

**MINORITY INSTITUTION/CANCER CENTER PARTNERSHIP
PROGRAM TECHNICAL ASSISTANCE WORKSHOP**

**Westin Hotel
Chicago, Illinois
June 3–4, 2002**

SUMMARY REPORT

Final Draft July 1, 2002

**Minority Institution/Cancer Center Partnership Program
Technical Assistance Workshop**

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Monday, June 3, 2002

The Minority Institution/Cancer Center Partnership (MI/CCP) Program's Technical Assistance Workshop convened at 9:00 a.m. on June 3, 2002, at the Westin Hotel in Chicago, Illinois.

WELCOME AND PERSPECTIVES ON COLLABORATIONS AND PARTNERSHIPS

Welcoming Remarks and Objectives of Workshop—Dr. H. Nelson Aguila, Program Director, CMBB, OCTR, ODDES, NCI

H. Nelson Aguila, D.V.M., Program Director of the MI/CCP Partnership Program, Comprehensive Minority Biomedical Branch (CMBB), Office of Centers, Training and Resources (OCTR), Office of the Deputy Director of Extramural Science (ODDES), National Cancer Institute (NCI), National Institutes of Health (NIH), welcomed participants to the workshop. He presented the following objectives of the workshop:

- To learn about the MI/CCP Program initiatives and to determine what mechanisms are appropriate for participating institutions;
- To learn about successful collaborations between minority-serving institutions (MSIs) and cancer centers (Ccs);
- To learn details about the application process and review criteria for each initiative;
- To discuss other issues relating to the initiative;
- To discuss potential barriers to developing effective collaborations and strategies for overcoming those barriers;
- To meet and network with other individuals interested in developing collaborations and partnerships.

Dr. Aguila reviewed changes to the agenda and the workshop notebook; he also stressed to participants the importance of gaining a thorough understanding of the grant application process.

Opening Remarks—Dr. Brian Kimes, Director, OCTR, ODDES, NCI

Brian Kimes, Ph.D., Director of the OCTR, ODDES, NCI, NIH, welcomed everyone and explained that the MI/CCP has only been in existence for 18 months but already has some active grants that can be used to illustrate how others can become involved. Dr. Kimes provided background on the MI/CCP and explained some of the key principles behind the program.

The CMBB was a small program 4 years ago when three strategies for the CMBB were developed. The strategies included the Continuing Umbrella of Research Experiences that

involved individuals in their training, partnerships with major national societies, and the establishment of the Minority Institution—Cancer Center Partnerships. The NCI concept review of the initiatives that developed from the three strategies was presented to the NCI Board of Scientific Advisors (BSA) more than 2 years ago. Dr. Kimes indicated that the program's progress has been exciting and he anticipates having the BSA support the CMBB initiatives at the next review.

Key principles of the MI/CCP include:

- The partnerships are “true” partnerships, with neither partner serving as a second-rate member.
- There is a mutual benefit for each member of the partnership.
- The projects funded by the MI/CCP are not permanent grants; these are short-term projects that should lead to competitive NIH contracts and grants.

The areas of emphasis for the MI/CCP are cancer research, cancer research training and career development, cancer education, and cancer outreach. A unique characteristic of the MI/CCP grants is that they link a Minority-Serving Institution (MSI) with a comprehensive NCI-designated Cancer Center (CC). This is an opportunity for all MSI's to participate, not just those with medical schools (e.g., Howard University). Success in the program will be defined by the MSI's ability to compete within the NIH system for research funding.

Dr. Kimes reviewed eligibility for participation in the MI/CCP. The three types of grants available through the program are the P20 (exploratory and planning grants), U56 (planning grant for a partnership), and U54 (partnership). Partnerships may have no more than two P20s, one P20 and one U56, or one P20 and one U54 at a time from the MI/CCP. Details on each type of grant, as well as review criteria, will be presented later in the workshop.

Dr. Kimes clarified that an institution that is not a designated NCI CC may apply as a CC if they are structured as a CC (e.g., Emory University, Tulane University).

Questions and Answers

A participant asked if three schools could apply for one partnership grant. Dr. Kimes responded that this may be possible, although there can only be one MIS and one CC on the grant application. The third partner would have to be listed as a subcontractor.

Perspectives from a Cancer Center—Dr. Daniel Nixon, President, American Health Foundation

Daniel Nixon, M.D., President of the American Health Foundation (AHF), New York, commended the MI/CCP for attempting to address health disparities among U.S. minority populations. Cancer risk is much higher in minorities and the poor, and the AHF is charged with working to understand and address these disparities. The AHF is a research foundation devoted to prevention of chronic diseases, including cancer. The AHF is a successful applicant for an MI/CCP P20 grant, in partnership with the City University of New York (CUNY), the MSI

partner for the grant proposal. The initiative addresses health disparities in seven low country cancer clinics in South Carolina. The clinics are linked with the AHF in New York.

The low country has a high rate of prostate and cervical cancers. The focus of the AHF P20 is to investigate nutrition as a risk factor for cancer. The churches have been very supportive of the initiative in providing educational programs on health. In addition, the initiative is supported by a regional health provider that has clinics to serve more than 100,000 residents. Data from the clinics are transmitted to AHF via telemedicine; tests being used to assess prostate health among African-American and Hispanic patients include dietary history, digital rectal exam, and prostate-specific antigen (PSA) testing. Proteomics will be used to assess the data to develop chemopreventive strategies. The search for, and manipulation of, protein patterns related to prostate cancer will be the first area investigated. Selenium will be the first nutrient investigated experimentally, with clinical trials being planned for the future. The P20 provides the framework for beginning this long-term project.

