

June 2, 2011

James Doroshow, MD  
Director, Division of Cancer  
Treatment and Diagnosis  
National Cancer Institute

Harold E. Varmus, MD  
Director  
National Cancer Institute

**RE: Public Comment on the Implementation of the Institute of Medicine's Recommendations to Transform the NCI Cooperative Group Program**

Dear Drs. Doroshow and Varmus:

Thank you for taking the time to host leaders from the cancer cooperative group program and the cancer center directors at the Institute on May 16, 2011. Since that meeting, the group chairs, through the Coalition of Cancer Cooperative Groups, have completed and released a public comment in response to the Institute's request for stakeholder input on the Institute of Medicine's recommendations to transform the NCI Cooperative Program. We hereby submit the public comment via enclosure, and welcome further discussions with you during these final days of the comment period.

Group chairs previously endorsed the IOM position through a public comment in September 2010, stating that the recommendations should be implemented *in their entirety*, through reasoned implementation plans. The guiding principles submitted to you today take into account the importance of strong scientific programs as well as the structure and flexibility of the groups to ensure innovation, efficiency and adequate financial support for clinical trials.

In short, the guiding principles are:

**1. Patients are best served by having strong scientific programs**

The re-configuration should enhance the ability of the groups to perform innovative, science-driven clinical trials. To do so, the new review funding criteria for the groups should give the greatest consideration to each group's scientific expertise, followed by what it brings to the network as a whole. This will help ensure that the groups remain focused on improving the outcomes for patients with cancer.

- 2. The cooperative groups will function as an integrated hub for large Phase II and Phase III studies**  
Cooperative groups are connected by their cross-group scientific and administrative interactions. While each possesses unique capabilities, the cooperative groups are best viewed collectively, within the newly integrated network, as the hub for and Phase III and large Phase II studies. The NCI should clearly declare that the re-configured coop group system is its major vehicle for performing large Phase II and Phase III studies within its translational research continuum.
- 3. Flexibility is required to maximize the potential of the restructured system**  
The cooperative groups are in the process of restructuring, and once consolidations are complete, the groups will look different from one another based upon their need to preserve and enhance areas of scientific and functional expertise. The new federal guidelines for grant review should allow groups to make their own decisions about the formation of their structures—scientifically and operationally.
- 4. The strong membership culture of the groups is worth preserving**  
The cooperative groups are member driven networks, which engender a culture of team science, commitment and volunteerism across three core areas of membership: cancer centers and academic sites; Community Cancer Oncology Programs (CCOPs), Minority-Based CCOPs and other community based practices; and patient advocates involved in research. The new review criteria should reward their strong membership culture.
- 5. The study review process should incentivize scientific innovation**  
In the area of scientific proposal review, we agree that extramural peer review facilitated by the NCI should be employed in assessing scientific proposals, and in helping to define the strategic landscape for a given malignancy. The steering committee approach is in varying stages of development and implementation across diseases; this approach should be evaluated primarily for its ability to encourage and incentivize scientific innovation. The entire concept of task forces should be reconsidered. We are developing a white paper discussing the Steering Committee process and its optimization.
- 6. The viability of the new cooperative group hub is linked to its critical resource needs**  
While it is widely known, accepted, and acknowledged by the IOM report that the cooperative group system is grossly underfunded, we also recognize the enormous economic challenges that face our nation. Unfortunately, the crisis in the economy occurs at a time when we are all committed to re-thinking how we operate and work together to enhance the opportunities for patients to participate in innovative ground-breaking clinical trials. As funding priorities within the NCI, NIH, and the federal government are assessed; it is still important to define the critical needs: a) increase in per-case reimbursement; b) increase in the number of U10 grants; c) adequate investigator compensation for their scientific participation in the groups; d) a common IT platform; e) robust biorespository system made available for peer-reviewed research; and, f) an IT platform to link all group biorespositories aka a *virtual biorepository*.

**7. Multi-sector involvement generates funding and science that would not otherwise happen**

The groups bring significant incremental resources to the publicly funded system. Aside from the increased levels of funding defined above, the federal guidelines must continue to provide the flexibility for the cooperative groups to seek and maintain multi-sector funding relationships. These relationships provide a critical financial supplement to the federal funding, in support of NCI-approved clinical and laboratory based studies.

**8. Applicants for cooperative group funding should possess *Essential Characteristics***

The purpose of the new federal funding guidelines should be to produce excellence in science and ensure groups remain focused on improving the outcomes for patients with cancer. To do so, we recommend that applicants to the upcoming funding opportunity possess certain *Essential Characteristics*.

The cooperative group chairs appreciate the opportunity to enter the attached full public comment for consideration by the various NCI committees and the National Institutes of Health review bodies. These guidelines are widely available to the public at [www.CancerTrialsHelp.org](http://www.CancerTrialsHelp.org). Individual cooperative groups have distributed the document to our membership bases and have posted it on our web sites as well.

Sincerely yours,

**Mitchell D. Schnall, MD, PhD, Chair**  
American College of Radiology Imaging Network

**Philip J. DiSaia, MD, Chair**  
Gynecologic Oncology Group

**Heidi Nelson, MD and David Ota, MD, Co-Chairs**  
American College of Surgeons Oncology Group

**Norman Wolmark, MD, Chair**  
National Surgical Adjuvant Breast and Bowel Project

**Monica Bertagnoli, MD, Chair**  
Cancer and Leukemia Group B

**Jan C. Buckner, MD, Chair**  
North Central Cancer Treatment Group

**Peter C. Adamson, MD, Chair**  
Children's Oncology Group

**Walter J. Curran, Jr., MD, Chair**  
Radiation Therapy Oncology Group

**Robert L. Comis, MD, Chair**  
Eastern Cooperative Oncology Group

**Laurence H. Baker, DO, Chair**  
SWOG

Attachment

CC w/Att.: Linda Weiss, PhD  
Jeffrey Abrams, MD  
Meg Mooney, MD