# NCI Guidelines for Administrative Supplements for Minority Biospecimen/Biobanking - Geographic Management Program (BMaP)

**Supplement Title:** Administrative Supplements for Minority Biospecimen/Biobanking

Geographic Management Program (BMaP)

**Application Deadline:** July 1, 2009

### **Eligibility Requirements:**

The Center to Reduce Cancer Health Disparities (CRCHD) of the National Cancer Institute (NCI) announces for the fiscal year of 2009 the opportunity for grantees to seek administrative supplemental funding for cancer health disparities planning research to create state-of-the art networks/centers dedicated to ensuring the adequate and continuous supply of high-quality human biospecimens from multi-ethnic communities for cancer research, using a Geographic Management Program (GMaP) approach. This administrative supplement, known as **Minority Biospecimen/Biobanking - Geographic Management Program**, is limited to NCI CRCHD's Minority Institutions/Cancer Center Partnership (MI/CCP), the Community Networks Program (CNP), and the Patient Navigation Research Program (PNRP). These programs may apply for an administrative supplement providing the following conditions are met:

- 1. The original cancer research grant or cooperative agreement involves cancer health disparities basic, clinical, behavioral or population-science research that is designed to overcome cancer health disparities.
- 2. Costs for the proposed implementation research cannot have been included in the original award.
- 3. The Principal Investigator (PI) for the supplement must be the PI of the original award.

Trainees from the Continuing Umbrella of Research Experiences (CURE) would also be encouraged to be included as active participants or collaborators.

# **CRCHD General Guidance for ARRA Funded Administrative Supplements**

- Eligible PIs may apply for this administrative supplement opportunity even if they have applied for other ARRA administrative supplements. Applicants may request administrative supplements for up to two years of funding. Preference will be given to requests of approximately \$100,000 in direct costs.
- Unobligated balances in the current grant, progress on previous CRCHD grants/supplements, and the number of other ARRA awards will be considered in NCI/CRCHD's evaluation of the supplement request.
- Funding priority will be given to those applications addressing ARRA goals of hiring and preserving jobs and accelerating the tempo of scientific research on active grants. All applications must clearly specify the purpose/projects for which funds are to be used.

#### **Purpose:**

The purpose of this administrative supplement is to support planning for the creation of state-of-the-art BMaP networks/centers dedicated to ensuring the adequate and continuous supply of high-quality human biospecimens from multi-ethnic communities for cancer research.

### **Background/Planning Objectives:**

Overcoming cancer health disparities is essential to lessen the burden of cancer. To achieve this strategic objective, the National Cancer Institute's (NCI) is committed to the study and identification of factors contributing to disparities, developing culturally competent approaches, and disseminating interventions to overcome disparities across the cancer control continuum from disease prevention to end-of-life care.

NCI has continued to sustain and, in some areas, expand its research efforts in understanding and addressing the impact of cancer health disparities (CHD) nationally. Yet despite best intentions, we have not been able to reduce disparities, particularly among some racial and ethnic populations. In addition, little coordination of these efforts has been achieved to date. As a better understanding of the key determinants, intensity, and complexity of CHD has become more apparent, NCI recognizes that CHD cannot be overcome through incremental change in existing activities and that a range of current economic factors restrict opportunities to overcome our national struggle to overcome health disparities. Instead, it requires a fundamental transformation in the way that we approach this growing and complex issue.

The NCI's Center to Reduce Cancer Health Disparities (CRCHD) is proposing new strategies and opportunities to better coordinate NCI CHD efforts and to establish structures and processes with potential to improve NCI's impact on overcoming CHD. These efforts are an attempt to envision this challenge as an entrepreneurial undertaking since there is both social and economic value to overcoming health disparities, as is evidenced by a growing body of studies highlighting the negative impact of the existence of health disparities on the nation's economic and social well-being.

CRCHD seeks to create state-of-the-art networks/centers dedicated to ensuring the adequate and continuous supply of high-quality human biospecimens from multi-ethnic communities for cancer research (BMaP), using a geographic management program approach. BMaP will provide a systematic and comprehensive strategy for building "hubs" to help stimulate effective, high quality biospecimen collection, processing and banking and analysis systems within diverse communities.