Perspectives from a Minority-Serving Institution—Dr. Bruce Macher, Associate Dean of Research, San Francisco State University

Bruce Macher, Ph.D., Associate Dean of Research, San Francisco State University (SFSU), reported on the collaboration between SFSU and the University of California, San Francisco (UCSF). Dr. Macher described the partnership between SFSU and UCSF (SFSU is the MSI in the partnership). Dr. Frank Bayliss is the Principal Investigator (PI) at SFSU, the MSI in the partnership, and Dr. John A. Watson is the PI at UCSF. The partnership is in the second year of the P20 grant and focuses on basic science and research. A U56 grant is underway for a pilot project and nursing program to investigate breast cancer and prostate cancer. In addition, a community outreach program and education programs are beginning, which should help in recruiting minorities to the partnership.

Questions and Answers

Dr. Kimes commented that one of the purposes of the MI/CCP is to create pathways to encourage minority Ph.D. students to enter fields of research, not just to encourage minorities to secure teaching positions.

Perspectives from Awardees—Dr. James Strickland, Associate Professor, New Mexico State University and Dr. Beti Thompson, Member, Fred Hutchinson Cancer Research Center

James Strickland, Ph.D., Associate Professor, New Mexico State University (NMSU), and Beti Thompson, Ph.D., Member of the Cancer Prevention Research Program, Fred Hutchinson Cancer Research Center (FHCRC), presented information on their U56 planning grant between NMSU and FHCRC. Dr. Strickland addressed the history of the partnership and commented that the distance between NMSU (New Mexico) and FHCRC (Seattle, Washington) has not been an impediment to working together because e-mail and teleconferencing have made contacts very easy and economical. The objectives of the partnership are:

- To establish a long-lasting infrastructure to conduct cancer research at NMSU;
- To develop a structure to recruit, train, and mentor undergraduate and graduate minority students for careers in cancer research; and
- To provide both NMSU and FHCRC with new research experiences that will benefit scientists at both institutions as well as populations served by each institution.

Five pilot projects have been developed as part of the U56 planning grant. Success of the partnership will be determined by the number of R01s they can secure in the future.

Dr. Thompson said that FHCRC is interested in developing the partnership with NMSU because large numbers of Hispanics reside in both New Mexico and Washington, although in contrast to the permanent population of Hispanics in New Mexico, the population of Hispanics in Washington has traditionally been migrant workers.

Lessons learned during the MI/CCP application process are useful to future applicants. Dr. Thompson described the strengths and weaknesses of the FHCRC–NMSU initial proposal, which was unsuccessful. Strengths included the focus of the proposal, strong letters of commitment, a high confidence that the objectives of the proposal could be reached, and strong initial pilot projects. Weaknesses included not enough integration with existing minority-training programs, a lack of detail for recruiting new faculty in the area of cancer research, lack of specificity for identifying pilot projects beyond those included initially, the complexity of the administrative reporting scheme, and insufficient information concerning an ongoing interest in cancer research by some staff members. These are important lessons to be considered for those hoping to submit proposals.

In summary, factors that must be considered by those hoping to apply for an MI/CCP grant include the following:

- Collaboration begins with proposal preparation.
- Development of the proposal is an iterative process.
- Partners need to commit to final product.
- Good communication of ideas is necessary.
- NCI staff are extremely helpful.
- There is never enough time to do everything.

Questions and Answers

A participant asked why the FHCRC and NMSU bypassed applying for a P20 grant and applied for a U56 grant instead? Dr. Thompson responded that there was an existing infrastructure at NMSU that indicated a planning grant (P20) was not necessary. In addition, they were attempting to create a broader program. Dr. Kimes added that a P20 is not required before a U56; neither are the P20 or U56 required before a U54.

Another participant asked if there were benchmarks within the grant proposal other than future acquisition of an R01. Dr. Strickland responded that there were many other benchmarks for each objective, but not evaluation outcomes assessment. To support the pilot projects, there will be an

annual meeting of partnership members, and there will be progress reports that address the benchmarks.

A participant asked if the pilot projects will cover the entire length of the U56 grant? Dr. Strickland responded that the external steering committee will recommend to PIs at the annual meeting whether pilot projects, which must be completed within 3 years, will be continued and whether new ones should be initiated.

When asked whether projects on public health are considered for MI/CCP research grants, Dr. Thompson responded that public health is considered research, but the focus of the MI/CCP is to encourage minorities to pursue medical careers in research. Dr. Kimes added that the NCI does not distinguish between medical or translational research. The purpose of the MI/CCP is to increase the number of minorities in cancer research fields. Also, Specialized Programs of Research Excellence (SPORE) grants are focused on translational research.

PROGRESS REPORTS FROM MI/CCP AWARDEES

Drs. Carolyn Cousin and Peter Shields—University of the District of Columbia, Georgetown University, and the Lombardi Comprehensive Cancer Center

Peter Shields, M.D., Associate Director for Population Sciences, Lombardi Cancer Center (LCC), Georgetown University Medical Center (GUMC) described the partnership between the LCC at GUMC, and the University of the District of Columbia (UDC). The specific aims of the partnership include fostering a cancer research focus at UDC, developing a UDC undergraduate training program, promoting cancer disparity research at LCC, and developing a joint outreach program. Dr. Shields described the structure of the partnership administration and the focus of the P20 for faculty research training to develop a cancer program at UDC. The LCC has a health disparities program, but it needed UDC to help provide a joint outreach program.

Dr. Shields explained the recruitment efforts for research and for increasing research faculty positions at UDC. LCC will work with UDC to provide research facilities for UDC and will integrate course work.

Carolyn Cousin, Ph.D., Professor, Department of Biological and Environmental Science, UDC, spoke on her responsibilities for designing and implementing a model outreach program to the African-American community. During the first year of the grant, the partnership assessed community and cancer-related needs, identified and designed effective activities, and selected community sites. During the second year, they have begun to implement cancer awareness activities and conduct follow-up activities. During the final year of the grant, they will hold a summer Workshop. She presented a short video on community programs that supported outreach activities. In addition, promotional activities included posters at grocery stores or libraries and radio or television ads for upcoming outreach activities. An important aspect of outreach activities is the inclusion of local ministers in the planning of activities, and the use of houses of worship as activity centers.

