

**129th MEETING OF THE NATIONAL CANCER ADVISORY BOARD (NCAB)
MEETING OF THE SUBCOMMITTEE ON CANCER CENTERS**

February 18, 2004
3:30 p.m. – 4:45 p.m.

Welcome—Dr. Arthur Nienhuis

Dr. Nienhuis, Director, St. Jude's Children's Research Hospital, Memphis, TN, chaired the Subcommittee and welcomed the attendees. The Subcommittee convened to discuss suggested changes to the National Cancer Institute (NCI) Designated Cancer Center Support Grant (CCSG) Guidelines in the context of addressing the recommendations of the P30/P50 Working Group.

Cancer Centers Update

Staff members from the NCI Cancer Centers Branch provided Subcommittee members with an overview of the proposed changes to the NCI CCSG Guidelines.

In addition to implementation of the P30/P50 Working Group recommendations, CCSG revision goals include: simplification of the guidelines, coordination of Centers and Specialized Programs of Research Excellence (SPOREs) with other NCI programs to facilitate translation research objectives, improvement of data collection to promote accomplishments, and making the guidelines more user friendly for the targeted audiences.

The guidelines revision process began in December 2003. An additional review before presentation to the NCAB, possibly at the June meeting, is expected to occur at the Center Directors' Retreat on March 8, 2004. The current CCSG Guidelines are lengthy, and the goal is to simplify the guidelines; currently, there is cross-referencing that is sometimes contradictory, and this needs to be addressed.

A discussion of changes to sections of the guidelines included:

Section 1.1

The P20 grant mechanism is being phased out, and the P30/P50 mechanism will be the primary mechanism under the new guidelines. Many Cancer Centers have been successful without use of the P20 mechanism, and it was no longer considered necessary for this program.

Section 1.2

Over the next 5 years, the rate of growth of the Cancer Centers Program budget should be slightly above that of the R01 budget. This recommendation is to be implemented in the context of development of the annual budget.

Section 2.1

Cancer Centers Directors should be included in NCI's strategic planning process to offer guidance in developing new NCI initiatives and to disseminate research findings. The Annual Cancer Centers Directors' Retreat, strategic planning meetings, and revival of "NCI Listens" at the Association of American Cancer Institutes (AACI) meetings are areas to pursue to achieve this objective. The AACI meetings would offer information to those not currently part of the NCI-funded community that might aid in their success at eventually becoming NCI-funded Cancer Centers.

Section 2.2

Cancer Centers should be considered as sites for piloting new research and dissemination programs to assure cost-effective integration with existing resources. This already is the strategy for many proposals (e.g., Cancer Biomedical Informatics Grid [caBIG], U54 minority institution partnerships, etc.) with funding of almost \$30 million available only to CCSGs. Such initiatives are approximately 14 percent of the CCSG budget. Staff were asked to provide a summary of initiatives over the past several years for review at the Center Directors' Retreat to identify others that might have been considered for implementation.

Section 2.3

A change in the wording of this section will allow clinical researchers without peer review funding to be included in the program.

Section 2.4

Revise the funding of P30 shared resources to provide more appropriate support for critical and underfunded activities as well as for essential new exigencies such as regulatory compliance. After discussion by the Subcommittee members, Cancer Centers Branch staff agreed to provide a template of what additional wording needs to be included in this section concerning modeled guidelines with better instructions to applicants.

Section 2.5

Encourage geographic distribution by creating a new category of Cancer Centers for academic institutions that cannot meet all requirements of P30 applications; these institutions would be associated with and funded through an existing P30 center. Three models were discussed: (1) two institutions each without current funding by a CCSG, combining resources in a single application reviewed as a single unit; (2) an existing Cancer Center affiliating with another institution to add a research program, shared resource, or access to a unique patient population (funding for the CCSG in this model should be independent of whether a specific affiliation is approved); and (3) a separate program analogous to the minority institution/Cancer Center partnership, which is reviewed independent of the CCSG. Further definition and confirmation of these options and their implications are anticipated.

Section 2.6

Provide support through the P30 mechanism for Cancer Centers actively seeking links with state health departments or other state agencies, or with the Centers for Disease Control and Prevention. Current funding occurs for prevention and control (P&C) programs and for cores, as

well as for full time employee support for outreach. Pending increased budget support, supplements or planning grants might be available.

Section 2.7

Modify the P30 award to encourage and support Centers to develop an infrastructure in the P&C program or core; to test novel methods for disseminating new knowledge in clinical, cancer control, and early detection research; and to develop supplements or planning grants.

Section 3.1

An NCI clinical research and informatics system integrated with such systems at the Cancer Centers, AACI, industry, and other interested parties should be a priority. The Cancer Centers have a substantial investment in the caBIG database that is being developed, and partnerships with industry should be aggressively pursued.

Section 3.2

Limit the additional review of clinical trials that are supported by previously peer-reviewed funding mechanisms to safety and regulatory issues. Cancer Therapy Evaluation Program (CTEP) review applies to CTEP and the Division of Cancer Prevention; it should be eliminated for grants or Phase I and II studies unless CTEP holds the Investigational New Drug Application. Impose a 30-day turnaround on those studies requiring review (CTEP currently has a turnaround slightly higher than 30 days). This topic should be discussed at the Directors' Retreat to identify areas of concern.

Section 3.3

Work with the Federal Office for Human Research Protections to engage Cancer Center Institutional Review Boards (IRBs) in developing a strategy for centralized review of multicenter trials. There is a Central IRB in place for Phase III, and a Central IRB for Phase II is being added.

Section 3.4

Streamline the review of P30s by eliminating the need for some site visits. Experience has demonstrated that if a site visit is removed from the review process, the quality of the submitted applications improves.

Section 3.5

Adjust the P30 review process to consider and accord weight in scoring activities involving collaboration with P50s, cooperative groups, and participation in networks, as well as community service, outreach, and dissemination. There should be a balance in clinical trial activity with no penalty for cooperative activities.

Section 3.6

Initiate a planning process to develop quantifiable metrics for determining the size of the P30 award to reflect the broad spectrum of involvement of individual Cancer Centers in discovery, dissemination, and delivery of care. There currently is a flat 15 percent of NCI funding guidelines for a request that is not advantageous to smaller Cancer Centers. A cap in overall funding at \$10 million would penalize a few large Centers, while a 50 percent (or some other

level) growth rate cap on a current award would penalize small Centers. A sliding scale of NCI funding to CCSG with smaller Centers receiving a higher ratio was judged to be too complex. Some regulatory requirements should be removed from the ratio.

Section 3.8

Develop a process to describe and quantify, on an annual basis, the overall contributions of the P30/P50 programs. Consider a proposal to collect information from the Centers annually to be used in support of NCI presentations before Congress.

The meeting was adjourned at 4:45 p.m.



Dr. Arthur Nienhuis
Chair

2-26-2004

Date



Dr. Karen Antman
Executive Secretary

2-26-2004

Date