

**National Cancer Advisory Board (NCAB)
Cancer Centers Subcommittee Meeting**

Susquehanna/Severn Suite
Hyatt Regency Bethesda Hotel
One Bethesda Metro Center (7400 Wisconsin Avenue)
Bethesda, MD
June 10, 2009
6:00 to 7:40 p.m.

FINAL SUMMARY

Participants:

Subcommittee Members

Dr. Kim Lyerly
Dr. Bruce Chabner
Dr. Victoria Champion
Dr. Judith Kaur
Dr. Karen Meneses
Dr. Jennifer Pietenpol

Other Participants

Dr. Carolyn Runowicz (NCAB)
Dr. Diana Lopez (NCAB)
Ms. Mary Lester (NCAB)
Ms. Kathryn Giusti (NCAB)
Dr. Daniel Von Hoff (NCAB)
Dr. John Niederhuber (NCI)
Dr. Linda Weiss, Subcommittee Executive Secretary (NCI)
Dr. Robert Croyle (NCI)
Chad Ellis (NCI)
David Maslow (NCI)
Gail Bryant (NCI)
Beth Whelan (NIOSH)
Devi Venbu (NCI)
Sonya Roberson (NCI)
Ann D. Hudson (NCI)
Hasnae Shafiq (NCI)
Peggy Rhodes (NCI)
Steven Kleerger (NIEHS)
Kathleen Meister (The Scientific Consulting Group, Inc., rapporteur)

Planning for the Next Revision of the Cancer Center Support Grant Guidelines—Dr. Linda Weiss and Subcommittee Members

Dr. Linda Weiss, Executive Secretary of the Subcommittee, provided an overview of the process of updating the Cancer Center Support Grant (CCSG) Guidelines. She noted that the Cancer Centers program is currently operating under interim guidelines released in September 2008, which include clarifications and minor revisions of the 2004 Guidelines but no substantive changes. The next version of the Guidelines will likely include more substantive revisions.

As background, Dr. Weiss told the Subcommittee that the CCSG Guidelines were formally established following the 1971 National Cancer Act and have undergone numerous revisions since then to reflect changes in National Cancer Institute (NCI)/National Institutes of Health (NIH) policies, to respond to formal evaluations and working group reports, to respond to issues raised by grantees, to clarify existing guidance, to address new NCI priorities, and to build Cancer Center capability. Some of these revisions have been more significant than others. The overarching principles of the Guidelines are to foster intra- and interdisciplinary cancer research, while allowing for diversity in the types of research conducted and flexibility in approaches. The Guidelines also ensure accountability and adherence to standards and assess the added value of Cancer Centers.

Important events since the 2004 revision of the Guidelines include:

- Reports from the Clinical Trials and Translational Research Working Groups. Initiatives are underway to address the recommendations made in those reports.
- The 2006 report of the Cancer Center Directors' Working Group.
- The Development of the CaBig network of informatics infrastructure and tools and the Clinical Trials Reporting Program (CTRP).
- The publication of NCI Best Practices for Biospecimen Resources.
- Establishment of the NCI Community Cancer Centers Program pilot.
- The advent of Clinical Translational Science Awards (CTSAs) from the National Center for Research Resources.

Many topics will be considered during the Guidelines revision process. The fact that these areas are being examined does not necessarily imply that changes will be made, however. Issues for consideration include the following:

- Support for scientific programs and specifically for clinical and translational science
- Options for speeding the clinical trials process
- Encouragement of cross-center/community research collaborations
- Sharing of core resources—a topic in which some Centers have expressed interest
- Coordination with other NCI and NIH programs, including mechanisms of integration with CTSAs
- Support for addressing health disparities
- Advancement of NCI priorities
- Funding approaches and policies

- Reporting metrics (Cancer Centers have reported difficulty in adhering to the different reporting metrics of all of the various sources from which they receive funding.)
- Metrics for program evaluation

Dr. Bruce Chabner asked Dr. Weiss to clarify the definition of disparities. Dr. Weiss stated that the Public Health Service's guidelines on disparities are followed and that it is not within NCI's purview to change the definition. There is also an NCI monograph on addressing disparities that provides guidance on this topic.