Drs. Carol Magai and Sherri Sheinfeld Gorin—Long Island University, Columbia University, and the Herbert Irving Comprehensive Cancer Center

Carol Magai, Ph.D., Professor of Psychology, Department of Psychology, Long Island University (LIU), presented information on a P20 grant implemented through a partnership between LIU and the Herbert Irving Comprehensive Cancer Center (HICCC) at Columbia University, New York. LIU is based in Brooklyn, New York, which has the most ethnically diverse population of any place on the Earth. Originally, LIU investigated human emotion, emotion regulation, and human motivation as they influence human behavior. The populations studied included African-American subpopulations from Haiti, Jamaica, the English-speaking Caribbean, and others, in a study of deterrents to breast cancer screening in older African-Americans. After forming a partnership with HICCC, they applied for a P20 grant to broaden this study.

Dr. Magai described the structure of the administration for the grant and how the partnership is managed. Meetings, workshops, and retreats were scheduled to bring together research partners for planning and progress discussions. Activities during the first year of the P20 grant included two pilot projects, one at each institution. The pilot project at LIU was built on existing peer-reviewed grants that examined the economic, socio-cultural, and psychological factors responsible for low rates of cancer screening among older minority groups. Dr. Magai presented some preliminary results showing that rates of screening are very low among these populations, but that there are profound differences among subpopulations.

Sherri Sheinfeld Gorin, Ph.D., Assistant Professor, Mailman School of Public Health, Columbia University's HICCC, discussed the role of HICCC in the partnership with LIU. The focus of the pilot project being implemented at HICCC is on increasing colorectal cancer screening among primary care physicians in underserved communities. The use of "academic detailing," similar to that employed by the pharmaceutical industry, is being used to increase knowledge about colorectal cancer and colorectal cancer screening among these physicians. Data were presented showing that there are differences in behavior of primary care physicians based on the socioeconomic status of patients. The project is meant to assess these differences and to implement strategies to overcome barriers.

Drs. Joel A. Okoli and Edward Partridge—Morehouse School of Medicine and the University of Alabama, Birmingham Comprehensive Cancer Center

Joel Okoli, M.D., Assistant Professor of Surgery, Morehouse School of Medicine (MSM), discussed his collaboration on a U56 with the University of Alabama at Birmingham (UAB) Cancer Center to enhance the cancer research capabilities of each institution, and to contribute to the reduction in cancer disparity between African-Americans and whites. Dr. Okoli presented the organization of the administrative core, executive committee, scientific review committee, and program development committee. Two satellite cores were established during the first year of the grant. These include a Recruitment and Retention Shared Facility at MSM and a Biostatistics Core at UAB. A goal of the project is to recruit and retain patients and faculty for research.

Five projects have been planned for the first year of funding. These include investigations on the role of growth factors in colorectal cancer, the regulation of cyclooxygenases in human cell lines, mitochondrial DNA mutations in colorectal cancer progression, the role of community lay health advocates in adherence to diagnosis and follow-up for abnormal mammograms, and the comparison of prostate cancer screening among population subgroups.

Edward Partridge, M.D., Director, Division of Gynecologic Oncology, Cancer Prevention and Control, UAB, explained the history of discussions that occurred 2 years ago at the MI/CCP meeting in New Orleans, when the concept of establishing a “research triangle” for the South was discussed. This has resulted in a P20 partnership with Tuskegee University and the U56 partnership with MSM described by Dr. Okoli. Dr. Partridge presented information from the SEER database showing that the incidence of cancer in this triangle is dramatically higher than in many areas of the South. In particular, there is a disparity in the incidence of cervical cancer among African-American women in the South.

Dr. Partridge described the minority populations to be served by the partnership and the capabilities that UAB, MSM, and Tuskegee bring to the triangle. In particular, Tuskegee houses the National Center for Bioethics in Health Care and Research, which is an important asset for the partnership. This summer, the partnership will hold a summer institute with investigators from each member of the partnership to discuss the research agenda.

Drs. Duane Smoot and William Nelson—Howard University Cancer Center and the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University

Duane T. Smoot, M.D., Associate Project Director for Howard-Hopkins Partnership, Associate Professor and Chief, Department of Internal Medicine, Howard University (HU) Hospital, described the partnership between HU and the Sidney Kimmel Comprehensive Cancer Center (SKCCC) at Johns Hopkins University (JHU). Dr. Smoot described three main research projects investigating prostate, breast, and gastric cancers. Two pilot projects are investigating breast and colorectal cancers. There also is an education component, a tissue repository to be established at HU, and clinical trials. He described the strengths of each institution and how these are positive for the partnership.

William Nelson, M.D., Associate Professor of Oncology, Urology, Pharmacology, Medicine and Pathology, Department of Oncology, SKCCC, presented information that was used to help focus the institutions on potential collaborations. In particular, data show that there is a high incidence of prostate cancer in the areas served by HU and the SKCCC, especially among minority populations. SEER data also show that both incidence and mortality for prostate cancer have a dramatic impact on minorities in Maryland. Research projects planned or underway at HU that can be enhanced by the partnership include the following:

- DNA sequencing/SNP discovery to find polymorphisms in Africans and African-Americans;
- Population-based studies of prostate cancer risk in Africans and African-Americans;
- Genetic epidemiology case/control studies of prostate cancer risk;
- Participation in African-American Hereditary Prostate Cancer (AAHPC) Study; and

- African-American prostate tissue archiving for transcriptome profiling analyses.

SKCCC has a strong SPORE program for translational research and a population epidemiology program that can help support the genetic component derived from HU studies. Other research areas that will be enhanced by the partnership include the use of microarrays, molecular pathology, clinical trials, population studies, and training/career development projects that have been strong at SKCCC.

Questions and Answers

A participant asked if the tissue repository to be established by the partnership will be a public repository. Dr. Smoot responded that at this time it will only be accessible to researchers in the partnership. He will maintain a central repository for all cancer-related research that can be used by individual projects affiliated with the partnership.

