SUMMARY REPORT OF THE FIRST ANNUAL MINORITY INSTITUTION/CANCER CENTER PARTNERSHIP FUNDED INVESTIGATOR WORKSHOP
BETHESDA, MARYLAND – NOVEMBER 20-21, 2003

The ***First Annual Minority Investigator/Cancer Center Partnership (MI/CCP) Funded Investigators Workshop*** took place in Bethesda, Maryland on November 20-21, 2003. Two hundred and eight (208) investigators, institutional grants administrators, and government representatives attended.

The objectives of the workshop were to learn about accomplishments of the partnerships and programs; to meet and network with investigators and administrators from other partnerships; to establish potential collaborations with investigators from other partnerships; to learn about barriers and/or problems within partnerships and how to solve them; and to learn about the availability of resources in other partnerships.

Welcoming and Objectives

Welcoming Remarks - Dr. Sanya Springfield, Chief of the Comprehensive Minority Biomedical Branch and Dr. Brian Kimes, Director of the Office of Centers, Training and Resources

Drs. Springfield and Kimes welcomed the attendees.

Dr. Springfield pointed out that this was the first time that program directors, principal investigators and grants administrators were invited to a common workshop to share their ideas. She went on to state that one of the major objectives of the workshop were to enhance and reassure open and honest communication among all participants of the MI/CCP program and bring together during the Breakout Sessions, individuals who were doing similar work from several geographic areas. She pointed out that the Breakout Sessions would allow the attendees to interact and exchange ideas from both, the administrative and scientific areas, in order to set up future collaborations. The workshop also will review the status of the program and on obtaining input from the attendees that would help in the rewriting and reissuance of the three Requests for Applications (RFAs).

Dr. Kimes pointed out that although a great deal of trust had been established between the Minority-Serving Institutions (MSIs) and the Cancer Centers (CC), there must be more in order to fire up the program completely. He expected that it would take about 10 years for that to happen. He went on to explain that the MI/CCP program is a mainstream NCI program. This is an equal partnership where each partner is expected to help the other; the cancer center is helped by the minority institution to achieve better research in minority health disparities and the minority serving institution is helped by the cancer center in establishing research priorities and acquiring expertise, resulting in increased competitiveness within the NIH peer review system.

The MI/CCP program is based on three hypotheses: (1) If the MSI and CC are clearly linked, then the MSI would have less difficulty recruiting quality investigators because the MSI would be more research oriented and the intellectual resources of the CC would be readily available; (2) Historically, the MSIs have not developed competitive

research programs as priorities, instead, they focus on education and care. The more the MSIs successfully compete for R01s, R25s, etc., the more money will come to the institution. At present, the larger MSIs have great laboratory facilities but do not have the critical mass of investigators to compete successfully for mainstream funding. The MI/CCP program will challenge that situation. (3) The MI/CCP program is unique at NIH, and because cancer is a fundamental issue to biology, the research conducted through any of the partnerships should orient resources of other NIH programs, such as EXPORT, RCMI, and MBRS, in an effort to integrate them with the goals of the MI/CCP.

Objectives and Expectations of MI/CCP - Dr. Nelson Aguila, Program Director Comprehensive Minority Biomedical Branch

Dr. Aguila reiterated the major objectives and expectations to be achieved by the workshop. He stated that some important issues that need consideration in order to facilitate the success of the partnerships are: (a) further establishment of open and honest communication between the Co-PIs and among all the partnership participants; (b) involvement of more senior investigators from the cancer centers and investigators and students from the MSIs into partnership activities; (c) obtaining concrete and measurable institutional commitment and accountability from the CC and MSI administrators; (d) deriving productive scientific work measured by peer reviewed publications, attendance and presentations at national conferences, and peer reviewed grant submissions; (e) and getting the Program Steering Committee (PSC) involved in the partnership process.

Achievements

Investigators from currently funded U56, U54 and P20 grants presented their achievements and future plans.