The ultimate goal of BMaP is to create unique, centralized, public resources for multi-ethnic biobanking/biospecimens. The primary mission of which is to ensure high-quality human biospeciments for cancer research that also takes into account the cultural sensitivities of diverse communities in specific regions. To this end, BMaP includes strong community outreach and supports the development of training in biospecimen science among underrepresented minority students from undergraduate through PhD and postgraduate level to faculty positions. This supplement proposes to lay a foundation for the development of these "hubs" to address and

develop multi-ethnic biospecimen/biobanking systems within various geographic areas and populations (including rural).

This administrative supplement will fund planning for the creation of these BMaP networks/centers by addressing the following three planning phases:

#### **PHASE 1: Core Services/Elective Opportunities**

Provide supporting BMaP infrastructure through the establishment of five core services:

- o Administrative core (to include a designated BMaP coordinator and a defined coordinated committee, along with strong commitment from a sponsoring institution)
- o Communications and Dissemination core
- o Community and Socio-cultural Beliefs core
- o Ethical, Legal and Policy core
- o Collection, Processing, Storage and Analysis of Biospecimens core

#### **PHASE 2: Needs Assessment**

Assess a region's current strengths, resources, capabilities, needs and interest in developing a BMaP network or hub.

### **PHASE 3: BMaP Implementation Plan**

Based on the findings in the assessment, develop a detailed BMaP implementation plan which will provide the foundation for establishing an operational BMaP network, to include providing training and research opportunities, and community engagement/outreach.

Thus, with funds from this administrative supplement, each prospective regional BMaP hub will establish and work through a BMaP coordinator and coordinating committee with strong institutional commitment, as part of an administrative core (Phase 1); provide additional core services in communications, community/socio-cultural beliefs, ethics, and biospecimen collection (Phase 1 continued); conduct a needs assessment as part of a broader planning process (Phase 2); and develop a BMaP implementation plan, to include providing training and research opportunities, and community engagement/outreach (Phase 3).

A description of each of the three planning phases comprising the BMaP concept follows below. For specific guidelines detailing the essential elements to include in each submitted application for this administrative supplement, please see the section entitled, "Applicants Guidelines to Address Each of Three BMaP Planning Phases" within the "Applicant and Submission Guidelines.

#### **Important Note**

This administrative supplement *will not* address BMaP implementation. Rather the focus of this administrative supplement is to fund *planning* for the creation of a BMaP hub, the final product

from which will be a comprehensive BMaP Implementation Plan. Subsequent funding is anticipated to allow each proposed BMaP hub to fully implement their BMaP Implementation Plan.

# **BMaP Planning Phases**

## **PHASE 1: Core Services/Elective Opportunities**

BMaP networks will be organized and administered to maximize the potential of their research and training base so that the whole is more than the sum of its parts. Organizational and programmatic arrangements will ideally maximize the advantages and strengths in cancer health disparities research and training within each hub. Each GMaP hub will also ideally promote joint initiatives, collaborations and interactions within and among its programs.

The infrastructure of each BMaP network will include **core services**. In this way, intended communications and programmatic research activities from each BMaP hub will help to strengthen the sharing of information, tools and resources, as well as planning for opportunities, for developing culturally competent biospecimen systems among diverse communities for use in cancer research and clinical practice. In addition, BMaP will support on-going programmatic partnerships (e.g. partnerships within and between MI/CCP, CNP and PNRP) and foster new collaborations among these programs and their community partners to promote scientific interactions and take maximum advantage of the collaborating institutions' CHD research and training capacities related to biospecimen science.

Five *core services* are required elements for each BMaP management infrastructure to maximize collaboration among the regional partners. The five cores are: 1) Administrative core 2) Communications and Dissemination core, 3) Community and Socio-Cultural Beliefs core, 4) Ethical, Legal and Policy core, and 5) Collection, Processing, Storage and Analysis of Biospecimens core.