Guidelines for Non-Competing Applications—Dr. Sanya Springfield, Chief, CMBB, OCTR, ODDES, NCI

Sanya Springfield, Ph.D., Chief, CMBB, OCTR, ODDES, NCI, NIH, listed the partnerships that were awarded this year and said that the NCI is committed to supporting the MI/CCP partnerships and on expanding the number of awards in subsequent years. Dr. Springfield described supplemental guidelines for non-competing applications and encouraged workshop participants to read the material in the workshop notebook and consider applying for new grants. She also asked that participants consider becoming involved in the NCI CURE program.

Dr. Springfield emphasized the importance of submitting a correct and complete application and presented information on the P20 progress report. Four aspects must be reported, which are described in detail in the workshop notebook. They are:

General Issues: such as changes or substitutions in key personnel, redistribution of the budget between partners, new research projects or programs, and changes in institutional commitment leadership.

Combined Director's Overview: for the P20, three areas should have a collective response: response to the summary statement concerns, mentoring, and career development.

Planning and Prioritizing Stages: should include a chronological list of planning activities with details on participants and outcomes, a discussion of the process used for prioritizing and selecting pilot projects, and a timetable for submitting the pilot project or program to the NCI for a competitive grant application. In addition, for 3-year grant recipients, there must be a statement on the adequacy of the initial planning stage.

Implementation Stage: must include specific aims of the partnership; studies and results; significance of the studies on minority health; plans for future projects; a list of grant applications that already have been submitted that are pending or funded; publications or

presentations that have resulted from the partnership; and a list of project-generated resources that resulted from the grant.

Dr. Springfield stated that the progress reports for U56 and U54 grants are similar to those described for the P20, but there are a few important differences. A significant difference is that funding within the U56 and U54, unlike in the P20, may be redistributed among the various components of the project, although this must be noted in the progress report. Other characteristics of the progress report for U56 and U54 grants include the following five components:

Combined Director's Overview: must include a collective response to the summary statement, the leadership of the administrative core, and elements of the planning and evaluation core.

Developmental Core: should include specific aims of the partnership, studies and results, significance of the studies on minority health; plans for future projects; a list of grant applications that already have been submitted that are pending or funded; publications or presentations that have resulted from the partnership; and a list of project-generated resources that resulted from the grant.

Resources and Infrastructure: should include the status of all fully operational resources, how each is being used, changes in the organization of the project, problems that have been recognized during the current project, and how those problems will be addressed during the next budget year.

Recruitment(s): should include the process and outcome of all recruitment efforts, how each recruited individual fits into the organizational structure of the project, steps for mentoring junior investigators, and plans for future recruitment.

Peer-Reviewed Publications: should include a complete list of publications that have been produced from the project, a list of grant applications (competing or non-competing) that already have been submitted that are pending or funded, and publications or presentations that have resulted from the partnership.

Dr. Springfield concluded by requesting participants to review the complete guidelines included in the workshop notebook.

Minority Online Information Service Demonstration (MOLIS)—Mr. Russell Peek, Sciencewise, Inc.

Russell Peek, B.A., Director of the Minority Online Information Service (MOLIS) Program, ScienceWise, Inc., demonstrated the MOLIS Program for workshop participants during a working lunch. Mr. Peek gave an historical context for the MOLIS Program and said that his company began developing MOLIS approximately 12 years ago to serve as a database of research information on minority institutions. He highlighted the ability of MOLIS to identify MSIs and their capabilities. There are 268 institutions in the database that represent MSI's,

including historically Black colleges, Hispanic-serving institutions, and Native-American tribal colleges and universities. There are approximately 600 institutions identified by the U.S. Department of Education as Minority Serving Institutions.

The MOLIS database can be accessed online at <http://sciencewise.com/molis/>. The MOLIS Program has a search capability to find MSIs that focus on specific areas of cancer research, and one of its most important functions is the ability to find MSIs that have been awarded research funds. An important initiative in the next few years will be signing up those institutions that are not included in MOLIS. Mr. Peek gave an online demonstration of the MOLIS Web Site.

There is no fee for MOLIS for MSIs, but non-MSI institutions are charged for accessing the database. Mr. Peek offered to help institutions sign up for MOLIS, especially during the process of providing information required in the database.

Questions and Answers

A participant commented that MOLIS is an excellent tool for allowing medical and science students from across the nation to search for schools with research programs they may be interested in applying to for furthering their education. Another participant asked why some states do not have listings on MOLIS. For example, Massachusetts does not appear to have any MSIs. Mr. Peek responded that it may be that Massachusetts schools have not applied to be listed in MOLIS. In addition, most of the historically Black universities are in the southern United States.

APPLICATION PROCESS FOR MI/CCP

Common Features and Differences of MI/CCP Program Applications—Dr. Brian Kimes

Dr. Kimes presented features and differences of MI/CCP Program applications. The P20 grant is a planning grant that should focus on a few activities that can be developed over a 2- or 3-year period. The U56 grant is a planning activity specifically for an eventual comprehensive partnership; it should be a very broad planning activity encompassing a variety of different approaches to establishing this comprehensive partnership. The U54 grant is designed for a comprehensive partnership. The grants are designed to generate real competitive peer-reviewed research support (i.e., R01, T32, R25) over the long term. Appendix A lists features of each of the grants. The following is an abbreviated list of these features.

- **Eligibility.** The eligibility criteria are very similar, but in the case of the P20 there are eligible institutions that function as CCs but are not necessarily NCI-designated CCs.
- **Budget.** There are direct cost budget caps for each of these grants. Indirect costs through subcontracting are not included in the direct cost total. The annual cap for the P20 is \$250,000, for the U56 it is \$500,000, and for the U54 it is \$1.5 million. The cap

represents the total amount of dollars for the two applications together. No more than 20 percent of the budget can be allocated to administration.

