STRATEGIC ISSUES AND PRIORITIES FOR THE COMMUNITY CLINICAL ONCOLOGY PROGRAM AND

THE MINORITY BASED COMMUNITY CLINICAL ONCOLOGY PROGRAM

November 2010

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Strategic Issues and Priorities for the Community Clinical Oncology Program and the Minority-Based Community Clinical Oncology Program

November 2010

The Community Clinical Oncology Program (CCOP) was designed 27 years ago to engage community physicians in National Cancer Institute (NCI) clinical trials and thus improve the incorporation of the research results into practice. The program was envisioned as a network that would participate in cancer treatment clinical trials and be ready to participate in and lead the way for innovative cancer prevention and control strategies. The Minority-Based Community Clinical Oncology Program (MB-CCOP) was developed as a means to provide a similar structure for clinical trials in those institutions that serve large minority and underserved communities.

The CCOP and MB-CCOP programs have demonstrated substantial success in developing local clinical research infrastructures, accruing significant numbers of cancer patients onto cancer treatment clinical trials and implementing several very large-scale cancer prevention clinical trials. The MB-CCOP program is now almost 20 years old, and is the program with the highest concentration of minority participants accrued onto NCI-sponsored clinical trials.

The CCOP Network has worked very well, but now, cancer research is poised for significant change. The drive to translate genomic information into medical practice is changing how scientific concepts are moved into practical reality. Consequently, the design of cancer clinical trials is getting more complicated. There is a need to collect tissue, analyze markers, and develop trial designs that are often difficult to explain to patients. At the same time, the regulatory requirements for the ethical conduct of research, which protect clinical trial participants, can be daunting for experienced investigators and may overwhelm the new community investigator.

In this setting, a strategic planning process was established to explore issues that need to be addressed to ensure the CCOP and MB-CCOP programs continue to successfully contribute to the NCI mission. Extramural investigators were brought together in person and by conference call to discuss specific questions related to

research priorities, programmatic structure to facilitate the research, and enhancing the inclusion of underserved populations.

Mission

The CCOPs and the MB-CCOPs are a community-based clinical trials network, which brings academic investigators (through the Research Bases) together with community physicians to conduct scientifically important and clinically meaningful clinical trials that result in better care for cancer patients and persons at risk for cancer. The MB-CCOPs brings the CCOP structure to communities with greater than 40 percent minority cancer populations to facilitate the inclusion of underserved populations in the same clinical trials.

Strategic Goals

- Incorporate emerging science and novel trial designs into cancer prevention and control research
- Maximize community resources to conduct complex clinical trials (both cancer prevention and control
 and cancer treatment trials)
- Use epidemiological and biological data from under-represented populations in clinical trials to address disparate clinical outcomes
- Improve clinical trial access and participation among populations under-represented in cancer clinical research
- Build on the success of the CCOP/MB-CCOP programs to further improve the ability of community institutions to accrue patients to clinical trials

Incorporate Emerging Science and Novel Trial Designs in Cancer Prevention and Control Research

The CCOP network provides a stable infrastructure for the design and conduct of NCI-approved cancer prevention and control clinical trials. The Cooperative Groups and Cancer Centers are competitively funded as CCOP Research Bases to develop a portfolio of cancer prevention and control trials that is commensurate with its scientific interest and expertise. The breadth and scope of the research portfolio includes prevention, screening and early detection, pain control, symptom management, toxicity mitigation, and quality of life. The CCOPs and MB-CCOPs have demonstrated its ability to enroll large and varied populations, to obtain tumor and host DNA, and to record the outcomes following standardized interventions.

The ability of the network to conduct trials that span the spectrum of the cancer care continuum provides the opportunity to utilize the trials to validate basic science concepts and evaluate novel strategies and interventions. For example, there has been considerable success in the conduct of phase III cancer prevention trials, with two large trials leading to Food and Drug Administration indications. However, with limited resources for conducting large-scale trials in the general population, efforts should be encouraged to identify high-risk populations in which to study cancer prevention interventions.

The cancer control portfolio has grown during the past decade, due mainly to an emphasis on symptom management and treatment-related toxicity reduction. Many of these trials address common cancer-related symptoms, toxicities resulting in functional impairment, and cancer treatment dose-limiting toxicities. Patients and physicians require this acute and chronic toxicity information to better define the patient's individual risk-benefit ratio.

