April 17, 2013

Sandra Swain, MD, FACP  
President  
American Society for Clinical Oncology  
2318 Mill Road, Suite 800  
Alexandria, VA 22314

Dear Dr. Swain:

Thank you for your letter dated April 11th and for your interest in the proposed NCI Community Oncology Research Program (NCORP). It was a pleasure to present NCI’s thinking and goals for NCORP in the public forum sponsored by the Institute of Medicine’s National Cancer Policy Forum and the American Society of Clinical Oncology. NCI is very committed to designing a successful program that continues to provide access to cancer research in the community setting during a challenging yet exciting period for our health care system and cancer care, in particular.

Since April of last year, NCI has received substantial valuable input from all components of the two existing community programs, the Community Clinical Oncology Program (CCOP), Minority-Based CCOP (MB-CCOP), the Research Bases for prevention and cancer control (Cooperative Groups and Cancer Centers), and the NCI Community Cancer Centers Program (NCCCP). As we explained at the Institute of Medicine Meeting in February, we reiterate that clinical trials will continue to be the foundation of our clinical research program and that NCORP will be designed to commit the majority of its funding to support the clinical trials network as it adapts to various organizational changes to meet the challenges of a new generation of clinical trials, emphasizing trials that incorporate molecularly targeted therapies and genomics.

Expanding the scope of research in community practice to include cancer care delivery research has been driven by a desire to sustain and expand upon the historical strengths and successes of the existing programs. We are encouraged that continued dialogue since the February 13th meeting has helped to allay some of the questions and concerns about NCORP. Likewise, we are pleased you have recognized in your letter our extensive efforts to engage constituencies in the cancer research and clinical care community. One of the critical goals of proposing cancer care delivery research in the community setting is the development of research questions that are of clinical importance to today’s oncology practices in the context of a dynamic healthcare delivery system. Many of NCI’s funded community practice sites are undergoing mergers with hospitals and other corporate entities. Moving molecularly targeted therapies into community settings is complex and may require new system supports to assure optimal delivery. These organizational and practice changes reflect only a snapshot of the challenges imposed by many factors, including policy, economics, and advances in medicine.
In order to effectively integrate cancer care delivery into community practices, we believe that all performance sites should participate in CCDR in order to make sure the network of research sites reflect the diversity of organizational arrangements characteristic of oncology practice in our country. However, in order to assure that this new scope of work does not detract from the need to maximize accrual to clinical trials, NCORP will offer considerable flexibility to sites in attaining this goal. For example, our proposal requires that applicants only propose a minimum of one performance site to participate in CCDR. However, additional performance sites within an applicant’s network certainly would be encouraged. Additional opportunities would be available to sites that either have experience with or a demonstrated capacity to address a broader scope of cancer care delivery research while still meeting all requirements to support clinical trials. Importantly, funds supporting cancer care delivery research in this program will come from new sources of funding not associated with the current CCOP, MB-CCOP, or Cancer Prevention and Control Research Base programs.

We have learned from the current CCOP program that maximizing the diversity and commitment of oncology practices within the existing community programs is essential to building new science into community settings. For example, during the earlier years of the Community Clinical Oncology Program Network, NCI collaborated with the community sites and researchers to introduce cancer control and symptom management into the community practices. Today, we are proud to say that the expansion into this area of research has been very successful. It did require modifications of the existing infrastructure for treatment and a culture change among both the patients and physicians, but the payoff was large. We anticipate that a similar process is needed and will take place as cancer care delivery research is introduced into community practices, but only if the program addresses these challenges within at least one component of each member network.

The CCOP Network Research Bases have unanimously and enthusiastically agreed to support the inclusion of CCDR into NCORP. The Research Bases will modify existing infrastructure and bioinformatics support to encompass the conduct of CCDR. Cancer care delivery research is already being conducted and implemented through CCOP/MBCCOP and NCCCP sites. For example, one active study conducted by the Division of Cancer Prevention’s SunCoast Research Base is a cluster randomized controlled trial comparing interventions to enhance utilization of genetics services among breast cancer patients among community oncologists. A goal of this study is to evaluate to extent to which there is adherence to existing guidelines and implementation of appropriate genetic testing outside of academic settings. The scope of cancer care delivery research provides an opportunity for experts in this area within and outside of the Research Bases to develop questions that are feasible and appropriate for practices with a variety of capacities, involving small practices and well as larger distributed practices or integrated health systems. The NCORP concept will include a comprehensive portfolio analysis of cancer care delivery research for its approval and inclusion in the Funding Opportunity Announcement.

NCI is committed to developing a program that will be successful and include adequate resources to support clinical trials and cancer care delivery research in community settings. As noted in our presentations and in our calls with a broad range of stakeholders, we are structuring the funding to be consistent with the goal that clinical trials continues to be the foundation of our clinical research program in community settings and by proposing additional and dedicated funds for CCDR. Maximum flexibility will be available to community sites to structure their contributions to CCDR, which we believe will enable them to preserve and enhance network arrangements to support clinical trials.

Again, thank you for your thoughtful comments and your continuing commitment to clinical research through NCI programs.
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cc: Harold Varmus, MD
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