- **Research Requirements.** All of these initiatives support research or research training as a primary emphasis. The P20 can have a primary emphasis on research or research training. The U56 and U54 must have a primary emphasis on research.
- **Commitment.** These applications must show a level of institutional commitment. It is not acceptable to simply provide a form from an official at an institution stating “we are committed to this.” Rather, it means providing facilities, committing to recruitments, and so on.
- **Mutual Benefit.** The mutual benefits of these partnerships must be clear; there should be reasonably equal advantages for both the MSI and the CC.
- **Co-leaders.** Every project under these initiatives must have a co-leader from the MSI and a co-leader from the CC. This shared-leadership concept is similar to that found in the SPORC initiatives, in which there must be a basic science leader and an applied science leader.
- **Common Planning Process.** Each application must have an identical planning process even though two applications will be submitted.
- **Time Period.** The funding period is 3 years for P20 grants and 5 years for U56 and U54 grants.
- **External Advisory Structure.** Both the MSI and the CC must have the same external advisory structure.
- **Research.** If the research is conducted primarily at the MSI, it can be any kind of cancer research. If the research is conducted primarily at the CC, it must be focused on the disproportionate incidence and mortality issues associated with minority populations.
- **Workshops.** P20, U56, and U54 grantees will be expected to send representatives to an annual workshop to learn from experiences and to make improvements to these initiatives.
- **Score.** Even though there are two applications, the peer reviewers will consider them together and there will only be one score given for the two applications.

Key Components for Planning Grant for MI/CCP (P20)—Dr. H. Nelson Aguila

Dr. Aguila explained that planning within the P20 grants has two goals:

- To plan and implement focused collaborations in cancer research, cancer research training, and career development or cancer education; and

- To assist collaborations between scientists and faculty at MSIs and CCs, which will lead to future traditional NCI grant applications (e.g., R01s, P01s, and T32s).

Dr. Aguila stressed that the P20 initially contained an outreach component, but this has been discontinued in the current Requests for Application (RFAs). Key components of the P20 include the following:

- ***Evidence of Working Together:*** This can be achieved by listing a chronology of meetings, conference calls, and special activities, a listing of the number of meetings or activities held to develop the applications, and a listing of the number of meetings held to address reviewer questions.
- ***Demonstration of Mutual Benefits:*** There should be convincing descriptions in both applications of the benefits for each institution by presenting an overview of the MSI and the CC, showing evidence of complementary strengths and weaknesses, and specifying mutual benefits.
- ***Letters of Support:*** The letters of support should reflect that they were written by the individual rather than being a template letter. If the partnership involves development of a training or educational program, a commitment of institutional resources from the MSI President and CC Director will be needed. If a Co-PI is/are less experienced, the letter must be from a senior member of the MSI or CC. This letter must identify a mentor responsible for career and professional development of the individual, and institutional support for the P20 activities that provides the maximum chance of success.
- ***Duration of Support Requested:*** For 2-year proposals, the MSI and CC must identify areas of collaboration and describe how they will be developed, describe prior planning activities, and describe a priority-setting and implementation stage. For 3-year proposals, the MSI and CC must state that past collaboration between the institutions does not exist or has been limited. They must describe a planning stage (first year), and a priority-setting and implementation stage.
- ***Evaluation of the Partnership:*** The proposal must include a time-table with objectives and expected time for completion of the project(s), describe the procedure to evaluate and prioritize pilot projects and pilot programs, include an organizational chart, and specify the role of the committees or advisory groups and their participants.

Questions and Answers

Dr. Springfield commented that mutual benefit between the partners is not as important for P20 grants as it is for U56 and U54 grants. One participant asked why outreach was excluded for the P20. Dr. Aguila responded that P20 projects are short in duration (2-3 years) and that outreach programs generally take much longer than that to complete. Outreach activities are more appropriate for U54 or U56 grants, which are of longer duration.

Key Components of the Cooperative Planning Grant for Comprehensive MI/CCP (U56) and the Comprehensive MI/CCP (U54)—Dr. Peter Ogunbiyi, Program Director, CMBB, OCTR, ODDES, NCI

Peter Ogunbiyi, D.V.M., Ph.D., Program Director, CMBB, OCTR, ODDES, NCI, NIH, presented information on the key components of the Cooperative Planning Grants for U56 and U54. Budgets for each of the grants should be submitted for four budget areas: the Total Initial Budget for All Cores, the Administrative Core, the Planning and Evaluation Core, and the Developmental Core. Dr. Ogunbiyi described items that should be included in each of the budget areas. He suggested that potential applicants read the RFA carefully before beginning the application process. There are some specific instructions that must be met before the application will be considered for funding. Applicants need to be aware that there are differences between the U54 and U56 requirements that need to be addressed in the application. For example, in the Developmental Core, both U54 and U56 direct costs may be up to \$100,000 for pilot projects or programs; however, a U54 also may have direct costs of up to \$250,000 for full projects or programs.

Dr. Ogunbiyi emphasized that the information submitted for the U56 and U54 applications must be more detailed than that required for the P20, particularly in the area of institutional support. The expectation of the NCI and peer reviewers regarding the U56 and U54 applications is that there must be strong evidence that the team of investigators and support personnel are experienced in cancer research. If the research is taking place at the MSI, the project can be on any area of cancer research; if the research is taking place at the CC, the project must be on an area of cancer research that disproportionately affects minority populations. As in all grant applications, it is imperative that the individuals and their roles are explicitly detailed in the application and listed as the core activity they are to perform. In addition, if mentoring activities are planned, the application should include the extent that the mentor will be involved with the designated investigator, how much time will be spent in the mentoring process, and what outcomes are expected from this activity.

Dr. Ogunbiyi presented conditions for budgeting consortium or contractual arrangements for partnerships with more than two partners. In these cases, only one MSI and one CC may be primary grantees, with subcontracts being developed for additional MSIs or CCs. This must be reflected in the proposal and in the budget for the project or program. He also specified items that must be included in the introduction for revised applications. These include highlighting additions, deletions or changes; emphasizing responses to criticisms and issues raised by reviewers; including activities conducted since the last submission; and clearly marking the changes in the text (unless extensive).