U56 Partnership – Drs. Elizabeth Klonoff and Ana Navarro, Co-Principal Investigators, San Diego State University and University of California at San Diego, Rebecca and John Moores Cancer Center

This partnership has been strengthened by the previous existence of a joint doctoral program between San Diego State University (SDSU) and the University of California at San Diego (UCSD). This U56 involves, within its organization, a Local Advisory Committee (LAC) whose members are equally represented from both SDSU and UCSD. This equal mix of members facilitates the opportunity to build institutional networking and commitment. The PSC also has been very active and responsive to the partnership needs and activities. Institutional barriers have, in part, been solved by making the SDSU faculty participating in the partnership full members of the cancer

center. Thus, they have been able to participate in the CC's activities and compete for institutional funds. In order to enhance SDSU faculty participation in applying for these funds, the SDSU administration forfeited the indirect costs for these grants. In addition, the partnership has been successful in establishing a research resources core which

provides translation services, community contacts, statistical support, etc. The funding for this activity is shared by the partners. The partnership has also successfully sponsored students that have obtained F31 Fellowship funding from NCI and NIMH. Future activities include submission of an R25 grant application for the February 1, 2004 receipt date. This R25 grant, if awarded, would greatly help to consolidate the training objectives of the partnership.

U54 Partnership – Dr. Louise Canfield, Co-Principal Investigator University of Arizona Cancer Center/ Northern Arizona University

The overall goal of this partnership is to increase the number of Native American students and faculty at Northern Arizona University (NAU) performing cancer research. Accomplishing this goal will require the creation of a grass root effort that would lead to a long-term partnership between the institutions and the Native American community. Progress is slow because of the extensive geographical area involved. The formation of students' groups, networking and involvement of the Tribal Elders is essential for the success of this activity. One of the most evident barriers in performing research using human subjects in the Native American populations is the process of obtaining IRB approvals. A significant reason for this is that all the work using human subjects must be approved by the Navajo Nation. The internal and external evaluation of the partnership was briefly explained. A consultant has been hired to perform an evaluation of the entire process. Future plans for this partnership include hiring two faculty members at NAU and the involvement of more students. To date, one Native American student has submitted an F31 application to the NCI.

P20 Partnership – Dr. Jack Pledger, Co-Principal Investigator H. Lee Moffitt Cancer Center and University of Puerto Rico

This partnership is characterized by a very strong institutional commitment. The existence of open communication and interaction among all the participants has been very important. Distance has not been an impediment in developing the programs of interest and importance to both institutions. Interactions have been by teleconferences, videoconferences, and meetings at both Puerto Rico and Florida. Dr. Pledger presented the objectives and summary of results for three pilot projects and two pilot programs. A major part of the projects involves the establishment of Early Phase Clinical Trials Programs with significant correlative laboratory studies. Although not always possible, the goal is to use Oncology Fellows to write and conduct the trials. An R21 grant application was already submitted to NCI. The partnership is entering its last year.

Challenges and Improvements

NCI Commitment to the MI/CCP Program - Dr. Mark Clanton, Senior Policy Advisor, NCI

On behalf of Dr. Andrew von Eschenbach, Dr. Clanton conveyed Dr. von Eschenbach's message of NCI high commitment to the partnership program and to reducing the

cancer health disparity in this country. Dr. Clanton went on to state that the gap that exists between African Americans and White Americans also exists among other races and groups. In view of this observation, the success of the NCI in achieving its goal of reducing cancer suffering and mortality by the year 2015 is in large part linked to the success in reducing the cancer health disparities and to increase the participation of minorities in clinical trials. He then presented a slide that showed that the proposed cancer disparities funding for FY 04 is $61.35M, which includes research funding and support for individual investigators.

Institutional Commitment - Dr. Carol Garrison, President, University of Alabama at Birmingham

First, Dr. Garrison congratulated the attendees for their hard work, energy, enthusiasm, and accomplishments. She stated that her presentation represents the common views of the Presidents of Tuskegee University, Morehouse School of Medicine, and the University of Alabama at Birmingham. The commitment to the partnership program by all three institutions is strong, emphasizing the importance of community outreach. She also talked about recent progress and future plans for this three-way partnership.

The three presidents have decided to meet four times a year to discuss partnership issues. Their first meeting set the groundwork for a mutually beneficial partnership, with communication being a very important issue. All of the presidents read the PSC report, which helped them to understand the strengths and weaknesses of the partnership, and how the institutions could be of help. One recommendation that came out of that meeting was the importance of considering a mechanism for those investigators that do not get funded for their pilot projects. The reason for this is to keep those investigators interested and willing to try again. The presidents will have an important role discussing and establishing infrastructure that will contribute to the issue of time-release for investigators. The presidents also found that the Partnership Newsletter provided them with useful information to help support the program. Among the future plans for this three-way partnership is the submission of a U54 grant proposal in the near future. This is a realistic step in keeping this partnership working and, hopefully, expanding.