Core Services

Core services within each BMaP hub will include:

#### **Administrative Core**

A designated BMaP Coordinator to facilitate administrative organization and ensure
clear lines of communication among and between partnering grantees and between
grantees and the NCI's CRCHD. The BMaP coordinator will be responsible for
managing the development and forth coming recommendations from the BMaP
implementation plan, as well as managing the day-to-day activities of the BMaP network.
Working together with the Coordinating Committee, the BMaP coordinator will be
responsible for providing the overall direction, management and administration of the
BMaP network.

- A defined internal coordinating committee (appropriately balanced for laboratory, clinical, community-based research, community members, advocacy, and administrative staff) that meets regularly (minimum of once a month) and provides advisory, decision-making and priority setting actions for the conduct of BMaP network's activities. Members should include representation from each of the three NCI-funded programs in the region, MI/CCP, CNP, and PNRP as well as representation from the CURE in the region. Membership should also include representation from CRCHD and the Office of Biorepositories and Biospecimen Research (OBBR).
- Demonstrated commitment from the sponsoring institution that will receive the supplement funds. The institutional commitment should be long-term and sustainable, aimed at building a BMaP network, and demonstrated by noting specific resources that will be dedicated to the priorities of the hub.

#### **Communications/Dissemination Core**

- Identification of a coordinated set of **communication/dissemination** activities focused on raising awareness of the critical need for human biospecimens among diverse populations for cancer research, and of guidelines and research recommendations related to biospecimens/biobanking; enhancing access and utilization of human biospecimens; addressing regional, local and socio-cultural barriers to human biospecimens collection, storage, and processing; and developing mechanisms to engage community participation in setting the human biospecimen agenda in their regions; and to enhancing communication, information exchange, and resource sharing among BMaP partners within and among BMaP sites and with NCI staff.
- Given the diversity of stakeholders with an interest in multi-ethnic human specimen collection and the complexity of tissue procurement, each BMaP will need to formulate a comprehensive communications and dissemination strategy. NCI has several resources, including caBIG<sup>®</sup>, caHUB, and the Office of Biorepositories and Biospecimen Research (OBBR), as well as strategies to elicit support and commitment from the biobanking community. Expected BMaP linkages with caBIG and caHUB include the following:
  - o We expect that each BMaP region will become knowledgeable about *caBIG*<sup>®</sup> tools and resources and utilize them whenever possible. caBIG<sup>®</sup> is a collaborative information network that accelerates the discovery of new approaches for the detection, diagnosis, treatment, and prevention of cancer, ultimately improving patient outcomes. caBIG<sup>®</sup> has also developed a suite of tools and resources for biospecimens and biobanking research. For example, The Tissue Banks and Pathology Tools (TBPT) workspace provides for the integration, development, and implementation of tissue and pathology tools. There is strong interest and investment in this area throughout the cancer center community, and this workspace provides an opportunity to bind systems together into a unified resource through a shared informatics infrastructure.

- o It is anticipated that BMaP will also serve to complement and ensure the diversity of tissue and specimen collections acquired and housed at *caHUB*. As a national resource, caHUB will serve as a unique, centralized public resource that will collect and store specimens required for research and development, and will ensure the adequate and continuous supply of human biospecimens and associated data of measurable, high quality acquired within an ethical framework.
- Each BMaP Communications/Dissemination core will be expected to build on existing communication channels to reach potential sources and end-users of multi-ethnic biospecimens. Targeted communication strategies will need to be developed for partnerships management and for education and outreach (e.g. biobankers, researchers, clinicians, policy makers, advocacy, and patient populations.)

### **Community and Socio-Cultural Beliefs Core**

- The Community and Socio-Cultural Beliefs core will ensure that research participants, patient advocates, and members of the community are engaged throughout the BMaP planning process in order to maintain equal partnership, transparency and public trust. Fostering community partnered research will help to generate community-based research, support efficacious and effective interventions, and enhance implementation of research results into practice. Community engagement will be particularly important during the discussion of ethical, legal and policy issues to help ensure that appropriate socio-cultural sensitivities and adaptations are made.
- Biospecimens/biobanking research and training is needed to identify, define, and address the impact of socio-cultural factors, as they pertain to cancer health disparities and intervention effectiveness. It will be necessary to identify how the perceived community cultural, racial/ethnic, and social contexts that biospecimens/biobanking research are viewed since there may be significant issues related to biospecimens in some communities, particularly for sites working with Native American or Alaska Native populations.