Questions and Answers

A participant asked if there were strategies to use to raise the awareness of the MI/CCP RFA requirements among institutions. Dr. Ogunbiyi responded that the NCI is committed to educating the institutions on their responsibilities regarding MI/CCP grants. Investigators also need to work with their institutions to educate their administrative leaders. Dr. Kimes added that one of the purposes of the Steering Committee is to assess support from the institutions. This

may help encourage the institution to uphold their commitment. Dr. Springfield added that it is important to get commitments from the institutions written into the letters of support during the application process.

Tuesday, June 4, 2002

Before beginning this session, Dr. Kimes said that a few participants wanted him to clarify some items discussed in the previous session. On the question of the grants being renewed, he said that the P20 and U56 grants are not renewable, although the CMBB has the administrative authority to carry the project for 1 more year. The U54 is renewable, and will begin with a pilot project for 1 year before beginning the full project, which can last for the duration of the project. At the same time as the partnership has a U54, the individuals may apply for other grants. This allows the investigators to continue to receive support while progressing to more competitive grants. On another question, Dr. Kimes clarified that it is very important that grantees need to be honest in reporting on their progress reports regarding issues such as support from their institutions. For example, if the project is not receiving the support that was committed to in the application, the investigator needs to let the NCI know this so that corrective action can be taken if needed.

Dr. Kimes added that although the intent of the P20 grant is to develop the partnership, under some situations it may serve as an entry to a project that develops into a comprehensive partnership under the U56 grant.

Review Criteria for P20—Dr. H. Nelson Aguila

Dr. Aguila reviewed the criteria that will be used by reviewers to assess P20 applications, which are listed in more detail in the workshop materials packet. He stressed that the purpose of the P20 is to plan and implement focused collaborations in one or two of the targeted areas: cancer research, training and career development, and/or cancer education. If all three areas are targeted, it would be expected that the application is more appropriate for a U56. In addition, outreach activities, as stated earlier in the workshop, are not required for P20 projects. The P20 must provide support for pilot projects and cancer programs to obtain preliminary data to develop competitive grant applications. Review criteria will emphasize equally the three targeted areas and is not organized on the traditional headings of Significance, Approach, Environment, Investigator, and Innovation. Reviewers will use flexibility of criteria to determine if applications can expand research, training, and career development for minority scientists and students. Applicants can apply for 2- or 3-year grants and will depend on previous experience, interactions and collaboration between the partner institutions, and evidence that the co-PIs have identified areas of collaboration and the manner in which they will be developed.

Dr. Aguila listed the review criteria for P20 applications. They are:

- Strength of the evidence that the MSI and CC worked closely together, that they have identified mutual benefits, and can achieve the goals of the project within the 2- or 3-year time period;
- The degree to which the letters of support address the need for mentoring to less experienced Co-PI(s);
- The specific commitments to ensure success of the partnership activities (adequacy of the resources, level of authority of official signing the letter);

- The adequacy of provisions made for day-to-day oversight coordination, support and logistical service; and,
- The overall responsiveness to the RFA.

The initial planning stage for 3-year applicants must include evidence of the adequacy of the planning methods proposed by the MSI and CC to explore areas of opportunity and ensure interactive and integrated efforts among scientists. Also, the duration of the initial planning stage needed to identify areas of potential collaboration must be included. For 2-year applications, there must be evidence that there is adequacy and merit in the documented planning process used for identifying areas ready for prioritization and for pilot testing; and the appropriateness and adequacy of faculty and scientists identified from the MSI and the CC to contribute effectively to the goals of this planning effort must be included.

The priority setting stage for both 2- and 3-year applications must include the experience and qualifications of individuals participating in the project, and the process used for selecting the pilot projects and/or programs for implementation. The process for evaluating pilot projects or programs must fall within the time-line proposed in the application. Proposed pilot projects or programs will be evaluated by reviewers based on the following criteria:

- There must be a co-PI from the MSI and a co-PI from the CC.
- The co-PIs must be qualified for the project or program.
- The merit of the proposal will be based on specific aims, experimental design, preliminary data, and other criteria.
- The degree to which the proposal contributes to the objectives of the partnership must be noted.
- The potential of the proposal to acquire preliminary data that can be used to develop a competitive grant application must be noted.

Pilot projects or programs will be recommended to be funded at the recommended budget levels, or to not be funded. Funding for the pilot project or program may be withheld because of low scientific merit, low relevance to the objectives of the partnership, or low potential to develop into a competitive grant application.

Dr. Aguila presented additional review criteria, listed below:

- Adequacy of the proposed budget. The P20 has a maximum funding level of \$250,000 per year, and does not have to be shared equally by the MSI and CC.
- Adequacy of plans to include and retain women, children, and all racial and ethnic groups, as appropriate for the scientific goals of the study.
- Adequacy for the protection of human/animal subjects.
- Adequacy of the plan to share data.
- The safety of the research environment.

The evaluation and scoring of applications will assign the same priority score to the application from the MSI and the CC. The score will reflect the overall degree of merit for the collaboration. Scores for 2- and 3-year projects will be based on the potential to develop projects that will

compete successfully for specific grant support. Dr. Aguila stressed that applicants carefully read and follow the RFA and supplemental instructions because these applications are not like traditional applications.

Questions and Answers

A participant asked if there is a limit on the number of P20s that each institution can have. Dr. Aguila clarified that each institution can have two P20s, one P20 and one U56, or one P20 and one U54. In addition, an institution does not have to have a P20 before they apply for a U56 or U54. Another participant asked Dr. Aguila to explain the review score. Dr. Aguila responded that scoring is the same as that for all RFAs; applications are scored on a scale of one–five, with 1 one being the highest score and five being the lowest score.