Ongoing Interactions and Internal Communications - Dr. Peter Ogunbiyi, Program Director, Comprehensive Minority Biomedical Branch

Dr. Ogunbiyi emphasized the activities that the participants have been or should have been doing. He further conveyed to the audience some observations noted by the NCI Program Directors during the site visits.

First, he reiterated the fact that the MI/CCP program is unique and novel, where communication among the participants is always challenging, and at the same time, critical to the success of the program. The Co-PIs need to create awareness about the program and the program's activities that will help to recruit participants. The site visits have shown that there is a definite weakness in disseminating the partnership activities beyond the academic departments originally involved in the program.

Another observation was that although, as a rule, the Co-PIs of the partnership interact well, there is a lack of communication and interaction among project leaders. Both Co-PIs have the responsibility of establishing communication channels. Communication and interaction must be open and honest in order to prevent or solve issues or situations before they become real problems.

It is important that institutional leaders be kept abreast of the partnership activities and plans. The PSC is a very important component in the development of the partnership and should be used more efficiently. One way to do this is through communication throughout the year, not only at PSC meetings. Proper communication will ensure that projects and programs reach higher levels and will also help in recruiting new participants. Development of a website to convey partnership activities is a necessary tool. All partnerships should have a website up and running as soon as possible.

Program Evaluation – Role of the PSC - Dr. Michael Caligiuri, Chair of the Program Steering Committee of the UPR/MD Anderson Cancer Center U54 Partnership. Director, Ohio State University Comprehensive Cancer Center

Dr. Caligiuri described the role of the PSC as he views it, according to his experience as. But first, he noted that this partnership program demonstrates NCI's commitment to addressing cancer disparities; what he called "righting a terrible wrong." He then went on to the role of the PSCs, in his view.

(1) Partnership participants should make sure that the PSC adheres to their tasks. (2) Members of the PSC should include experienced cancer center members that will help secure commitment from senior management. (3) The basic research activities performed are the engine to achieve the goals of any partnership. A cancer program can exist without clinical effort, but a clinical program cannot exist without basic research. (4) It is important that equality exists between the MSI and the CC in their levels of research and exchange. (5) Early success of the partnership will result in successful grant applications, which in turn will translate to changes in how cancer education is delivered at both the MSI and the CC. (6) CCs often under fund minority outreach, which involves the community, churches, organizations, and electronic communication. (7) Institutional commitment, organizational capabilities, facilities, and senior level involvement are crucial to achieving the long-term goals. (8) Programs should be novel and inclusive, where all departments of the institution are involved. (9) Facilities are important in attracting new faculty. (10) Interdisciplinary coordination and collaboration within and across institutions should be looked at critically by the PSC.

Responding to a question about the obligations of the PSC, Dr. Caligiuri stated that he believes that the PSC should be continually available to review any U54 component that needs external input. If members of the PSC are not available for meetings or consultation, they should be replaced, with agreement from the NCI.

Program Evaluation – Internal Evaluation - Drs. Karen Hubbard and Bruce Rapkin, Co-Principal Investigators, City College of New York and Memorial Sloan Kettering Cancer Center U56 Partnership

Challenges and solutions pertaining to any partnership involve heavy reliance on Internal Advisory Committees (IACs) and PSCs. The evaluation process includes detailed monitoring and descriptions of obstacles facing pilot studies. These steps are necessary to overcome future problems and they help to develop seamless communication within the partnership. The responsibilities of the IAC must be outlined in detail, and modified if necessary, to fulfill the emerging needs of the partnership. Changes in the role of the IAC, especially those that redefine their tasks, will help them to focus and shape strategies for reviewing and soliciting pilot studies. It is crucial to set a clear vision for the partnership's future.

The review process for the pilot studies must be clear to everyone. The IAC, PSC, and the investigators should have input in how the review process will be managed. This collaboration needs to be used both for the overall partnership and per project.

Interdisciplinary teams across institutions reflect the need for mentors that are both person and project specific. In addition, realistic timelines for each project must be set.

Also important is the need to establish funding alternatives for investigators not recommended for funding or not involved in projects of the partnership. Other mechanisms available at the CC, such as SPORE projects, should be considered.

