National Cancer Advisory Board (NCAB)
Cancer Centers Subcommittee Meeting

Hyatt Regency Bethesda Hotel
Old Georgetown Room
1 Bethesda Metro Center
Bethesda, MD
June 24, 2012
6:40 p.m. – 8:10 p.m. EDT

SUMMARY

NCAB Subcommittee

Jennifer Pietenpol, Vanderbilt University (Chair)
Victoria Champion, Indiana University
Judith S. Kaur, Mayo Clinic

NCAB and BSA Members
Bruce Chabner, Harvard Medical School/Massachusetts General Hospital
Donald Coffey, The Johns Hopkins University
Brian Druker, Oregon Health & Science University
Stan Gerson, Case Western Reserve University
Olufunmilayo Olopade, University of Chicago

Other Participants
Gail Bryant, DEA, NCI
Michael Burgio, SCG
Henry Ciolino, NCI
Paul Goldberg, The Cancer Letter
Nga Nguyen, NCI
Krzysztof Ptak, NCI
Hasnaa Shafik, OCC, NCI
Shannon Silkensen, NCI
Shamala Srinivas, DEA, NCI
Linda Weiss, OCC, NCI

Welcome and Introductions

Dr. Jennifer Pietenpol introduced herself and thanked the participants for coming to discuss proposed revisions to guidelines and policies relating to Cancer Center Support Grants (CCSG). Members of the BSA or NCAB who were in attendance were invited to join the discussion.

2013 Cancer Center Support Grant Guidelines: Proposed Revisions

Dr. Linda Weiss gave a presentation summarizing proposed changes to the NCI CCSG guidelines. Proposed guideline revisions were discussed in concept with this subcommittee in 2009. However, their development was somewhat delayed by the staff workload associated with the distribution of American Recovery and Reinvestment Act (ARRA) funds and the arrival of Dr. Harold Varmus as the new Director of NCI.

Proposed guideline revisions came from multiple sources including Clinical Trials and Translational Research Advisory Committee (CTAC) working group reports on Guidelines Harmonization and Operational Efficiency, a NCAB *Ad hoc* working group report on developing an overall vision for the NCI, Cancer Center Director retreat reports, a series of visits to Cancer Centers by program staff, discussions with staff from the Division of Extramural Activities (DEA), feedback from the Cancer Center Administrators Forum, and discussions with NCI senior leadership.

The major objectives behind the proposed revisions are strengthening the focus on quality of science, harmonizing NCI mechanisms, fostering collaborations between Centers, offering a broader array of support options, reducing the burden of the application and review process, and providing new guidance on eligibility and budget requests. The application contains more than 40 reviewable components. Each of the objectives involves revisions across multiple components in multiple sections of the application. Draft guidelines were sent to the Cancer Centers for comments in April 2012 and presented to Scientific Program Leaders in May. The intent is to submit a Program Announcement (PA) in July for publication in September. The effective date for applications would be January 2013.

There was broad agreement that some elements of the application were irrelevant and added significant burden to the application. The proposed revisions place a greater emphasis on scientific impact, quality of clinical trials, movement of findings through the translational continuum, and strategic value of shared resources. There is a lesser emphasis on accrual as a primary metric for evaluating clinical research. In all areas, there is a strengthening of accountability for senior leadership of the Cancer Centers. A new staff investigator category has been added to facilitate research in underserved populations, clarifications have been made to the consortium partner requirements, and the former Comprehensive Stage II requirements have been aligned with the Centers' scientific goals.

At present for Cancer Centers to receive the comprehensive designation, a two-stage review is required. The first stage focuses on the breadth and depth of laboratory, clinical, and population science research, as well as the transdisciplinary research that bridges those areas. The second-stage review focuses on training, service, and outreach and can occur up to one year after the scientific review. The two-stage review is seen as cumbersome to applicants and reviewers. A single, comprehensive review is proposed in the revised guidelines. This review will focus on evaluating the Centers' basic and transdisciplinary research, effectiveness in defining and serving the catchment area via supported research, and effectiveness in the training of scientists and health care professionals. Other proposed revisions to the application include elimination of redundancies across components, usage and capacity tables in shared resources, and meeting agenda requirements. A new-application only option has been added, which eliminates the site visit.