Review Criteria for U56 and U54—Dr. Peter Ogunbiyi

Dr. Ogunbiyi reviewed the criteria that will be used by reviewers to assess P56 and U54 applications, which are listed in more detail in the workshop materials packet. He stated that the primary purpose of the U56 grant is to make the partnership ready to apply for a U54 or to move ahead to competitive grants, such as the R01, P01, and training and education grants. General features that the reviewers will be looking for in U56 and U54 applications are listed below.

- Evidence that the partnership has worked closely together, has established priorities and objectives, has identified mutual benefits, and can achieve objectives in a 5-year period.
- Evidence that the partnership will result in the MSI increasing its cancer research capability and training of minority cancer researchers, and that the CC has focused its research on cancer problems in minorities and improved effectiveness of activities aimed at minorities.
- Evidence that the scientific and administrative leadership is qualified and experienced to fulfill the research agenda of the partnership.
- Evidence that letters of support for the project show that the institutional administrators demonstrate familiarity with the project, including the extent of the relationship between the MSI and CC.
- Evidence that the U56 has the potential to develop into a project/program in 3 years or less; the U54 must have the potential to develop into a competitive grant application in 3 years or less.
- Evidence that the Program Steering Committee (PSC) members have the expertise and qualifications in providing appropriate evaluation and advice, as well as the ability to make recommendations for mid-course corrections, and evidence that the plan for using the PSC effectively is adequate.
- Evidence that proposed resources and infrastructure contribute to the overall priorities and objectives, provide long-term stability to the activities of the partnership, and have qualified key personnel to complete the activities.

Dr. Ogunbiyi reviewed the criteria for the Administrative Core, the Planning and Evaluation Core, and the Developmental Core. It is important that for proposed recruitment of research associates or assistants, applicants need to specify the quality of each specific individual relative

to their background, their ability to contribute substantially to the project, and the kinds of qualifications that will satisfy the most important strategic needs in strengthening the future capability of the partnership.

Dr. Ogunbiyi stated that after review, the review committee can recommend support at the recommended budget levels, or recommend support with specific modifications in the operation of the resources. The committee can also recommend no support due to low merit and/or low relevance of the proposed resources to the objectives and priorities of the partnership.

Questions and Answers

A participant asked how the pilot project could be rejected by the review committee, but the application can be funded. Dr. Ogunbiyi stated that if there are projects other than the pilot project that meet the criteria, those funds will not be denied. Another participant asked if more than two institutions could apply as a partnership. Dr. Ogunbiyi responded that if this is the case, there can be a contractual arrangement with a third partner, whether it is a CC or MSI, but that this will have to be written outside of the review process. The review committee only will consider an application with one MSI and one CC.

Another participant asked if honoraria can be a part of the budget for a project. Dr. Ogunbiyi explained that honoraria are not allowed at this time, but it is possible that they may be allowed in the future. Several participants asked Dr. Ogunbiyi to explain what an applicant's response should be if a pilot or full project is not recommended for funding. He addressed the issue by saying that a new project would have to be approved by NCI through the same process, but there may be a way to have this completed on an ad hoc basis in the future. A follow-up question was raised to clarify what is meant by an ad hoc process. Dr. Ogunbiyi responded that the new project will replace the denied project and NCI will have to be notified. This application may or may not have to go through a formal review. An example would be an application for a U56 or U54 that contained four different projects, one of which is denied funding. The other three projects could begin while the applicants resubmit an application that replaces the denied project.

A participant asked if the U54 is renewable. Dr. Ogunbiyi responded that the U54 is renewable, but the hope is that after completion of a U54 the partnership will have progressed in capabilities to want to apply for an R01, P01, or other competitive grants or contracts.

To clarify a statement made during the presentation, Dr. Kimes said that it probably is not possible for an MSI to attain the research capabilities that would qualify it to be a CC. The purpose of the CMBB is to develop stronger partnerships with existing CCs. He added that a previous statement identifying institutions such as Louisiana State University, Emory University, and Tulane University, recognizes that there are institutions that have set the goal to become a CC. Within the structure of the CMBB, these institutions can be counted as a CC for partnership purposes.

KEY PERSPECTIVES FROM REVIEW

NCI Special Review Administrator—Dr. Ray Bramhall, Chief, PCRB, NCI

Ray Bramhall, Ph.D., Chief of the Program Coordination and Referral Branch, NCI, presented the perspective of the NCI Special Review and Referral Branch regarding the CMBB MI/CCP review process. More detailed information was provided in the workshop notebook. Dr. Bramhall, the Scientific Review Administrator (SRA) for MI/CCP grants, described the forms that must be completed for each application, paying particular attention to those items requiring budget disclosure. He discussed the composition of the review committee, which includes a cancer survivor, and the schedule of review meetings. Until an application is submitted, Dr. Springfield may be contacted to address questions; after submission of the application, all questions should be directed to the SRA. Dr. Bramhall reviewed the process and deadlines for submitting applications that are listed in the RFA. The SRA will be responsible for overseeing the review process, giving direction to the review committees, and reporting results of the review. The iterative process will be extensive, and he expects the process to be rather lengthy because of the stringent standards described in the RFA.

Dr. Bramhall emphasized that directions that may not be listed in the RFA will be listed in PHS-398, a government form that is referred to in the RFA. Directions in the PHS-398 are followed unless the RFA specifically addresses a topic. For example, PHS-398 specifies type size and line density and the RFA is silent on this issue; therefore, the PHS-398 should be adhered to for type size and line density. He stressed the directions for documenting the use of human and animal subjects and said that the application must address specifically how the project will include women, children, and minorities, or if applicable, document why they are not being included. For example, if the project is focused on prostate cancer, a statement that women were not included in the project should be added to indicate that they were not included because they do not get prostate cancer. There also is a new requirement in the RFA that requires investigators to have education in the protection of human subjects. A training course is offered online by the NIH at <http://cme.nci.nih.gov>.