It may be necessary to pay external reviewers when specific expertise is needed.

It is important to build review capacity at the MSIs, including issues relating to human research, HIPPA, informed consent, data safety monitoring.

A program such as the MI/CCP, in order to be successful and achieve its goals, must have the flexibility to make changes.

During the Q&A, and in response to whether mentors are compensated, Dr. Rapkin responded that the mentors are part of the IAC and they can be compensated. Compensation makes them take their roles more seriously. Other mentors may not be

paid, but the relationship can lead to a more established collaboration. Mentors are solicited where needed; even leaders can have mentors.

Budget - Ms. Barbara Fisher and Mr. Brian Martin, Grants Administration Branch, NCI

The roles and responsibilities of the Grants Management Specialist (GMS) and the Program Director (PD) were delineated. These roles are shown in detail in the handbook *"Everything you wanted to know about the NCI Grants Process…"* (A copy of the handbook was distributed to all the workshop participants.) One important issue

that was established referred to requests from grantees requiring approval from the awarding agency. These requests must have the recommendation of both the NCI PD and the GMS. The PD and the GMS work as a team for many of the partnership activities.

Some specific procedural necessities relating to the budget, especially for non-competing renewal applications were made. (1) budgets must be clearly justified; (2) non-competing renewals are due at the NCI 60 days before the grant anniversary date (this date can be found in the Notice of Grant Award); (3) changes of 25% or more in the budget must be justified or will be challenged; (4) Expanded Authorities allow the grantee the ability to re-budget within certain categories for unanticipated needs and other administrative issues; (5) re-budgeting is allowed in the MI/CCP program between partnership grants prior to submission of the non-competing renewal application; (6) carryover requests must be submitted after the Financial Status Report (FSR) is submitted and accepted by NCI. Carryover requests must include all signatures and a categorical budget page from the PHS 2590; and (7) carryover funds may not be rebudgeted between partnership grants.

During the Q&A, in response to a question about the procedure to obtain carryover funds, Ms. Fisher said that the grants policy states that you must include a term in the progress report stating that you intend to carry money over. After it is submitted, the PI is responsible for developing an official request letter and budget that is sent to the GMS. The request must be signed by the PI and a business official of the institution. Even if funds are less than 25%, they cannot be spent until the FSR is approved by NCI.

When asked whether an investigator can purchase a computer without NCI authorization, Ms. Fisher explained that the Expanded Authorities allow re-budgeting for anything up to 25% of the bottom line. Therefore, such expenditure is allowable providing the funds are not restricted.

Human Subjects and IRB Approval - Dr. Valery Gordon, Extramural Human Subjects Research Policy Officer, Office of Extramural Research, Office of the Director, NIH

Dr. Gordon recommended that the audience attend the NIH regional seminars about the topic of human subjects.

Dr. Gordon stated that, human subjects include women, minorities and children. In order to determine research with human subjects she told the audience to just think about human subjects on any application to read as “risk to people.” She also referred to the term “engagement” and stated that an institution becomes “engaged” in human subject research whenever it receives a direct HHS award to support such research. The term “engaged” applies to subcontractors and subcontracting out human subject research. The grantee bears the responsibility regardless of the research location.

Regarding exemptions from regulatory requirements, she stated that the PI's definition are not likely to be neutral, therefore should not be used. Exemptions seen at NIH are usually different than that of other agencies.

If the grant applications are not correctly marked, the review committee will code them with a "human subjects concern." Concerns are questions or issues that must be resolved prior to award.

"Just-in-time" information may include e-mails from the PI; however a formal document is needed, which includes the signature of the authorized institutional official.

She emphasized that it is important to read the Notice of Grant Award (NGA). The Grants Administration Branch may issue a restricted NGA with specific terms and conditions regarding human subject research. These terms and conditions clearly specify deadlines for submission of documentation in response to the restrictions imposed.

"Delayed onset" is a term that the GAB uses to issue an award that does not have definite plans for involvement of human subjects, or does not meet the requirements to perform studies with human subjects. Therefore, no funds related to human subject studies may be used.

The responsibilities of the institution apply to the role of the lead investigators. The investigators must make sure that all sites are in compliance and that any changes are reported to NCI.

Human Subjects and IRB Approval - Ms. Freda Yoder, Office for Human Research Protections, HHS, OS

The assurance of compliance with regulations regarding Human Subjects and IRB approvals were presented. Compliance with these regulations is paramount in conducting studies with human subjects.