Often commercially available and investigational agents are used to evaluate symptom treatment. Existing data are limited on treatment toxicities and symptom biology. Now, many of the newly targeted agents have unique toxicities differing from those of cytotoxic chemotherapy, and many are in oral formulations.

Therefore, evaluation of these new and existing toxicities will be ongoing, and knowledge about their pathophysiology will accelerate the development of rational therapeutic or prevention approaches.

Evaluation of chronic toxicities is particularly important, as there are now more cancer survivors, often living with functional impairment from chronic toxicities. Research on ameliorating the toxicities and reducing the development of these toxicities is of high importance to the CCOPs, MB-CCOPS and patients. Cancer survivorship research encompasses cancer care issues, including the assessment of acute, late, and chronic toxicities; long-term quality of life; disease recurrence; and second malignancies. Therefore, the CCOP Research Bases have a broad range of topics to study at any time point in the cancer continuum.

In addition, the CCOP Research Bases are funded to collect Health-Related Quality of Life in association with treatment trials. This research has helped refine the understanding of cancer treatment-related toxicity. It also provides a means to determine patients' functional status. However, the reporting of Quality Of Life data is not currently linked to clinician reporting of adverse events. NCI has initiated the development of a system to collect real-time patient reporting of adverse events on clinical trials. Studies to validate real-time patient reporting of adverse events are under development.

The following recommendations are designed to address the need to incorporate scientific advances and new technologies into clinical practice:

- 1. Develop and enhance survivorship research, specifically focusing on the time after treatment completion.
 - a. Support longitudinal studies to understand the natural history of toxicities and to identify and evaluate symptoms toxicities, and other survivor-specific concerns.
 - b. Support biospecimen collection for pharmacogenetics and other means to predict chronic toxicities.
 - c. Develop research on the etiology of treatment-related toxicity and interventions, with a goal of preventing long-term toxicity.
- 2. Enhance research on acute treatment toxicities and cancer symptoms.
 - a. Focus research on the mechanisms of treatment-related toxicity and cancer symptoms to inform toxicity and symptom mitigation strategies, with a goal of preventing long-term toxicity.
 - b. Support research regarding compliance with oral cancer therapeutics.
 - c. Develop and validate patient-reported outcomes measures for toxicities and symptoms, especially with new target agents and biologics.
 - d. Facilitate the integration of patient-reported outcome measures with biomarker studies.
- 3. Foster research on risk assessment and risk modeling for cancer prevention and early detection.
 - a. Support validation studies of novel markers for early detection of cancer in general and high-risk populations.
 - b. Focus on research regarding risk assessment and prevention strategies for ductal carcinoma in situ.
 - c. Support validation studies of cancer risk models in different populations.
 - d. Support studies in communication of cancer risk, especially for patients' families.
- 4. Develop funding mechanisms for correlative studies in association with clinical trials in cancer prevention and control.
- 5. Foster relationships with basic science researchers in cancer prevention and treatment as well as basic science researchers in other areas pertinent to toxicities and symptoms.
 - a. Collaborate with SPOREs to facilitate the development of phase II and III cancer control and prevention trials.

- Collaborate with early drug development consortia to facilitate clinical trials related to toxicity mitigation.
- c. Collaborate with investigators in other National Institutes of Health institutes in areas pertinent to cancer treatment-related toxicities.
- 6. Develop mechanisms to encourage training for young and mid-career cancer prevention and control investigators within the CCOP Research Bases and other academic centers.
 - a. Encourage applications to NCI and other existing program, which sponsor cancer research and training awards.

Maximize Community Resources to Conduct Complex Clinical Trials (Treatment and Cancer Prevention and Control)

The commitment of the local physicians and hospitals and the additional resources they bring to the CCOP structure has been substantial. Most CCOPs and MB-CCOPs bring resources and funding equivalent to 80 percent of its grant funding to the research activity. However, the potential changes in health care reform and the complexity of the trials pose new issues in how community sites can continue to participate in clinical trials and, ultimately, to incorporate the successful strategies and treatments into practice.