### **Ethical, Legal and Policy Core**

- The **Ethical, Legal and Polic**y core will be concerned with access and informed consent, as well as assessing the impact of socio-cultural beliefs on biospecimens use among racial and ethnic diverse populations. Issues of access will likely encompass several key issues: access to specimens (e.g. how will requests be priorized?), access to clinical data (e.g. how will patient privacy by protected?), and access to research data (e.g. will data sharing by recipients be encouraged or required?).
- Additional issues that may be appropriate for the Ethical, Legal and Policy core to consider may be: intellectual property, privacy protection, and biospecimen custodianship/ownership.

### Collection, Processing, Storage and Analysis of Biospecimens Core

- The Collection, Processing, and Storage of Biospecimens core will be focused on the scientific aspect of BMaP operations. This will include defining quality metrics (e.g. NCI's Best Practices for Biospecimen Resources and other evidence-based standard operating procedures for biospecimen collection, process and effectiveness, as well as linking participants to valuable education, training and biobanking management resources, and planning for improving performance.
- Tissue collections among BMaP networks will be expected to utilize the NCI Best Practices for Biospecimen Resources both for tissue and specimen collections. This will help ensure that diverse tissues and samples collected and processed through the BMAP program are of premium quality, thus maximizing both their integrity and utility for cancer and health-related disparities research.
- All tissue and specimen-associated data and information collected through BMaP will also be required to be caBIG compatible. Information derived from tissues/specimens collected through BMaP will, in turn, be made available to the research and clinical communities in caBIG compatible formats.

The formation of each of these cores should be based on defining a scientific focus in biospecimen research and training that will be clear from each proposed BMaP network's grants and contracts, and from the structure and objectives of its joint initiatives and programs.

It is envisioned that each BMaP network will be linked to the strategic and overall programmatic priorities and scientific opportunities identified within each proposed GMaP hub and with caBIG and caHUB. A subsequent round of competitive supplemental funds will be made available to provide a source of budgetary flexibility to a proposed BMaP site to implement their proposal, and allow each BMaP network to develop new collaborations and technologies; strengthen weaker scientific areas; provide scientists with the opportunity to explore innovative ideas; and take some risks. These initial research ventures will ideally enable BMaP networks to build competitive research teams to successfully pursue future RFPs.

#### **PHASE 2: Needs Assessment**

Each BMaP pilot will be developed by regionally examining all CRCHD and NCI-funded research and training programs. After the programs and corresponding investigators have been identified, documentation should be compiled that provides a complete listing of both partners and biobanking/biospecimen resources within the participant region. The BMaP needs assessment will allow for a global or comprehensive assessment of state-, city-, local-, community-, and regional resources. The needs assessment will be multi-faceted and is expected to be inclusive of community care providers, navigators and advocacy groups. Further, special consideration should be given to those activities or programs that enable the ability to effectively engage and impact racial and ethnic diverse populations with a given region. An accurate and comprehensive depiction of the current biobanking activities and resources will provide a clear picture to infrastructure that is currently in place and beneficial opportunities for the future. This

is an integral activity that is required to analyze the strengths and opportunities present at each site.

One of the most critical components of the needs assessment is the portfolio analysis of the region. This analysis will be required to identify regional areas of strength and expertise in biospecimen research within each BMaP pilot. The portfolio analysis exercise is expected to provide a foundation for the design and implementation of infrastructure and programmatic (research, education and outreach) BMaP initiatives. The analysis will also help ensure that programs, partners and resources related or of potential benefit to addressing cancer health disparities or supporting biospecimen science within a region are either appropriately connected or have the potential to be appropriately connected. In addition, it will help encourage researchers to strategize on ways they can begin to work together to enhance region-based scientific exchange and strengthen research and training capacity focused on overcoming cancer health disparities and increasing the infrastructure to allow for biospecimen research and biobanking activities.