Most comments on the revised guidelines received from the Cancer Centers focused on documentation of activities, clarifying the definition of catchment area, and defining the forms of tangible support required for consortium partners and the role of the grantee in the cancer activities of consortium

partners. In response to feedback, evaluation of accrual of women and minorities to non-interventional studies has been included as an option. It should be noted that official NIH definitions of minority groups still apply. Cancer Centers are including information about accrual of underserved populations that are not easily defined (i.e., Appalachian populations and other groups that do not fit into NIH minority categories). Reviewers can consider accrual of these groups in their evaluation of applications.

Current guidelines encourage collaboration within Centers but have not fostered collaboration across Centers or between Centers and other entities. Recognition of a Center's contributions to team science is a goal of the revised guidelines. Efforts to promote collaborations include standardization of summary data definitions with the Clinical Trials Reporting Program (CTRP), allowing global health projects, and eliminating the Benchmark Ratio (BR). The BR focused Centers on 'counting' NCI grants, potentially inhibiting collaborations between Centers.

The revised guidelines provide greater support for clinical and translational research; current guidelines often do not reflect clinical realities. The clinical trials office has been separated from shared resources and made into a separate component, freeing it from the restrictions and requirements of shared resources. The revisions allow support of a broader array of functions for clinical trials, including protocol writers, database tracking programs, CTRP reporting, and legal staff. A broader range of activities for early phase clinical research, including IND/IDE applications, imaging scans, and pharmacodynamic studies, also can be supported.

The amount that a peer-reviewed, cancer-related funding center must have to be eligible to submit a CCSG application in the revised guidelines has been increased from $4 million to $10 million in direct costs. A few small Cancer Centers expressed concern that $10 million was too large and suggested that this requirement should be reduced to $8 million. Eligibility to apply is determined by program staff prior to review, and all current Centers already have well over $10 million in funding. Therefore, that requirement has not been adjusted in the proposed guidelines.

Changes to guidelines for budget requests for re-competing Centers include elimination of the BR. The BR is a metric established in the 1970s that provided guidance regarding budget requests. The BR was the ratio of a Center's NCI research base to its current CCSG award. It was intended to restrict the size of budget requests. However, the benchmark does not apply well to many types of Centers, and its disadvantages outweigh its advantages. NCI's ability to fund Centers at ratio levels has declined over time, and new guidance for budget requests is necessary, considering current fiscal realities. The proposed interim approach caps applications with an award equal to or greater than $6 million (direct cost) at their current level. Applications below that level may request a 10 percent increase over the direct cost in their last non competing award or a budget of up to $1 million (direct cost). Larger increases may be requested under specified circumstances after consultation with program staff. Actual awards will depend on the budget for the Cancer Centers Program. The expectation is that funding will remain flat for the next several years.

QUESTIONS

A participant observed that the proposed revisions appear very positive and the program is being responsive to concerns expressed by review committees and investigators, and asked whether the revisions significantly simplify the application. NCI staff confirmed that the application has been simplified. One of the goals of the revision was to eliminate elements that were not relevant in practice.

It was noted that many community research projects actually involve little direct contact with the community, and that Cancer Centers have a responsibility improve the health of underserved populations. A participant asked how community involvement would be judged. NCI staff responded that these grants are intended to be research grants. Community research cannot be successfully performed without having service and outreach programs in place. Reviewers will evaluate community for service as it relates to research. These guidelines align research objectives with community needs. Community outreach is addressed in several parts of the application. Ensuring that community research activities truly identify underserved populations and impact cancer prevention, care, and survival in those populations may require some education for reviewers.

A question was raised about the sense of sites already at the $6 million level going through the arduous application process, and whether the application process could be simplified for established Centers. NCI staff said that, per NIH guidelines, all groups must re-compete and that there is no mechanism for extending the award without review.

A participant commented that it is possible that opting for an application only review and not having a site visit will be perceived as putting those Centers at a disadvantage. In such a case, it is likely that no Center will take that option. The question of whether the program has surveyed Cancer Centers to see if any plan to exercise that option was raised. NCI staff responded that such a survey has not been conducted. However, past experience with the limited site visit option indicates that sites often do not follow their stated, preferred review path for the actual review.

Subcommittee Recommendation

The Cancer Centers have been an outstanding program. However, the application process is extremely burdensome. The NCI should focus on a further reduction in the burden of the application process with a review focused on only the most relevant metrics.

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Dr. Jennifer Pietenpol Chair	Date	Dr. Linda Weiss Executive Secretary	Date