Efforts will be made during the Guidelines revision process to devise a simpler approach to funding, probably eliminating the benchmark ratio.

Dr. Chabner asked Dr. Weiss to elaborate on the possible revisions in the metrics for program evaluation. Dr. Weiss explained that it has been difficult to compile information on the accomplishments of the Cancer Centers as a group. Often, CCSGs are not cited in publications even though they provided core resources. Thus, better ways of assessing the Cancer Centers program's contributions to NCI are needed.

Dr. Weiss explained that the process of revising the guidelines has already begun with a review of the current guidelines, which is now underway. The next step will be to consult other pertinent resources, including guidelines from other programs at NIH, input from Cancer Center directors and administrators, input from other stakeholders, and the views of this Subcommittee and NCAB as a whole. Revised guidelines will then be drafted, and the draft version will be revised based on feedback from multiple sources, after which the guidelines will be submitted through approval channels and the final version will be released.

Dr. Kim Lyerly stated that it is not clear whether the current Guidelines are delivering the tools that allow the Cancer Centers to meet their current goals—rather than the goals of the 1970s. He urged that the Guidelines revision process should look at the big picture and address fundamental questions about the Cancer Centers' future. Other Subcommittee members brought up additional issues to be considered during the Guidelines revision process, including the relationship between Cancer Centers and CTSA's and the role of Cancer Centers in developing capabilities that communities need.

Dr. Weiss stated that NCI is very aware that the Cancer Centers program has served as a template for other programs and is often regarded as the "jewel in the crown" of NCI. However, the Guidelines have not evolved as quickly as scientific research and the roles of Cancer Centers have evolved. All aspects of the Guidelines are open for consideration, and some can be revised at a broad level, if needed.

Dr. Lyerly said that it would be important in the Guidelines revision process to obtain input from Cancer Center directors and from senior academic medical center leaders.

Dr. Chabner noted that in the process of writing any type of guidelines, there is a tendency to be specific. However, because the field of cancer research is changing rapidly, it would be

desirable for the Guidelines to be maximally flexible. The goal, he said, is to cure cancer, not to preserve institutions.

Dr. Chabner also noted that under current procedures, the review of Cancer Centers is divorced from the review of the science conducted with their resources. He suggested that this separation may need to be rethought during the revision process. Dr. Jennifer Pietenpol observed that the Guidelines do not preclude outreach and the evaluation of science. Dr. Weiss pointed out that the Cancer Centers are a P30 mechanism that provides infrastructure support and does not fund research directly. Dr. Chabner noted that P01 grants and Specialized Programs of Research Excellence (SPOREs) fund both science and infrastructure; perhaps the CCSGs should do the same.

Dr. John Niederhuber, Director of NCI, noted that in 2002, a committee met for a year to discuss many of the same issues raised by members of the Subcommittee. He noted that the Cancer Centers have been a very successful infrastructure program. In his view, however, if the program is to be adjusted, a top priority would be to strengthen the position of the Cancer Center and its director within the university where it operates. The Cancer Center is a core that must leverage resources within the larger institution, a task that has become increasingly difficult because Cancer Centers now face competition from CTSA's and other programs. Therefore, it may be desirable to give the Cancer Centers more support not directly for science but for the leadership of science, for example by giving the Center directors salary incentives and protected time. Subcommittee members suggested the possibility of linking the Cancer Centers to SPOREs, but Dr. Niederhuber expressed concern about this idea, noting that linking would weaken the SPORE program. Moreover, some Cancer Centers have no SPOREs.

With regard to the funding of science by Cancer Centers, Dr. Weiss noted that there are developmental funds, but that currently more money is being put into shared resources than into development.

Dr. Weiss outlined the proposed timeline for the Guidelines revisions, projecting that the first complete draft would be ready in February 2010, that the final complete draft would be ready in June 2010, that approval and release would take place in Fall 2010, and that implementation would occur in January 2011. She noted that this is an ambitious schedule and that it may be delayed by factors outside of the Centers Program's control. The timeline may also need to be extended if a decision is made to broaden the scope of the revisions. In addition, if the changes in the Guidelines are extensive, implementation may need to be delayed to give the Cancer Centers time to adapt to the new procedures.