The portfolio analysis is expected to include data from each of the three eligible NCI-funded programs (CNP, MI/CCP, and PNRP) related to research (e.g types of cancers and funding by cancer type), training, education, outreach, infrastructure and personnel (e.g. numbers, expertise, training, and function), as well as associated trainees, partnerships, resources, activities and infrastructure. The assessment of trainees, partnerships, resources and activities should include, but not be limited to data on the number/type of trainees and partnerships, and awareness/education and outreach materials (e.g. print and on-line). The assessment would also describe the infrastructure (e.g. tissue resources, clinical trials accrual, clinical research management, and special equipment) which is currently available within the region for development of a BMaP hub. The inclusion of resources that are funded by other organizations and federal agencies is also important and encouraged (e.g Centers for Disease Control and Prevention, Food and Drug Administration and the National Comprehensive Cancer Control Program).

Additionally, current minority biobanking activities and ongoing biospecimen research within the region as it pertains to underserved populations should be a point of focus. The laboratories and faculty that are actively engaged in biospecimen research should be identified as well as the associated clinical staff. The involvement and participation of medical oncologists and pathologists within the region will be critical, along with the support of the medical facilities or institutions that they are affiliated with. Lastly, the available catalog of reagents specific for underserved populations should also be explored (e.g specimen type, cancer type, and minority cell lines). Areas of biospecimen research focus for the region may emerge such as racial/ethnic populations of study and cancer focus. CRCHD strongly supports the protocols and guidance provided in the NCI Best Practices for Biospecimen Resources published by NCI Office of Biorepositories and Biospecimen Research (OBBR). This office is responsible for developing a common biorepository infrastructure that promotes resource sharing and team science, in order to facilitate multi-institutional, high throughput genomic and proteomic studies and facilitate multi-national research. Utilizing this office and all their available resources is highly encouraged.

In sum, the BMaP needs assessment will provide information and data for population-, city- and state-wide cancer patterns and illuminate barriers both within the individual institutions/organizations, and in the broader research community. Such barriers may include disciplinary and funding silos that limit biospecimen research, lack of mechanisms for ensuring cultural competency and clinical care, having a limited number of minority faculty, and/or perceptions among basic and clinical scientists that biospecimen science is too challenging or expensive. Strategies currently being used to address barriers and identification of factors at the state and federal level to facilitate efforts would also need to be identified. The analysis will likely utilize both conventional (such as analysis of data from archival sources) and participatory (such as in-person interviews and telephone surveys) approaches, and would be initiated by the PMC, and then, enhanced and completed by grantees within each regional hub. NCI staff will gladly facilitate and identify appropriate individuals and contacts for consultation and guidance.

# **PHASE 3 – BMaP Implementation Plan**

With the establishment of a coordinated management structure/infrastructure composed of an administrative core (composed of a regional coordinator and coordinating committee, along with institutional commitment) and related communications/dissemination; community and socio-cultural beliefs; ethical, legal and policy; and collection, processing, storage and analysis of biospecimens core services (Phase 1), and the completion of a needs assessment to assess the region's current strengths, capabilities, needs and interest in developing a BMaP regional hub (Phase 2), a period of time should be devoted to the conceptualization, coordination and identification of the personnel, laboratories, and elective opportunities that will be included in a BMaP implementation plan (Phase 3). Building on the findings in the assessment, this plan will detail the background development of the proposed BMaP hub, outline immediate and long-term objectives, specify plans and programs for each of the core services (administrative; communications/dissemination; community and socio-cultural beliefs; ethical, legal and policy; and collection, processing, storage and analysis of biospecimens), and describe the resources and infrastructure proposed for the BMaP region. This phase 3 planning period is the time when anticipated tenets of a BMaP regional hub will be established.

#### **Application and Submission Guidelines**

Applicants are encouraged to discuss their administrative supplement request with the NCI BMaP Program Director prior to submission.

Use the <u>PHS 398</u> research grant application instructions and forms (rev. 11/07). Follow standard PHS 398 instructions for font size. NIH will return applications that are not submitted on the 9/04 version. For further assistance contact GrantsInfo at 301/435-0714 or via email at <u>GrantsInfo@nih.gov</u>.

