

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
DIRECTOR'S CONSUMER LIAISON GROUP**

**Summary of Teleconference
June 30, 2008
1:00 P.M. EST**

DIRECTOR'S CONSUMER LIAISON GROUP

June 30, 2008

**1:00 P.M. Eastern Standard Time
TELECONFERENCE**

Minutes

Members Present

Dr. Beverly Laird, Vice Chair
Ms. Peggy Anthony
Mr. Bill Bro
Dr. Grace Butler
Ms. Lourie Campos
Dr. Yvette Colón
Ms. Kelly Cotter
Ms. Marie Dahlstrom
Mr. Everett Dodson
Ms. Cece Whitewolf

Office of Advocacy Relations Staff

Ms. Shannon Bell, Director
Ms. Barbara Guest, DCLG Executive Secretary
Ms. Brooke Hamilton-Leggin, Program Analyst
Mr. James Hadley, Advocacy Program Manager
Ms. Amanda Woodfield, Presidential Management Fellow

Other NCI Staff

Ms. Anne Lubenow, Special Assistant to the Director
Dr. John Niederhuber, Director

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Welcome

Dr. Beverly Laird welcomed participants to this meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG). She reviewed the rules governing confidentiality and conflict of interest, and Ms. Barbara Guest determined that a quorum was present.

The DCLG unanimously approved a motion to approve the minutes from the DCLG's March 27-28, 2008, meeting.

The DCLG's next meeting will take place on October 14-15, 2008.

NCI Director's Report

Dr. John Niederhuber expressed his appreciation to DCLG members for participating in this call. He projected the following budget-related figures at the end of FY 2008 on September 30:

- R01 grant payline at the 14th percentile
- New investigator payline at the 20th percentile and 220 new investigators funded
- Total grant portfolio of approximately 5,100 grants
- Renewal of 1,283 grants
- 11% of grant budget for exceptions funding (funding for certain applications whose scores did not quite reach the payline)
- A 1% increase in existing grant budgets (in contrast with previous decreases of approximately 2%)

NCI's 2009 budget is likely to be similar to its 2008 budget. This will be the fourth year in a row that NCI's budget will remain essentially flat. Dr. Niederhuber will therefore ask the divisions, offices, and centers to plan a 3% cut in their programs. NCI leaders will then review all Institute programs to determine which ones could be delayed or phased out and which need more resources.

In the past, NCI's Cancer Centers, Specialized Programs of Research Excellence (SPOREs), Cooperative Groups, and Community Clinical Oncology Program (CCOP) have been subjected to the same reductions as NCI's other programs. But this year, their budgets will remain unchanged.

NCI is continuing to work aggressively on implementing the Clinical Trials Working Group (CTWG) and Translational Research Working Group (TRWG) recommendations. In particular, NCI is trying to strengthen its ability to conduct translational research.

Scientists today are increasingly characterizing their patients to identify specific mutations in targets within the tumor and its microenvironment and identify changes that could be "druggable." In the future, tumors will be carefully matched with agents that address a specific defect. This will require a different approach to the initial phases of clinical research. NCI is holding a meeting of the Health Policy Forum, an Institute of Medicine committee, to begin discussing some the changes needed in the nation's clinical trials infrastructure.

NCI recently held the first annual meeting of the NCI Community Cancer Centers Program (NCCCCP) pilot program. The level of enthusiasm and commitment was high. Dr. Niederhuber praised the hospital CEOs and physicians who are finding new ways to work together in the centers, as well as the NCI staff that facilitates the project and the evaluation team that is studying the pilot's impact. Dr. Niederhuber senses great optimism and excitement about creating a more permanent, long-term program that interfaces the activities of the NCI research community with those of the local community in which patients receive their care.

Discussion

Dr. Laird attended the NCCCCP and also witnessed the high level of excitement and commitment among participants. Dr. Niederhuber commented that when he met with the CEOs, they reported that physicians in non-cancer fields now want to emulate the multispecialty approach to cancer treatment that the NCCCCP sites are using. Thus, the program is clearly having an impact not only on cancer treatment in the community but also on the treatment of other diseases.

Dr. Grace Butler asked about plans to expand the NCCCCP. Dr. Niederhuber replied that NCI will begin considering how to make this a more permanent program in the near future. This program has already demonstrated the importance for NCI of working not only with academic research centers but also with local community physicians, nurses, and patients. Dr. Niederhuber hopes that the pilot sites will invite their congressional leaders to visit their sites and share their enthusiasm.

Dr. Niederhuber thanked the departing DCLG members for all they have done for NCI: Ms. Peggy Anthony, Ms. Lourie Campos, Ms. Nancy Davenport-Ennis, Ms. Cece Whitewolf, Mr. Bill Bro, and COL Jim Williams. Dr. Niederhuber and Dr. Laird commented that their departure from the DCLG does not mean that they will not continue to hear from NCI.

