novel training opportunities, since complex biomedical problems will require a new type of workforce. Finally, the Roadmap initiatives highlight top scientific priorities for the NIH, including clinical research and translation of basic science to clinical applications, nanomedicine, and fulfilling the scientific potential provided by the human genome sequence and other recent technological advances. Regardless of the particular type of initiative or the theme which it addresses, Roadmap research is intended to be novel, ground-breaking, and not business as usual.

The cross-cutting nature of the Roadmap goals demands administrative collaboration as well as scientific collaboration. Each initiative is written and issued by NIH staff from many I/C's who as a group, constitute the Project Team. However, to usher applications through numerous administrative processes, a single I/C is designated as the Lead I/C for each initiative. The Project Team working closely together with the lead I/C is responsible for insuring that the initial review groups understand the goals of the Roadmap and of the specific initiative, for providing second level of review, and for coordinating the post-award administration for that particular initiative.

The second level review for each Roadmap initiative is conducted by the Advisory Council for the Lead I/C. Advisory councils for I/C's other than the Lead I/C will be informed of Roadmap applications but will not have review responsibilities.

3. Lead IC Council Members Should be Oriented to the Specific Roadmap Initiatives for which they are providing Second-Level Review.

As mentioned earlier, the lead IC council provides the second-level review for all Roadmap applications having a primary assignment to that IC. This is the only council review necessary for establishing Roadmap awards, whose support is borne by all the ICs. In this review, the NIH asks that the lead council members act as advisors to the NIH rather than to the individual IC on whose council they participate. To assist in this process, members of the Project Team, including the Scientific Review Administrator (SRA) will join senior IC staff in providing information regarding the specific initiative and to respond to questions regarding details on individual applications, should they arise.

Council members need to be oriented to the objectives of the RFA(s) and how they relate to the overall Roadmap.

At a minimum, the Project Team will indicate the number of applications planned for funding and stand ready to respond to questions which may arise from council member discussion. Individual comments may be helpful to the Project Team. Should discussion lead to a council recommendation for special consideration of one or more applications, this information will be further considered in subsequent discussion by the Project Team with the parent Roadmap Implementation Working Group.

Other lead councils whose tradition includes detailed discussion of responses to special initiatives may require more detailed information from the Project Team regarding plans for Roadmap funding. This may lead to one or more recommendations for high program priority (HPP), or low program priority (LPP), as Roadmap initiatives. Discussion by the Project Team should, whenever possible, provide council with specific information regarding its selections, (or additional information on those

recommended by council) but stop short of appearing resistant to further consideration of their recommendations for HPP or LPP.

Additionally, councils may wish to raise particular applications which appear to be of particular relevance to the lead IC as possible Roadmap-affiliated awards. These discussions are not likely to require input from the Project Team and should be managed by the appropriate Lead IC staff.

When lead IC councils review more than one Roadmap initiative during a council session, there may be a benefit, in early planning stages, to working with representatives from the several Project Teams involved.

The success of the NIH Roadmap process, like other research and research training programs throughout NIH, is dependent on critical review at both steps of the peer review process. It is imperative that the second-level of review not be seen as perfunctory.

4. Project Team Leaders and Lead IC staff need to address the Timing of Council Review/ and Related Funding Issues for FY 2004.

Council meetings where most Roadmap initiatives to be funded in FY 2004 will be reviewed are predominately scheduled in September. Given that all Roadmap grants to be awarded in FY 2004 must be made on, or before September 24, 2004, and time is needed for grants management, these reviews need to be conducted earlier than the scheduled date. In order to meet this goal, and yet allow for input from the lead IC Council, it will be necessary to schedule the second-level review of Roadmap initiatives in advance of the scheduled September council meeting.

It is the responsibility of the lead IC, working with the Project Team(s) to develop a plan for council review by web-based, or teleconference means in late August or early September. Therefore the orientation for the Council to the Roadmap and to the initiatives should be conducted in advance of their review.

5. The plan for Council review should take into consideration that some ICs may be interested in funding applications that may be beyond the Roadmap Implementation Working Groups funding plan.

This will allow the Project Team and IC Program Staff to be prepared in advance of the second level of review. In addition, other Councils may identify grant applications from the Roadmap RFA, which are not part of the Roadmap funding plan, but of relevance to their mission. If an I/C has identified a particular application as potentially relevant to its mission and that application is not funded as part of the Roadmap, the Advisory Council for that I/C must review that application before the I/C can fund the application from its individual resources. The application at this point will be referred to as Roadmap-affiliated.

CURRENT ACTIVITY (AS OF APRIL 23, 2004)

NEW PATHWAYS TO DISCOVERY

Building Blocks, Biological Pathways and Networks

- **Metabolomics Technology Development:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-002.html>

- **National Technology Centers for Networks and Pathways:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-005.html>

Bioinformatics and Computational Biology

- **National Centers for Biomedical Computing:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-003.html>

Structural Biology

- **Centers for Innovation in Membrane Protein Production:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-009.html>

Molecular Libraries

- **Molecular Libraries Screening Centers Network (MLSCN):**

<http://grants1.nih.gov/grants/guide/rfa-files/RFA-RM-04-017.html>

- **Molecular Libraries Small Molecule Repository:**

<http://grants1.nih.gov/grants/guide/notice-files/NOT-RM-04-003.html>

- **Molecular Libraries High Throughput Screening Centers:**

<http://grants1.nih.gov/grants/guide/notice-files/NOT-RM-04-001.html>

- **Development of High Resolution Probes for Cellular Imaging:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-001.html>

- **High Throughput Molecular Screening Assay Development:**

<http://grants1.nih.gov/grants/guide/rfa-files/RFA-RM-04-012.html>

RESEARCH TEAMS OF THE FUTURE

Interdisciplinary Research

- **Meetings and Networks for Methodological Development in Interdisciplinary Research:**

<http://grants1.nih.gov/grants/guide/rfa-files/RFA-RM-04-014.html>

- **Training for a New Interdisciplinary Research Workforce:**

<http://grants1.nih.gov/grants/guide/rfa-files/RFA-RM-04-015.html>

- **Supplements for Methodological Innovations in the Behavioral and Social Sciences:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-013.html>

- **Interdisciplinary Health Research Training: Behavior, Environment and Biology:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-010.html>

- **Short Programs for Interdisciplinary Research Training:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-008.html>

- **Curriculum Development Award in Interdisciplinary Research:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-007.html>

- **Exploratory Centers (P20) for Interdisciplinarity Research:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-004.html>

High Risk Research

- **NIH Director's Pioneer Award:**

<http://grants1.nih.gov/grants/guide/notice-files/NOT-RM-04-007.html>

RE-ENGINEERING CLINICAL RESEARCH

- **RFTOP-RM-169, Inventory and Evaluation of Clinical Research Networks:**

<http://nihroadmap.nih.gov/grants/NIHRoadmap-INVENTORY-RFTOP169.pdf>

- **Re-Engineering the Clinical Research Enterprise: Feasibility of Integrating and Expanding Clinical Research Networks:**

<http://nihroadmap.nih.gov/grants/rm-04-23.htm>

- **Dynamic Assessment of Patient-Reported Chronic Disease Outcomes:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-011.html>

- **Multidisciplinary Clinical Research Career Development Programs:**

<http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-04-006.html>

- **Development of a Conceptual Model and Feasibility Assessment of a National Clinical Research Associates Program:**

<http://nihroadmap.nih.gov/grants/NIHRoadmap-RFQ-NCRA-031804.pdf>