All requests must include the following:

**Cover letter**: Request the administrative supplement and refer to and provide contact information for the project leader of the application. The cover letter must be signed by the applicant's Cancer Center Director and the appropriate business official of the institution.

Include the following statement: "Per supplement instructions, a detailed budget request is enclosed."

### **PHS 398 Face page** (PHS 398, Form Page 1):

- Item 1: The request must have the same title as the original award. Please include the number of the original grant.
- Item 2: Identify the supplement as "Minority Biospecimen/Biobanking Geographic Management Program."
- Item 3: The request must have the same PI as the original grant.
- Item 4: Request a single year of support. There must be an active original award during the entire funding period.
- Items 7A-8b: Denote the direct and total costs for the first year, as well as for the entire period of support. Total costs should not exceed those stated under Allowable Costs above.

**PHS Biographical Sketch Format Page**: For key personnel in each of the three programs (MI/CCP, CNP and PNRP) and CURE, and the proposed Coordinating Committee members.

**PHS Other Support Format Page**: Documentation of active research funding (i.e., NIH, other federal, private sources) for all collaborating investigators.

**Detailed Budget for Initial Budget Period** [PHS 398 (O9/2004), Form pages 4-6) All applicants must provide an itemized budget, signed by the grantee institution's business office.

### **Applicant Guidelines to Address Each of Three Planning Phases**

Applicants should address all of the essential elements for each of the three planning phases (core services/elective opportunities, needs assessment and BMaP Implementation Plan) listed below.

### PHASE 1: Core Services/Elective Opportunities

Applicants are expected to describe the leadership and specific functions of the administrative core to be composed of a BMaP coordinator and coordinating committee, along with strong commitment and support from a sponsoring institution. Working together, the regional coordinator and coordinating committee will provide the necessary oversight, coordination, support and logistical services needed to make each collaborative BMaP center function effectively. Applicants are also expected to identify and describe the specific functions of the four additional cores: communications and dissemination; community and socio-cultural beliefs; ethical, legal and policy; and collection, processing, storage and analysis of biospecimens. This section would also included proposed organizing meetings, workshops and retreats, and processes for communicating among the BMaP coordinator, coordinating committee, sponsoring institution, key partners/stakeholders and the community, as well as for documenting, including secretarial services, the results of the activities among these same entities. In addition, the

applicant must include in this section a description of a process and criteria for selecting one or more elective opportunities.

It is preferred that individuals designated as the *BMaP coordinator* be well-established leaders within the region, with active programmatic experience and competitive research support. If the BMaP coordinator is not a well-established practitioner and researcher within the community, the application must demonstrate that this individual has substantial broad-based experience in cancer health disparities or a 2-3 year professional development plan for the individual to develop those capabilities, skills and experience must be provided. A biosketch and letter of commitment for this coordinator must be provided.

The *Coordinating Committee* (CC) will provide the advisory, decision-making and priority setting actions for the conduct of each BMaP regional network's activities. It is expected the CC will operate in a collaborative, mutually-beneficial relationship in which each member believes that by working jointly together they can help each other and their region develop stronger cancer programs. Applicants must list the names of the coordinating committee members, provide a biographical sketch and letter of commitment from each, describe how members were selected and the expertise they will bring to the CC. Applicants are also expected to outline each internal planning session (e.g., CC meetings, regular forums and seminars, workshops, retreats), and each communication/dissemination, evaluation, and training core activities that the CC would be involved in planning, conducting, and overseeing. A biosketch and letter of commitment from each member of the Coordinating Committee must be provided. The selection criteria utilized to identify the Coordinating Committee members must also be specified.

It is expected that a letter of commitment be provided from the *sponsoring institution*. The institutional letter of commitment should detail a long-term commitment to building a BMaP network by noting the specific resources that will be dedicated to the priorities of the hub.