While the full effect from the changes in physician and practice reimbursement are yet to be realized, there are concerns about the sites' continued ability to provide additional resources and funding to the conduct of NCI clinical trials. In addition, the actual work required to be fully compliant with the ethical conduct of clinical research is increasing and becoming more complex. The community physicians fully support the standardization of data collection, tissue collection, auditing, and the development of systems for electronic reporting. There is acknowledgement of the complexity of the clinical trials and an awareness of the importance of tissue collection.

The following recommendations for modifications to the programmatic structure are designed to address the need for additional resources at the community institutions in order for them to fully participate in the more complex trials that are actively under development:

- 1. Develop supplemental funding for biospecimen collection:
 - a. Funding would be for tissue collection in conjunction with ongoing clinical trials.
 - b. Provide funding for pathologist or interventional radiologist.
 - c. Provide funding for qualified personnel to collect, process and ship tissue specimens.

- 2. Develop a new funding model to support the true level of effort and incorporate more flexibility:
 - a. Give higher credit for more complex studies. Complexity encompasses specimen collection, added testing to determine eligibility, complicated consent forms, interventions and assessments requiring excess staff time, trials requiring coordination of various disciplines, studies with high potential for toxicity, and the need to contact former patients no longer seen routinely, among other things.
 - Provide funding for screening particularly for trials in which subjects are pre-enrolled pending eligibility-based research testing results.
 - i. Provide funding for individual site tracking/documentation of screened potential clinical trial participants including, predetermined/consistent demographic and disease information.
 - c. Allow a greater level of effort for the Principal Investigator than 15 percent.
 - Encourage multiple PI or other diversified PI models to allow more community physicians to share in the research and oversight.
 - ii. Permit level of effort for leadership of CCOP/MB-CCOPs to be proportional to accrual.
 - d. Provide funding proportional to CCOP/MB-CCOP accrual for:
 - i. Investigational pharmacists
 - ii. Regulatory staff
 - e. Fund work of IRB in cases where accrual is likely to be low.
 - f. Evaluate the expansion of CCOP/MBCCOP performance sites to encompass non-oncology practices.
 - g. Develop incentives for CCOP sites to mentor young investigators.
- 3. Encourage standardization and improve efficiency across the Network:
 - a. Ensure that NCl's plans for developing common data and tissue collection forms and an electronic reporting infrastructure work well in the CCOP network.
 - b. Improve the efficiency of audits for CCOPs and MB-CCOPs by conducting cross-group audits for all their affiliated Research Bases on a prescribed timeframe (e.g. yearly).
 - c. Explore the use of NCI's Central IRB as the official IRB of record particularly as it pertains to rare cancers.
 - d. Encourage Research Bases and/or the CTSU to develop and provide Web-based training for CCOP/MB-CCOP staff in regulatory matters, protocol-specific requirements, and clinical trials design and conduct.
 - e. Facilitate drug distribution for cancer control studies.

- 4. Develop a process to address those issues related to the changing health care environment that influence community practices and participation in clinical trials.
 - a. Consider modifications to the CCOP eligibility criteria.
 - b. Engage top hospital management in a continuing dialogue regarding the role and importance of clinical trials.
 - c. Recognize and acknowledge the support from grantee institutions and promote the CCOP structure nationally.
- 5. Provide support to, or partner with, professional organizations to develop mentorship programs for community physicians to participate in clinical trials.
- 6. Foster collaboration with the NCI Office of Communications and Education and other applicable resources to enhance efforts to provide specific tools to communities on the value of clinical trials.
- 7. Address the potential overlap of activities with other NCI community programs.

Use Epidemiological and Biological Data from Under-represented Populations in Clinical Trials to Address Disparate Clinical Outcomes

The CCOP network's scope of work contributes directly to NCI's efforts to reduce and eliminate the unequal burden of cancer. The MB-CCOP is at the helm of increasing NCI's understanding of how new agents, trial designs, and technologies are disseminated and implemented in underserved and under-represented populations in clinical trials. The NCI has identified under-representation in clinical trials among several groups, including the elderly, adolescents, rural populations, lower socioeconomic status, and racial/ethnic minorities. Rapid changes in demographics throughout the United States present significant challenges to cancer care providers in their efforts to provide state-of-the science cancer care to underserved populations.

The following recommendations are designed to increase the CCOP, MB-CCOP and Research Base scientific contributions to reducing cancer care disparities.