Exempt research is not subject to the requirement of assurance or IRB approval. Human subject research supported by DHHS is subject to Title 45 of the Code of Federal Regulations, Part 46. There are two kinds of institutional assurances; one that is requested for each project, and one that is used for cooperative projects where multi protocols are used.

The terms of assurance state that US institutions are bound by ethical standards in the Belmont Report. International institutions can designate the Helsinki or other applicable standards, as long as OHRP finds them comparable.

The PI of the grant is responsible for partners and subcontractors to have assurance. The IRB must be registered with OHRP and each IRB must have a minimum of five members. There are regional coordinators to answer questions about the Federal Wide

Assurance (FWA) application. The FWA is obtained within 1-2 weeks after the application is submitted. It can be done quicker if done electronically.

To a question that referred to working with human culture cells of different origin and whether there would be a need for IRB approval, Ms. Yoder responded that if cell lines are publicly available, if the information and people cannot be identified, it would likely be exempt from IRB approval. If samples from human subjects come from outside the institution and there is no way to trace them back to a living person, and if no interaction has occurred with them, the IRB may state that it is not human subject research. Further, someone knowledgeable regarding IRB issues should decide whether or not to submit for IRB approval if a case such as this arises. If there are differences of opinion as to whether the research is human research, OHRP will ask questions specific to that research in order to establish whether or not it is to be considered human research.

If a project is longer that one year, it will need annual IRB approval. Each investigator should check the institutional policy about IRB review requirements.

To a question about how year-to-year compliance among multiple IRBs and protocols should be documented, especially when all participants are not known at the time of award, Ms. Yoder responded that each project has to have IRB approval. Some institutions provide a list of each protocol, with the date of the IRB approval. Item 4 on the face page of the application must be answer YES when it is not known whether human studies will be included. This might constitute a case of "delayed onset."

To the question on the procedure to add a second IRB to an approved FWA, Ms. Yoder answered that the approved FWA needs to be updated. The electronic feature to do this is not yet available; therefore the information should be submitted by facsimile.

FRIDAY, NOVEMBER 21, 2003

Breakout Sessions

Breast Cancer Breakout Session - Chaired by Dr. Delores Grant, North Carolina Central University and Dr. Andrew Joe, Herbert Irving Comprehensive Cancer Center, Columbia University

Nineteen investigators attended this session; 10 basic researchers, 4 health behavior researchers, and 5 molecular epidemiology researchers.

One topic of discussion evolved around the lack of infrastructure especially at the MSIs, which translates into slow progress of the research. Most of the attendees experienced some problems in getting technical support and resources. Another issue is space to conduct research, even with the support of a U54 grant. It was believed that the PSC should have a greater role in influencing institutional officials, because advice from individuals outside the institution has a greater effect.

Another challenge, especially at MSIs, is the retention of faculty. Many times individuals must choose between the goals of the MSI and their personal career goals.

Specific issues related to breast cancer research were patient accrual, tissue acquisition, IRB delays, and HIPPA compliance. There were also concerns about the pressure of obtaining useful data with pilot studies that are only funded for one year. One year is not enough time to gain experience with equipment and still allow time to obtain enough useful data to allow for the extension of funding.

Prostate Cancer Breakout Session - Chaired by Dr. Rick Kittles, Howard University and Dr. Clifford Berkman, San Francisco State University

Thirteen investigators participated in this session. Many concerns of the participants in this session were not just prostate cancer specific, they referred to challenges of the MSI with infrastructure and space, and a main topic of discussion was the issue of time-release associated with grants.

A great deal of time centered on discussing cohort development and on the need to increase sample sizes and perhaps create a network or consortium for cohort development. One idea was to utilize the HBCUs and exploit their strong relationship with the African American population to help recruitment and project design. There was great interest in sharing resources, especially in molecular biology, statistics, and epidemiology.

Dr. Kimes added that cohorts are complex and require a lot of expertise, but there is now an RFA for cohort studies and he suggested that if the group moves quickly perhaps they can apply for this grant.

Outreach and Cancer Prevention Breakout Session – Chaired by Dr. Cathy Meade, H. L. Moffit Cancer Center, University of South Florida and Dr. Hope Landrine, San Diego State University.