Face-to-face informal meetings between collaborating members are among the most effective methods of *communication/dissemination*. In instances when distances or different locations are challenges, applicants are encouraged to consider and identify other methods of communication including e-mail, teleconferences and videoconferences. Communication processes should be defined, including how the progress of the collaborations will be reported to institutional leaders, and strategies for improving coordination and management of biospecimen collection, processing and analysis efforts within each region, as well as increasing their institutions' interest in biospecimen research and training. This section must also include a Coordinating Committee (CC) review and evaluation process for initiating and closing all BMaP projects, based on their merit and potential for achieving the objectives of the BMaP hub and its progress. In addition, processes must be defined for determining how partners, resources and infrastructure needs will be established for the BMaP hub.

Applicants must explain how they propose to evaluate the success of each BMaP hub in meeting its objectives. This would include identifying and describing metrics, goals and a process for the *community and socio-cultural beliefs* core as well as strategies for providing on-going feedback to the community and partners regarding progress in meeting objectives.

Applicants must specify how they would develop a comprehensive *ethical*, *legal and policy* plan to address access and informed consent, as well as assessing the impact of cultural beliefs on biospecimen use among their communities.

Finally, applicants are expected to describe the criteria and process for *collection*, *processing*, *storage and analysis of biospecimens* that will address the scientific aspects of BMaP operations, including metrics, assessment of current resources, and linking of participants with education and biospecimen resources.

#### PHASE 2: Needs Assessment

Applicants must clearly document how their BMaP network would be derived based on careful planning, needs assessment and priority-setting processes. The needs assessment should be based on an examination of each contributing CNP, MI/CCP and PNRP member's strengths/weaknesses and potential to help each other become stronger in relevant targeted areas, and guide development of the appropriate skills to recognize and address biospeciments/biobanking among their communities It is expected that the needs assessment will be an important activity in the overall planning, developing and implementing of each BMaP hub.

To assess the needs of a potential BMaP network, each applicant is expected to identify and describe a process for identifying the strengths, capabilities, needs and interests of the community, faculty, staff and investigators involved in cancer research and training in their geographic region and should be drawn from a careful examination of the NCI-funded MI/CCP, CNP, PNRP and CURE programs in the area. This process must identify and describe a methodology for conducting a needs assessment that will provide comprehensive and unbiased information to assist in the planning and prioritizing of BMaP cancer research and diversity training activities. The description of the needs assessment must also include measures to assess the interest and desire to address biospecimen related topics among the community, and to assess the interest in participating in a BMaP network and the strengths, capabilities and needs in cancer research and training among the faculty, staff and investigators associated with each of the NCI-funded MI/CCP, CNP, PNRP and CURE programs. In addition, a listing of the individuals who would participate in the needs assessment from each of the NCI-designated program and a plan for involving or reporting back to the CC must be described.

### PHASE 3: BMaP Implementation Plan

Using the needs assessment as a basis, each applicant must describe in this section the overall planning and priority processes that would be undertaking to develop, implement and evaluate a BMaP network in their geographic region. This description must clearly document how the BMaP hub would be derived, and present each process that would be used in planning and setting the priorities and objectives for the proposed BMaP region. Applicants must briefly describe, in chronological order, the nature of each planning activity that would be undertaken (e.g. meetings of higher institutional officials, planning committees, steering committees in areas of opportunity, workshops of MI/CCP, CNP, PNRP and CURE faculty), its purpose, the individuals who would participate from each of the NCI-designated programs, function and

involvement of the CC, and anticipated outcomes. In addition, a proposed timeline and budget for planning, developing, implementing and sustaining the BMaP hub must be included. This section should be identified as "Planning and Priority-setting Processes." It should also include background/objectives, plan development for each of the core services and elective opportunities, and for resources/infrastructure as described below.

Background/Objectives. Applicants must explain how the building of a region-based "hub" for the support and efficient management of cancer health disparities research, training and infrastructure can help each of the NCI-funded MI/CCP, CNP, PNRP, and CURE programs work better together to enhance access to high quality biospecimens for cancer and cancer health disparities research and training programs. Each applicant must also outline a process for determining immediate and long-term priorities of the BMaP network to be derived from a careful planning process that seeks to establish a research and training "hub" for addressing access to biospecimens at a regional level.