Special Review Committee Members—Panel members Drs. Miguel Berrios, Daisy De Leon, and George Hammons

Miguel Berrios, Ph.D., Associate Professor, Department of Pharmacology, University Hospital and Medical Center, State University of New York, provided insight from the perspective of a member of a review committee. Dr. Berrios indicated that the review committee examines each application differently; therefore, there is no common element in the review. It is important to have a clear channel of communication between the CC and the MSI, which must be well-maintained and very stable. It is important that this be laid out in the introduction to the application. Experience shows that from past reviews of MI/CCP applications, the CC generally has a very stable funding mechanism and appropriate support from their institution, but it has a relatively poor record of recruiting minorities. In general, the MSI has the opposite problem. Another observation is that the MSI generally produces a very well thought out application that addresses the goals and objectives of the MI/CCP, but the CC, which usually has a well-financed organizational program for submitting applications, spends too much time telling how successful

they have been in securing research funds. This may be viewed less favorably by the review committee. Both partners must have an application focused on the MI/CCP goals.

Daisy De Leon, Ph.D., Associate Professor, Department of Physiology, Loma Linda University, presented her perspective on the role of the reviewer. Dr. De Leon said that often it is clear in the applications that the MSI is very committed, but the same commitment is not present in the CC application. There must not be a patronizing relationship. This is clear when the CC offers a lower-level individual (i.e., Assistant Professor) as PI for MI/CCP projects. There needs to be a realistic expression of support from the CC and clear evidence that there is integration between the CC and the MSI. Dr. De Leon suggested that graphics and tables be included in the application to summarize information and make it easier for reviewers to access.

George Hammons, Ph.D., Philander Smith College, Little Rock, Arkansas, added a comment about the U56 application review. He said that it is important that the pilot projects reflect a high quality of scientific credibility and a clear indication regarding how the U56 will ultimately lead to a U54 or R01. Dr. Hammons also expressed the opinion that he likes to have a clear statement in the applications that indicates the MSI and CC have a stable, long-term relationship, which shows there is institutional commitment to the partnership. It is important to keep in mind that the purpose of these grants is to strengthen the MSIs' research capabilities and to strengthen the CCs' ability to complete research in the minority community. This takes a long-range vision for the partnership to meet these goals.

Dr. Hammons added that in reviewing P20 applications, he expects to see a clear indication that the initial planning activities are a key part of the process. This process should be focused and should have clear evidence that the partners have considered the outcome of the planning process. The expectation for the pilot project is to lead to U56 or U54, so it is helpful to have the application spell out how this leads to it.

Questions and Answers

A participant asked what scoring range most applications attain and how many applications get funded each year. A panel member responded that the typical scoring range for U54s is 140-350, and there are different numbers of projects funded each year. Another participant asked if there is an expectation that the MSI should generate an R01, rather than the CC. A panel member responded that either member can generate an R01, although the CC would be expected to generate an R01 for a project related to minority health disparities.

To the question of what type of split in funding should be expected between the MSI and CC, Dr. Bramhall said that there is no preconception of a percentage and that the budget split should reflect the project goals and activities. There is no formula. A participant asked if it is a liability to have research materials predominantly housed in the CC, especially if the MSI and CC are geographically close to each other. Dr. Kimes responded that there is an understanding that there will be a transition time needed to improve the research capabilities of the MSI. The opinion of most reviewers is that a training program across institutions would be beneficial to both the MSI and CC because that would exemplify a commitment from both institutions.

One participant commented that it seems realistic to think that reviewers should accept more administrative resources being delegated to the MSI since the CC generally has access to more in-house resources. Dr. De Leon added that this may indicate a patronizing attitude. She said it is important to see evidence of cooperation in the application. Dr. Bramhall added that if the MSI is to receive more resources than the CC receives, this should be clearly stated in the application. Another participant asked if an applicant should spread money equally over the 3 years of a P20 grant. A panel member responded that in a 3-year P20, it would be expected that less money is needed the first year because that year is for planning rather than implementation of the pilot project.

BREAKOUT SESSIONS/WORKING LUNCH

Breakout sessions were held in five separate rooms. Lunch was served during the breakout sessions. The breakout topics were as follows:

- P20 Planning for New Applicants;
- P20 Planning for Revised Applicants;
- U56 Cooperative Planning and U54 Comprehensive for New Applicants;
- U56 Cooperative Planning and U54 Comprehensive for Revised Applicants;
- Planning and Evaluation for Funded Investigators.

Wrap-Up/Closing Remarks—Drs. Kimes, Aguila, and Ogunbiyi

Dr. Kimes thanked participants and asked that comments or questions be directed to Dr. Springfield or other CMBB staff.

The workshop adjourned on June 3, 2002, at 3:00 p.m.

**Appendix A: Common Features and Differences Among P20, U56,
and U54 Funding**

	P20	U56	U54
Plan	X	X	(X)
Implement	–	–	X
Focused	X	–	–
Broad	X	X	

I.	Minority Scientists	X	X	X
II.	Minority Institutions	(X)	X	X
III.	Effectiveness of CCs	(X)	X	X
IV.	Export Approaches	-	-	X
Eligibility		X	X	X
Budget Cap:		\$250 K	\$500 K	\$1.5 M
I.	Pilot Projects/Programs	X	X	X
II.	Infrastructure	X	X	
Requirements:				
I.	Research or Training	X	X	X
II.	Commitment	X	X	
III.	Two Applications	X	X	X
IV.	Mutual Benefits	X	X	
V.	20% Administration	X	X	X
VI.	Project Co-leaders	X	X	X
VII.	Common Planning	X	X	X
VIII.	External Advisors	-	X	X
IX.	NCI Staff Involved	X	X	X
X.	Research at MSI/CC	X	X	X
XI.	Process for Dev Funds	X	X	X
XII.	Annual NCI Workshop	X	X	X
Review:				
I.	Application ONE Score	X	X	X
		Reviewed as ONE		
		X	X	X