One major concern of this group was that the peer review system at NIH may not provide an effective review of the proposals derived from the partnership collaborations because of the uniqueness of the studies conducted in health disparities. It was believed that the review groups lacked the necessary expertise.

Discussion also centered on the need of the MSI to play an active role in educating the CC investigators to increase cultural sensitivity. This has been difficult because of the low numbers of minority faculty at the CCs and the tendency of the CCs to focus on basic research in cancer biology and genetics. The research of the MSI faculty is more focused on behavioral science research.

The issue of what is defined as race and ethnicity was discussed at length. It was suggested that NCI should put together a work force to establish those definitions.

Comments were made about a study conducted by the SDSU/UCSD partnership as to how people define themselves, and in which category they think they belong.

Other Type of Cancer Breakout Session - Chaired by Dr. Adriana Baez, University of Puerto Rico and Dr. Jean Ford, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

Twenty-one investigators attended this session.

Discussed were cell cycle control research, translational research, and community outreach. The collaborations in the group ranged from those that were just beginning to those that were more established and have already submitted R01 applications. Reports were given on achievements, and there was genuine interest shown in networking and collaboration.

MSI investigators talked about the challenges faced in their institutions, such as laboratory space, access to data, and protected time. Concern was also expressed about professional advancement, especially on tenure review, which is often performed by people who value teaching more than research. One possible solution suggested to that particular problem was for the MSI to have oncology faculty. This is where the partnership could play an important role.

Mentorship was also discussed. Of concern was that young faculty members at the CC are expected to mentor more senior people at the MSI. A solution to this problem, as suggested, would be for mentorship to be more method specific; meaning that the investigator would learn from whomever he/she needs.

Cancer Training and Career Development Breakout Session - Chaired by Dr. Donald Coffey, Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University

Twenty-six people participated in this session. Two panelists, Ms. Belinda Locke, CMBB, OCTR, NCI and Dr. Lester Gorelic, CTB, OCTR, NCI participated by answering questions regarding funding mechanisms.

An important issue that came up was the lack of input reaching students that may be interested in pursuing a career in science. A specific example was the situation with the Native Americans in Arizona and the need for role models.

Retention of MSI faculty was also mentioned. Often, faculty exchange is one-way; from MSI to the larger institution with intensive research programs. An important role for the partnership is envisioned to help solve this problem.

The R25 mechanism was discussed as a tool that can be set up for special programs. One idea to increase the number of students was to bring teachers to the institutions and excite them about science in order to get their help in recruiting students.

Grants Management and Administration Breakout Session - Chaired by Ms. Sherri De Jesus, University of Texas M.D. Anderson Cancer Center and Mr. Earl Sanders, University of Alabama at Birmingham Comprehensive Cancer Center

This session had three panelists who were available to respond to any specific questions that came up. They were: Dr. Valery Gordon, OER, OD, NIH; Ms. Barbara Fisher, GAB, NCI, NIH; and Ms. Freda Yoder, OHRP, OS, HHS

The biggest challenge for this group were progress reports, carryover letters, pilots that overlap funding periods, and what happens with the money, expanded authorities, human subject compensation and confidentiality, and budget timing.

No solutions emerged regarding questions pertaining to human subject compensation and confidentiality, but there was discussion of ways to seek solutions. It was emphasized that everyone has a copy of the NCI Policy Statement in order to make the mechanisms work best at their institutions.

Principal Investigators Breakout Session - Chaired by Dr. Lucile Adams-Campbell, Howard University and Dr. Edward Partridge UAB Comprehensive Cancer Center and Dr. Brian Kimes, Director, OCTR, NCI, NIH

All of the partnerships were represented at this session.

The first topic discussed was that the 20% administrative time for PIs was not sufficient. A recommendation was that the new RFAs state that for the MSI PI, a minimum of 25% effort and for the CC PI, a minimum of 10% effort be allowed for administrative time. It was also suggested that the institutions buy out the release time. One possible solution to release time of MSI investigators conducting research was that postdoctoral fellows be utilized to help teach classes.

There was extensive discussion about IRB approvals. One recommendation was to set up an agreement or consortium between the partnership institutions to set up an IRB. The agreement must be approved by the heads of the institutions that oversee the IRB.

It was suggested that the reissue of the RFA define the procedure for replacing investigators to the partnership.

Another suggestion was that review committees for pilot and full projects be composed of both CC and MSI investigators.