- 1. Apply current and emerging science to identify and address research questions in under-represented populations.
 - a. Develop a process by which disparities in cancer outcomes can be communicated and incorporated into the design of clinical trials.

- b. Explore research collaborations with existing NCI programs and organizations to collect tissue from sites with under-represented groups in order to perform molecular characterizations of the predominant tumors in their respective populations.
- c. Determine particular barriers to clinical trial participation for under-represented populations and conceptualize interventions targeting these barriers (especially for newer trial designs).
- 2. Develop a trans-disciplinary working group to design pilot studies, which are nested within or independent of parent trials in order to evaluate the effect of interventions such as less stringent eligibility criteria for early and late stage cancers.
- 3. Promote cancer risk assessment of individuals in underserved communities.
 - a. Support the development and validation of new and existing cancer risk tools for specific race and ethnic populations.
 - b. Utilize these risk assessment tools to facilitate improved cancer prevention, screening, and clinical trial design for minority and underserved populations.

Improve Clinical Trial Access and Participation among Populations Under-represented in Cancer Clinical Research

The Minority Based CCOP has been instrumental in accruing racial and ethnic minorities and the underserved onto NCI-sponsored clinical trials. The MB-CCOPs contribute over 33 percent of the overall minority recruitment for all trials in the CCOP Network and 44 percent of minority recruitment to cancer prevention and control trials. Increasingly the entire CCOP network shares more of the challenges within the MB-CCOP institutions. However, the complicated referral patterns, diminishing institutional support and current economic conditions have enormous influences on the institutions serving minorities and the underserved populations.

The following recommendations are designed to sustain the network's goal of providing access to NCI clinical trials in under-represented communities while accommodating the needs, changes, and challenges of the current health system:

 Consider broadening the eligibility requirements for the MB-CCOPs to allow institutions that do not meet current criteria of 40 percent cancer patients from minority populations, but serve populations in need.

- 2. Facilitate language translation at the NCI and local institutional levels. Include language translation into the institution's budget to support local needs.
 - a. Ensure all clinical trial materials are available in Spanish.
 - b. Provide funds for local institutions to do translations appropriate to its populations.
 - c. Identify appropriate tools for communicating cancer-specific information to a variety of different populations.
- 3. Implement a plan for assigning CCOP credit for screening cancer patients and at-risk individuals for clinical trials, including screening within non-oncology practices, which serve underserved populations.
 - a. Include CCOP credits for screening of at-risk individuals within non-oncology practices to improve access to cancer control and prevention clinical trials in underserved communities and to establish sustainable relationships with those health care providers
- 4. Develop recommendations/guidelines for publications to contribute to the literature regarding accrual of the minorities and underserved populations.
- In conjunction with developing the flexible-funding model, review the accrual requirements for the MB-CCOPs, and consider differential accrual requirements for different community organizations.
- 6. Develop an effective model to incorporate patient navigation into the MB-CCOP/CCOP infrastructure.
- 7. Increase diversity in the workforce within the clinical trials infrastructure by collaborating with other organizations, which offer training support.
 - a. Develop a plan that would support the community-based sites as a training ground for cancer care providers (CRAs, oncology trainees and faculty/community practicing physicians).

Build on the Success of the CCOP/MB-CCOP Programs to Further Improve the Ability of Community Institutions to Accrue Patients to Clinical Trials

The CCOP and MB-CCOP programs have a long history of contributing patients to NCI-sponsored clinical trials, averaging 30 percent of the total enrollment to treatment, prevention, and control trials. This history can be attributed to the stable workforce of highly experienced and accomplished community investigators. The success of the four major prevention trials has led to the recognition of the program's leadership in clinical trial accrual, particularly accrual of underserved populations. In the context of today's changing

clinical trials arena and shifting US populations, the program will need to leverage current successful strategies and identify new approaches in order to maintain and broaden its accrual efforts and goals.

The following recommendations are designed to address the new challenges and opportunities facing community organizations that participate in NCI sponsored clinical trials:

- 1. Develop Best Practice Accrual Guidelines for the CCOP and the MB-CCOP Programs.
- 2. Systematically collect and maximize use of data in CCOP/MB-CCOP progress reports on patients screened for clinical trials including reasons for ineligibility, patient refusal, and other barriers.
- 3. Develop a process to rapidly identify and address clinical trials with lagging accrual.
- 4. Encourage the development of correlative studies that address accrual in trials that may pose challenges due to patient concerns, staff workload, the complexity of the trial, and the targeted patient population.