Dr. Niederhuber noted that the current revision of the Guidelines is not a radical review. Rather, it is a fine-tuning to improve an already successful program and hopefully to make the jobs of Center directors easier.

The role of the Subcommittee in the Guidelines revision process, Dr. Weiss explained, would be to provide advice on what principles, policies, and issues should be addressed; on the merits and drawbacks of options that are developed; on useful metrics for program evaluation; and on other topics. The discussions at this Subcommittee meeting have provided a fruitful start in this

process. In addition, the Subcommittee will provide a final recommendation to NCAB on the revised Guidelines.

Moving Evidence-Based Findings From the Cancer Center Into the Community to Impact Cancer Care: What Should Be Our Mandate?—Dr. Kim Lyerly and Subcommittee Members

Dr. Lyerly noted that the topic he wanted to address—the role of Cancer Centers in the community—fits in with the prior discussion of the revision of the Guidelines. In the current era in which CTSAs have a prominent role on university medical campuses, Cancer Centers have become involved in areas, such as community engagement, that were traditionally beyond their charge. A heavy investment in tackling community issues could easily overwhelm a Cancer Center's budget, but Cancer Centers do play a role in their communities. Indeed, people may be developing the expectation that Cancer Centers should directly touch the populations that they serve. Dr. Lyerly asked for members' views on this topic.

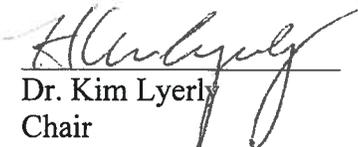
Dr. Chabner replied that part of his plea for flexibility in the revised Guidelines involves flexible funds for Cancer Center directors. It is difficult to do community engagement in the standard format of a clinical trial, but such engagement is important. Dr. Chabner also noted that the career track for researchers who become involved in community issues is not as favorable as that for those who do laboratory research. Other Subcommittee members agreed that it is possible for Cancer Centers to become involved in some community engagement but that such activities are poorly valued and poorly funded.

Dr. Lyerly pointed out that the CTSAs now have the mandate for community involvement. Several Subcommittee members suggested the possibility of partnerships between Cancer Centers and CTSAs—something that is already happening at some universities but not others. Dr. Lyerly noted that the fundamental mission of the Cancer Centers has been to provide infrastructure for innovative research; the importance of community involvement must be balanced against this core mission. He asked whether the Guidelines should be explicit about the role of Cancer Centers in community engagement. Dr. Carolyn Runowicz suggested that it may be valuable to rethink the roles of Cancer Centers and CTSAs. Given limited resources, what should each be doing? Dr. Pietenpol noted that there is nothing in the Guidelines that precludes collaboration with CTSAs or other entities. Subcommittee members noted, however, that partnering with CTSAs is more workable at some institutions than others. Several members expressed frustration about the opportunities that CTSAs have to fund research in ways that Cancer Centers cannot. They agreed that they would be pleased if Cancer Centers could receive the same treatment on university medical campuses that CTSAs do.

Dr. Weiss observed that CTSAs have problems of their own. Because they involve multiple diseases, their charge is even more complex than that of Cancer Centers. Some CTSAs feel overwhelmed by the scope of their responsibility. Moreover, the CTSA program is only in its third year, and CTSAs have resource problems, just as Cancer Centers do. CTSAs may offer opportunities for fruitful interactions, but Cancer Centers must also work to preserve their own roles in the institutions within which they operate.

Dr. Robert Croyle, Director of the Division of Cancer Control and Population Sciences at NCI, told the Subcommittee that at the next day's NCAB meeting, they would be hearing from three investigators, all at Cancer Centers, who have P50 and Center grants from NCI and who have been conducting multidisciplinary projects that include both cutting-edge science and community-based participatory research. These investigators have struggled with some of the same issues of interest to this Subcommittee, and Dr. Croyle urged Subcommittee members to engage them in discussion at the main NCAB meeting.

The Subcommittee meeting adjourned at 7:40 p.m.



Dr. Kim Lyerly
Chair

June 30, 2009
Date



Dr. Linda Weiss
Executive Secretary

6/30/09
Date