Office of Advocacy Relations (OAR) Update

Ms. Shannon Bell reported that the Office of Advocacy Relations (OAR) is working with the National Institutes of Health (NIH) on an implementation process for the NIH Research, Condition, and Disease Categorization (RCDC) system that will support dissemination of the best data to lay and scientific communities. At the same time, OAR is working to improve NCI's coding and reporting systems to ensure that they continue to address community needs and increase transparency.

Over the past 3 months, Ms. Bell has met with representatives of several Professional and Advocacy organizations. For example, she met with several groups at the American Society of Clinical Oncology (ASCO) meeting in Chicago. She hopes to continue to broaden the circle of people who are familiar with NCI and OAR. Ms. Bell has also been meeting with representatives of NCI's divisions, offices, and centers to learn what they do and educate them about OAR.

The NIH is drafting a report to suggest ways in which peer review can be enhanced. The document does not describe NCI's use of advocates in its peer review process. Ms. Bell met with

Dr. Lawrence Tabak, who chairs this effort, to discuss this issue. Dr. Tabak agreed to include information on NCI's inclusion of advocates in peer review in the "final draft" report.

OAR is currently working with the Division of Cancer Treatment and Diagnosis to identify appropriate advocates for the division's fall translational research meeting. OAR is also ensuring that advocates are represented appropriately at the meeting.

OAR is working with the Division of Cancer Control and Population Sciences to identify advocates who can help translate complex proteomics and biospecimen topics for lay audiences. This effort is part of a project that is developing a survivorship model for prostate and colorectal cancer.

OAR recently rolled out a new advocacy portal on the NCI website at <http://www.cancer.gov/aboutnci/servingpeople>. OAR plans to make this site more robust and useful in the future. The office will ask DCLG and other community members for input on the site and additional topics that should be addressed.

Discussion

Dr. Yvette Colón commended OAR and NCI for the Science Serving People website. She particularly appreciated the "Real People, Real Stories" feature and wondered how advocates could help expand this section. These kinds of stories help humanize NCI and make it more accessible by highlighting the people who benefit from NCI's research.

Ms. Bell invited the DCLG to submit their stories and ideas on this section as well as the rest of the site. Expanding the Real Stories section will benefit both the external and internal communities.

Central Institutional Review Board (CIRB) Update

Dr. Laird reminded the DCLG of the presentations at the March DCLG meeting from Mr. Mike Katz and Dr. Jeff Abrams on NCI's CIRB. During his presentation, Mr. Katz reported that the Eastern Cooperative Oncology Group (ECOG) was recommending that NCI reverse its decision to withhold Cancer Therapy Evaluation Program (CTEP) approval for multi-center clinical trial protocols pending CIRB approval.

Mr. Everett Dodson is a member of ECOG's patient advisory board. He represented the DCLG at a meeting with Ms. Bell and CTEP staff to address some of the issues raised by Mr. Katz, who had argued that delays associated with the CIRB, was harming patients. CTEP staff had several questions about the data that Mr. Katz presented. Ms. Bell sent Mr. Katz a letter requesting more specifics on his data. Mr. Katz's response will be available shortly, and the group will meet again in mid-July. At that time, the group should be able to submit enough data for the DCLG to develop recommendations on the CIRB for the NCI Director.

Ms. Bell hopes to determine when the CIRB ceased being a pilot program and the endpoints and measures of success used to determine whether to continue the CIRB. Dr. Niederhuber is anxious to hear the DCLG's thoughts on the CIRB.

Advocates in Research Working Group (ARWG) Update

Ms. Kelly Cotter reported that the ARWG has completed its first phase. Phase II will include an analysis of advocate involvement across NCI and the development of recommendations to involve advocates more effectively. Phase III will focus on writing a report summarizing the group's findings and recommendations.

One of the first steps in Phase II was the addition of several NCI staff members and community partners to the working group. The number of working group members has increased from 20 in Phase I to 42 members and alternates in Phase II. The ARWG held an orientation session for new members on June 19. The group plans to finish Phase II by October 2008 and Phase III by March 2009.

Ms. Cotter thanked Dr. Laird for presenting a poster on the ARWG at the American Association for Cancer Research (AACR) meeting. The poster generated substantial interest and feedback from the community.

Recommendations Working Group

Ms. Barbara Guest reported that the DCLG formed a Recommendations Working Group to refine the list of draft recommendations for the NCI Director. One of these recommendations will focus on clinical trials.