The need for incentives for mentors was mentioned, as well as the need for establishing a mechanism to keep interested investigators who do not get funded for their projects in the system until they are able to resubmit.

In response to a question regarding the consideration of supplementing existing partnership grants in order to pay students and avoid spending research funds, Dr.

Springfield responded that supplementation had not been considered and referred to the supplement mechanism in place for the P30 (CCSG) grants, which allows a CC to request up to $75,000 to fund research for high school and undergraduate students. When an investigator stated that it was not possible to fund pre-doctoral students with the partnership because of the expense, the response was that pre-doctoral students can be funded using the T32 mechanism. Most of the CCs have T32 grants from the NCI. Those grants provide slots for pre- and post-doctoral trainees and can also be supplemented by CMBB. Other possible sources of funding for students are the F31 mechanism as well as the possibility an MSI investigator identifying a CC investigator with an R01 grant, which can also be supplemented to support a minority investigator.

The Future of the MI/CCP Program

Dr. Springfield gave a short presentation of the genesis of the program and reported on the status of the program today. Currently the program is funding 26 P20 grants, 10 U56 and 10 U54 grants. These awards are funding 200 projects and programs that range from clinical pilot projects, training and education programs, basic cancer research projects to outreach programs.

Dr. Kimes expressed his opinion about the workshop and how much we are learning from it by having all the participants in one place who are providing input about the program. He explained the reason for not reissuing the RFA in FY 2003-2004, the process behind the issuance of the RFA, and also emphasized that the next generation RFA needs to be written using the active feedback from the participants of the program.

The importance of being aware of other opportunities and resources that can be linked to the MI/CCP program was also mentioned. Specific examples were the EXPORT Program, and RCMI. These programs are aligned with the same MSIs as the MI/CCP. Also, the CC and SPORE programs have developmental funds that are available to develop research projects. The supplement mechanism is an important source of funding that needs to be kept in mind. The P30 supplements support high school and undergraduate students, however only 17 of the 60 NCI designated cancer centers have applied for this mechanism. The MSIs should push for more applications.

Reference to carryovers was also brought up. There must be a good rationale and justification for requesting carryover funds. There are policies for preventing carryovers, and this is an issue that can be very important if large carryovers are requested, especially in the second year of the grant. Some of the issues of carryovers can be lessened by close consultation with the program directors.

Dr. Kimes went on to say that the MI/CCP program is one of excellence and is getting into the competitive system. This is important to consider when proper internal evaluation is established for the partnership. The program directors will be asking you very soon about measurable advances in the partnership, such as publications, grant submissions, pilot projects converted to full projects, etc. Within the procedures and success of the program, the scientific mentoring is of great importance, especially at the

CCs. It was suggested that CC investigators can reduce their effort on an RO1 by 5% or so, and that time can be spent mentoring. The co-leadership is another aspect of the partnership that is very important, because the MSIs are not currently in a position to conduct hard core biological research. The idea of the program is that the CCs would lead the effort and they would mentor MSI scientists who will eventually become independent scientists, with mainstream NIH grants. At this point, the CC scientists would act as consultants. Emphasis was made about the fact that MSI research expertise is different than that of the CCs, particularly in the behavioral sciences. The MSI can build in areas of weakness, and lead in areas of strength. It is most important to have this consideration early in the partnership to make better use of the resources available.

There are concerns as to whether the Co-PI, especially from the MSI, who has never had peer-reviewed support, could serve as a role model. The next RFA would stipulate that both Co-PIs of the U54 should have peer-reviewed support in the form of an R25, T32, or R01, etc. This does not have to be an immediate change, but it should happen.

Several questions were raised dealing with procedures and policies. The main points raised were: (1) The 20% administration costs ceiling is not practical and should be eliminated in the next RFA; (2) PSC members should be compensated, which will facilitate getting people interested in participating. (NIH policy regarding this matter will have to be studied because the term “honoraria” is not allowed); (3) NCI can help replace PSC members that are not committed or cannot participate; (4) All the requested budgets for the partnerships were recommended for funding in their entirety.

However, because of the budget crunch this year, carryovers will be reduced; (5) The PSC was not created to review pilot projects. They should, however, meet at least once a year and comment on new pilot studies approved by the partnership. The new RFA will more clearly delineate the role of the PSC; (6) Some PSC reports are good in identifying strengths and weaknesses of the partnership; others are not. Sharing PSC reports among the partners should help in understanding the role of the PSC. CMBB must be a member of the PSC; that fact is non-negotiable; (7) NCI will be more proactive in identifying good PSC reports and requesting distribution. Certain observations may be omitted from the reports to maintain confidentiality; and (8) possibly include a PI with experience in a U54 grant as a member of the PSC.

