July 15, 2013

To: Lawrence A. Tabak, D.D.S., Ph.D
Deputy Director, NIH

From: Deputy Director for Management

Subject: Request for Class Approval
Scientific Review Meetings and Advisory Board/Council Review Meetings

The purpose of this memorandum is to request a Class Approval for scientific review meetings and Advisory Board/Council Review Meetings for review of grant, cooperative agreement applications, contract proposals, and contract project concepts, estimated at or below $75,000, and held or planned to be held during the period March 26, 2013 through December 31, 2013. Approval of this Class Approval will negate the need for the Institutes/Centers to submit individual requests for each scientific review meeting and Advisory Board/Council Review Meeting.

Institutes/Centers will maintain appropriate data on these meetings to ensure full compliance with the reporting requirements set forth in Section 1.4 of the HHS Policy on Use of Appropriated Funds for Conferences and Meeting Space.

/s/
Colleen Barros

Attachment
The NIH is the nation's primary medical research agency, and the largest source of funding for biomedical research in the world. In fact, more than 80% of the NIH budget is directed to universities, hospitals, and research organizations for carrying out critical research activities in support of NIH's mission under grants, cooperative agreements, and contracts.

A critical step in establishing these awards involves the conduct of scientific peer review of research grant/cooperative agreement applications and research and development project concepts and contract proposals, the requirement for which is set forth in Public Health Service Act (42 USC 289a) and further defined in regulations and policy. Implementing regulations at 42 CFR 52h require that peer review members be selected based upon their training and experience in relevant scientific or technical fields, or upon their qualifications as authorities knowledgeable in the various disciplines and fields related to the scientific areas under review. Not more than one-fourth of the members of any peer review group may be officers or employees of the United States.

Applications and proposals to the NIH for grants, cooperative agreements, and contracts for biomedical and behavioral research are reviewed under a two-level scientific peer review system. This dual system separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, which permits a more objective and complete evaluation than would result from a single level of review.

For most grant and cooperative agreement applications, the initial or first level review involves panels of experts established according to scientific disciplines or medical specialty areas, whose primary function is to evaluate the scientific merit of grant applications. These panels are referred to as Scientific Review Groups (SRGs). A second level of review of grant and cooperative agreement applications is performed by National Advisory Boards or Councils composed of both scientific and lay representatives. The recommendations made by these Boards or Councils are based not only on considerations of scientific merit as a judged by the SRG, but also on the relevance of a proposed project to the programs and priorities of the NIH.

For contracts, typically, early in the acquisition cycle, an Advisory Board, consisting of authorities knowledgeable in the various disciplines and fields related to the scientific areas under review, conduct a review of the project concept to determine the scientific significance of the goals of the proposed project, the availability of the technology to achieve those goals, the extent to which there are identified and practical uses for the anticipated results, and the adequacy of the methodology to be utilized, in cases where the project approached is outlined. A separate peer review group subsequently evaluates contract proposals in accordance with
the criteria set forth in the request for proposal.

This well-established review system — from the selection of review members to the conduct of the review — is designed to provide NIH officials with the best available advice about scientific and technical merit of applications and proposals, as well as, program priorities and policy considerations.

The table below identifies the meeting type, and the approximate number of meetings held during Fiscal Year 2012, and categorizes these meetings based on various threshold levels. The NIH expects to hold approximately the same number and type of meetings during Fiscal Year 2013.

<table>
<thead>
<tr>
<th>Meeting Type</th>
<th>Purpose</th>
<th>Approximate Number of Meetings per Year</th>
<th>Less than $20,000</th>
<th>Between $20,000 and $75,000</th>
<th>Greater than $75,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisory Board and Council Meetings</td>
<td>Review of Contract Project Concepts Second Level Review of Grants</td>
<td>90</td>
<td>60%</td>
<td>40%</td>
<td>0%</td>
</tr>
<tr>
<td>Scientific/Technical Merit</td>
<td>Technical review of grants, cooperative agreements and contracts</td>
<td>2650</td>
<td>18%</td>
<td>80%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Boards, Councils, Review Groups and Panels provide review of project concepts and scientific and technical merit review of research grant/cooperative agreement applications and contract proposals. In Fiscal Year 2012, NIH hosted over 2,600 committee meetings, comprised of approximately 22,000 non-government independent experts. Most of the Scientific/Technical Merit Review meetings fell within the $20,000 to $75,000 range, averaging about $39,000 per meeting, while the majority of the Advisory Board and Council meetings were less than $20,000. Also, over two-thirds of the meetings were held within reasonable proximity to the NIH; while some of the participants are federal employees, the majority of the costs were for the travel of non-Federal experts, who hail from all parts of the US.

Project concept review and scientific/technical review are fundamental to the award of research grants, cooperative agreements and contracts. The conduct of these meetings is essential to meeting the basic requirements of law and regulation as it relates to ensuring that
groups of primarily nongovernment experts provide technical advice on the scientific and technical merit of grant applications, contracts proposals, and contract project concepts. Without these reviews, the NIH cannot proceed with awards critical to pursuing the health research initiatives on which the nation depends.

Initiation and tracking of requests for each individual meeting would impose a significant administrative burden on staff and interfere with the efficient operations of NIH’s well-established review system.

Based on the forgoing, and in accordance with Section 1.2., Definitions, subsection F., Events Designated for Class Approval, of the HHS Policy on the Use of Appropriated Funds for Conference and Meeting Space, a Class Approval is requested for all Scientific Review Meetings and Advisory Board/Council Review Meetings estimated at/below $75,000 for the period March 26, 2013 through December 31, 2013 in order to accomplish peer review of grant/cooperative agreement applications, contract proposals, and concept projects.

The NIH shall maintain appropriate data on all meetings covered by this Class Approval in order to comply with the reporting requirements set forth in Section 1.4., Reporting Requirements, of the aforementioned HHS Policy.

Approved:

/s/ 7/15/13
Lawrence A. Tabak, D.D.S., Ph.D
Deputy Director, NIH