Appendix 1: Overview of the Planning Process

The NCI's Community Clinical Oncology Program (CCOP) is funded through a Request for Applications (RFA). As an ongoing program, it is required to periodically come to the NCI Board of Scientific Advisors for review and approval. In preparation for the November 2009 review, an External Panel was constructed to provide a current assessment of the program. A four-member panel was formed, and found the program to be highly successful. A major recommendation of the External Review panel was for the CCOP Program to initiate a "strategic planning process" to identify how the overall Program can best proceed to meet the anticipated challenges and opportunities of the future. On November 2, 2009, the Board of Scientific Advisors approved the RFA re-issuances and fully endorsed moving forward with the "CCOP Strategic Plan."

On November 12, 2009, the CCOP Program held an one-day staff retreat to create a framework for the "plan" development.

Three areas were identified as critical to developing a strategic plan:

- CCOP infrastructure
- Scientific research priorities, including scope and breadth
- Research priorities of access and participation for underserved populations

The next step involved identifying individuals internal and external to NCI to participate in three committees (**Core, Research Priorities, and Underserved Populations**). Committee members were to identify the key issues that must be incorporated into a strategic plan to ensure the CCOP Program's continued viability and value as a mechanism for translation of science into medical practice. The process for soliciting committee membership was a combination of requests for volunteers from the CCOP, MBCCOP, and Research Base memberships as well as invitations to selected individuals who would provide additional expertise outside the extramural CCOP Program membership (See attached committee membership).

The mission of each committee was provided in the request for volunteers and invitations. The number of volunteers was much larger than the committee memberships' could accommodate, so NCI Program staff reviewed all names and identified a cross section of individuals, with the appropriate expertise, to serve on these committees.

The mission of the **Core Committee** was to determine what modifications or revisions needed to be considered to the infrastructure and the science of the CCOP Network. As the science rapidly evolves, it will have an impact on the design of the clinical trials and ultimately, change practice. This committee was tasked with identifying recommendations to the infrastructure and to the science such that the network will conduct clinically relevant, scientifically rigorous clinical trials that will have an impact upon the care of cancer patients and persons at risk for cancer.

The mission of the **Research Priorities Committee** was to assess future scientific priorities and directions for the CCOP Research Bases. In particular, the terminology "cancer control" has encompassed intervention trials in cancer prevention and symptom management. Areas of cancer control research may need to be reframed and consideration given to broadening the scope of the research. Data regarding natural history and mechanisms of symptoms and cancer treatment toxicities need to be obtained. Assessing and understanding cancer risks is needed. The complexity of the clinical trials is increasing with the integration of biomarker validation, risk identification, and correlation with Patient-Reported Outcomes. This committee was tasked to propose priorities for the research to be included under cancer control.

The mission of the **Underserved Populations Committee** was to (1) develop a strategic plan to ensure the CCOP network's infrastructure is adequate for the conduct of current and future research among the underserved; and (2) to ensure a scientific agenda for treatment, cancer control/prevention, and symptom management addresses relevant questions among under-represented groups in clinical trials. Specifically, the committee was asked to determine if the current funding mechanism supports the critical components of existing programs and of potential new applicants during the next decade. Due to rapidly changing U. S. demographics, this Committee will evaluate the eligibility criteria of the MBCCOP to ensure those institutions, which provide care to underserved communities, are not excluded by the current criteria. The committee also helped to identify a plan to better enable Research Bases to integrate research questions from the programs, which service the underserved. Discussions related to the expertise and data needed (i.e. co-morbidities) outside of NCI to ensure the sustainability of the institutions servicing the underserved and to sustain minority accrual were encouraged.

An initial one-day face-to-face meeting of committee members was held in Bethesda, Maryland on May 17, 2010. CCOP Program staff worked with the NCI's Office of Science Planning and Assessment to set the agenda and facilitate the sessions at this meeting to gather input and recommendations from committee members, in both general sessions as well as small group sessions.