When submitting applications with novel ideas to NIH, Dr. Kimes suggested including a cover letter explaining the origin of the submission and asking for specialized review, especially if the expertise in the current review group is lacking. Also, close contact with the program director from CMBB is very important. Anything that is generated by the MI/CCP program that is going into the peer-review system should be known to the leadership because they can then defend those grants as a part of the effort to end disparities. Also, be aware that not all of the submissions will come to the NCI to be reviewed. Many of them will go to other NIH institutes, which is fine because other institutes also fund the CCs.

Regarding the strategic plan, the program has already exceeded the 2005 goals. The program will likely level off between 10-15 U54s because they are intended to continuously generate research and that requires very strong partnerships. It is possible that in the next RFA the P20 will be increased by one year, making it a four year grant.

Open Questions and Answer Period

In response to the question on how to involve the CCs in identifying training grants for postdoctoral fellows so they can stay and conduct research at the MSI, the response was that that was one of the major goals of the MI/CCP and the NCI will continue to push for that kind of collaboration between the MSI and the CC.

As to whether there would be an increase of funding for three-way U54 partnerships, it was stated that the NCI will keep certain funding caps, but for three-way partnerships they will consider each case individually.

MSIs find it difficult to keep postdoctoral fellows. Therefore, it would be beneficial to have a program where the postdocs train at the CC for two or three years and at the MSI for a year. The response to that was that one of the objectives of the MI/CCP program is to develop models of training that cross cut institutions, allowing the students and trainees to move back and forth.

As to whether a mechanism exists whereby the third partner could be a community organization, it was advised that the NCI does many things with community organizations, but with this program, if it becomes too complicated, the proposal may not do well in review and will fail. Expanding the definition of “partner” needs to be made clear. However, the incorporation of a community partner can be done as part of the research project where the community organization becomes part of the pilot study, not the partnership. Incorporating community organizations into the research pilot should be done to address health disparities effectively.

Is it possible for an MSI with a U54 to apply for a P20 with a different majority institution? The RFA states that each institution is allowed to have a U54 and a P20 or a U56 and a P20, but cannot have two U54s or two U56s. There is no regulation prohibiting the use of a different school, however it may not look good in peer review. If an institution does not have a U54 and wants to apply for two P20s with the same institution, that would be fine because it will be using different expertise on the two grants.

As to the suggestion of allowing 25% protected time for the MSI investigators, it was mentioned that it may be necessary to have a letter from the president or provost that the university will protect that much time. Reference was made to the PI breakout session in which the importance of the institution formally committing to an amount of time was emphasized.

As to solidifying the procedure for replacing a PI that would be acceptable to the rest of the team, language will be included in the next RFA defining the procedure to be used.

The decision about incentives for mentors was that each pilot has to be co-led, so why not ask for a percent effort on the project and set aside funding accordingly. Because the CC investigators percent effort was usually 1 or 2%, and whether that issue will be part of the new RFA, the response was that it would be.

The NCI agreed with the suggestion of establishing pre-pilot funding.

With regard to the 20% administrative cap, it will be eliminated from the next RFA. Then, it will be left up to peer review to say whether the administrative costs are rational. The cap was originally established to assure that the grant was not only paying for administration.

Asked about whether convening focus groups to help NCI work on addressing RFA concerns and issues, the response was that although it was a good idea, focus groups take time and the CMBB has staffing problems. A teleconference or videoconference was suggested.

Dr. Kimes advised that a draft of the key points and issues brought up at the meeting would be posted on the CMBB website. Participants were asked to review it and comment on the report. The exchange of information is important, however it must be clear that some issues are DHHS or NIH policy and are not likely to change. Many things, however, could be worked out, including terminology.

Dr. Springfield and Dr. Kimes thanked all of the attendees for their hard work. They also thanked the people involved in the organization of the workshop. The next workshop will seek active participation from MI/CCP funded investigators and administrators. Individuals interested in getting involved, should contact Dr. Nelson Aguila.

NOTE: This report complements the PowerPoint presentations that are also available on the CMBB website.