Dr. Laird commented that the draft recommendations are probably ready to be submitted to the full DCLG. The recommendations address concerns about populations that are routinely excluded from clinical trials due to comorbidity, age, or other factors. The draft recommendation on clinical trials proposes that NCI develop strategies to include people in its trials unless a strong medical reason exists for excluding them. More inclusive clinical trials will generate more generalizable results.

Dr. Butler emphasized the importance of rewarding investigators who take steps to increase accrual rates for disparate populations and those with comorbid conditions. This would motivate other investigators who have not yet made efforts in this area. Dr. Laird agreed that NCI should institutionalize rewards and incentives for increasing accrual of populations that are often excluded from trials.

Ms. Guest will distribute the recommendation to the DCLG for feedback. The group will then discuss the recommendation at its October meeting. To facilitate the integration of comments on the document, OAR will develop a wiki site. DCLG members will receive a username and password to access the site. They will be able to post their own comments, view the comments of others, and respond to other people's comments.

Dr. Butler asked for more information on NCI's prevention and survivorship trials. Dr. Laird suggested including a session on these types of trials at the DCLG's October meeting. Ms. Marie Dahlstrom suggested that the proposed clinical trials presentation also address access to trials for people who are uninsured or underinsured.

DCLG Member Reports

National Cancer Advisory Board (NCAB)

Dr. Cólón is the DCLG's representative on NCI's NCAB, which advises Dr. Niederhuber on grants and other NCI activities.

During the June meeting, the NCAB discussed the NIH RCDC system, which categorizes all investment in biomedical research in all Institutes. NIH developed this system in response to the NIH Reform Act, which requires that NIH establish a uniform coding system for all of the agency's grants. However, NCI was mandated many years ago to develop its own system for coding and reporting on research grants. NCI's system uses different categories from the NIH RCDC system. For example, the RCDC includes only 16 cancer categories.

Currently, if 60% of an NCI grant's budget supports pancreatic cancer research and the remaining 40% supports colorectal cancer research, NCI would report that 60% of the funds support pancreatic cancer research and 40% support colorectal cancer research. However, the RCDC system would record the budget for this grant as 100% for pancreatic cancer and 100% for colorectal cancer.

NCI would like to establish dual levels of reporting for 3 years until the RCDC system adds all of the NCI categories. However, NIH is proposing that the dual reporting period be limited to 1 year.

If the NIH system does not report all categories of NCI funding, this will limit the amount of information available to advocates on the types of research supported and the amount of money spent on different types of research. Dr. Cólón suggested that the DCLG create a statement of support for the 3-year dual system and offered to prepare the first draft.

NIH has archived its RCDC webinar on the NIH website. Dr. Cólón offered to share the link for this webinar with other DCLG members.

Ms. Anne Lubenow requested the DCLG's assistance in informing advocacy organizations about the upcoming changes in the NIH coding system and the plan to maintain two coding systems for NCI and NIH.

NCCCCP Annual Meeting

Dr. Laird reported that the NCCCCP pilot program has been operating for a year now and the excitement level continues to be high. The Advocacy Subcommittee met during the annual meeting, and all of the sites are interested in the free resources offered by community

organizations. The NCCCP will develop an advocacy page on the project's website; this page will offer links to no-cost community resources. The sites also appreciated the visits from Mr. Bill Bro, who has posted videos of his visit on YouTube.

Cancer Survivorship Conference

Ms. Lourie Campos reported that the Cancer Survivorship Conference offered by NCI's Office of Cancer Survivorship was very successful. Advocates attended all sessions, participated in the plenary sessions, and stayed after the conference to discuss what they had learned. All of the breakout sessions Ms. Campos attended included a survivor in the panel, and their stories were very compelling.

Public Comment

No public comments were provided.

Closing

Dr. Laird closed the meeting by commenting that the DCLG will miss the members who are leaving. She promised to stay in touch with the departing members.

Certification

I hereby certify that the foregoing minutes are accurate and complete.

Date

Chair, Director's Consumer Liaison Group

Date

Executive Secretary
Director's Consumer Liaison Group

DIRECTOR'S CONSUMER LIAISON GROUP

ACTION ITEMS

1. DCLG members will submit their feedback on the Science Serving People website (<http://www.cancer.gov/aboutnci/servingpeople>) to Ms. Shannon Bell.
2. Ms. Guest will distribute the clinical trials recommendations to the DCLG for feedback. DCLG members will provide a prompt response.
3. OAR will set up a wiki site for comments on the clinical trials recommendations.
4. Dr. C3lon will write the first draft of a letter of support from the DCLG for the NCI's proposal to operate dual research coding systems for 3 years.
5. Dr. C3lon will share the link for the NIH RCDC webinar with other DCLG members.