In preparation for the meeting, committee members were provided, in advance, with the following materials:

- Report of the External Review Committee, which evaluated the CCOP Program in 2009 for the CCOP RFA re-issuances
- CCOP Program background materials provided to the External Review Committee panel members
- Journal of Clinical Oncology article entitled "Increasing Minority Participation in Cancer Clinical Trials:
 The Minority-Based Community Oncology Program Experience"
- The Institute of Medicine Report "A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program"
- Specific questions for each committee to use to address their assigned mission

Based on group discussions, each committee developed an initial list of high-priority issues to incorporate into the strategic plan.

The one-day meeting was followed by three subsequent conference calls per committee to further discuss, refine, and delineate additional issues, which may not have been identified at the face-to-face meeting.

The committee chairs, with support from a contractor, used the minutes from the face-to-face meeting and committee conference calls to develop the initial draft of the "CCOP Strategic Issues and Priorities" plan. The draft was further refined with review and input from CCOP Program staff and consultations with staff from NCI's Office of Science Planning and Assessment. The final draft plan was circulated to the committee membership for review prior presentation at the CCOP Program's annual meeting of CCOP, MBCCOP, and Research Base principal investigators and administrators.

The draft plan was circulated to registered meeting participants prior to the meeting in preparation for a two-hour plenary session on September 16, devoted to a presentation of the plan elements along with time for comments and discussion. Minutes of this plenary session were used to identify any important issues missing from the draft plan for subsequent incorporation.

The final version of the draft "Strategic Issues and Priorities" document for consideration by the Board of Scientific Advisors was developed per the process as described above.

Appendix 2: Timeline

November 12, 2009 Research Group Retreat – began the CCOP Strategic Planning Process

6701 Rockledge Drive

Bethesda, MD

January 25, 2010 Contractor Support Approved in Work Assignment – to provide writing

and support services for 3 Committees to hold conference calls, and to

provide support for one full in-person meeting

March 23, 2010 Planning Committee Meeting at DCP

May 17, 2010 2010 CCOP Strategic Planning Meeting

NeuroScience Center 6001 Executive Boulevard

Bethesda, MD

May 27, 2010 Underserved Populations Committee Conference Calls

June 23, 2010 July 7, 2010

June 2, 2010 Core Committee Conference Calls

June 22, 2010

June 10, 2010 Research Priorities Committee Conference Calls

June 17, 2010 July 7, 2010

July 13, 2010 Planning Committee Meeting at DCP

September 1, 2010 Planning Committee Meeting at DCP

September 16-17, 2010 Community Clinical Oncology Program — CCOP/MBCCOP and Research

Base Meeting

Doubletree Bethesda Hotel and Executive Meeting Center

Bethesda, MD

October 5, 2010 Planning Committee Meeting at DCP

November 2010 Production of Final Report

Appendix 3: 2010 CCOP Strategic Planning Roster

Division of Cancer Prevention Leadership

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Laurence Baker, D.O.

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William Carpenter, Ph.D.

UNC Gillings School of Global Public Health

Kandie Dempsey, M.S., R.N., O.C.N., CCRP

Christiana Care Health Services, Inc.

Marge Good, R.N., B.S.N., M.P.H., O.C.N.

Division of Cancer Prevention, NCI

Jeffrey Giguere, M.D., F.A.C.P.

Greenville CCOP

Jane Hajovsky

Colorado Cancer Research CCOP

John Kugler, M.D.

Illinois Oncology Research CCOP

Raymond Lord, M.D.

Kalamazoo CCOP

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Underserved Populations Committee Roster

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Luis Baez-Diaz, M.D., F.A.C.P.

San Juan MBCCOP

Andrea Barsevick, R.N., Ph.D., F.A.A.N.

Fox Chase Cancer Center

Debra Barton, R.N., Ph.D., A.O.C.N., F.A.A.N.

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James Bearden, M.D., F.A.C.P.

Upstate Carolina CCOP

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Boston Medical Center (RTOG)

Joe Kelaghan, M.D., M.P.H.

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Stephanie Land, Ph.D.

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Joseph Leach, M.D.

Metro-Minnesota CCOP

Benjamin Marchello, M.D.

Montana CCOP

Michael Method, M.D., M.P.H., M.B.A.

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Jaqueline Vuky, M.D.

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Appendix 4: NCI-DCP Community Clinical Oncology Program (CCOP/MBCCOP) External Review Panel

October 2009

Chair

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