Core Services. Each application must describe how each of the core services (administrative, communication and dissemination, community and socio-cultural beliefs, ethical, legal and policy, and collection, processing, storage and analysis of biospecimens) would be developed and implemented based on their respective plans described in Phase 1 of the "Guidelines to Applicants" section. It is expected that the final BMaP Implementation plan would include a full description of how each of the core services had been planned, would function and would be operationalized, as part of the infrastructure needed for a BMaP network to fully address cancer and cancer health disparities.

Applicants must prepare this section with the understanding that the final BMaP Implementation Plan would include a brief description of the nature of the biospecimen opportunity including its: 1) goals/objectives, 2) justification for how access to biospecimens would be linked to the strategic and overall programmatic priorities and scientific opportunities identified within their BMaP hub, 3) location and commitment of space for the BMaP network, 4) names of co-leaders who will direct the BMaP network, 5) experience of the key technical personnel, if applicable, who will be responsible for the day-to-day operation, 6) proposed budget using pages 4 and 5 from Form PHS 398, 5), and 7) training plans and objectives (if appropriate).

Resources/Infrastructure. Applicants must describe a process by which the Coordinating Committee (CC) would assess the resources and infrastructure (e.g. tissue resources, clinical trials accrual, clinical research management, special equipment) needed to develop a BMaP center, with the understanding that the final BMaP Implementation Plan would need to include the following information: 1) title of the resource/infrastructure to be developed, 2) description of the resource/infrastructure and how its development will further the priorities of the BMaP site, 3) location and commitment of space for the resource, 4) names of co-leaders who will direct the activity, 4) experience of the key technical personnel, if applicable, who will be responsible for the day-to-day operation, 5) proposed budget using pages 4 and 5 from Form PHS 398, 5), and 6) justification for the location of the resource.

### **Literature Cited**

Provide a listing of relevant publications.

### **Relevant letters of Support**

Provide letters of commitment from each of the Coordinating Committee Members, which is expected to include appropriate representation from each of the participating CNP, MI/CCP and PNRP programs in the region, and from the sponsoring institution.

#### **Post Award Requirements**

ARRA Related Reporting. Post award, BMaP awardees will be required to provide periodic reports for use by NCI/NIH to fulfill ARRA related reporting requirements. Details regarding the specific content and timeframes for these reports are yet to be determined. However, the expectation is that BMaP networks would fully comply with these requests.

Final Report. Within 90 days after the conclusion of the funded activity, the applicant must submit to their respective grant and CRCHD Program Official a Final Progress Report that constitutes the final BMaP Implementation Plan. The Plan must include, as noted in the section on "Applicant Guidelines to Address Each of the Three Planning Phases," a complete and detailed description of the planning and priority setting processes, activities, background/objectives, core services, as well as elective opportunities, resources/infrastructure and outcomes that address each of the three planning phases: 1) Core Services/Elective Opportunities, 2) Needs Assessment, and 3) BMaP Implementation Plan, as described in the "Background/Objectives" section. It is expected that the applicant will submit this final BMaP Implementation Plan in a format that could be readily adapted as a manuscript for submission to a peer review, scientific journal. Applicants must receive approval from the Coordinating Committee and the NCI program.

### **Submission of Administrative Supplement Request**

Requests for this administrative supplement must be submitted to CRCHD (see address below) as described in the program guidelines. This is a one-time announcement and formal requests must be received on or before July 1, 2009. Late applications will not be accepted. Note the NIH Center for Scientific Review (CSR) IS NOT involved in receipt and processing of these requests. Applicants are strongly encouraged to submit their administrative supplement requests electronically as an e-mail attachment in PDF format; however, the scanned application must include the signature of the AOR.

#### Electronic Submission

If sending an electronic PDF copy, the email address is **cmoten@mail.nih.gov. DO NOT** submit application via Grants.gov as the NIH Center for Scientific Review (CSR) **IS NOT** involved in receipt and processing of these requests.

### Paper Submission

Submit a signed, typewritten original of the proposal and **five** signed, single sided photocopies, Times Roman 12" pt in one package to:

Carmen P. Moten, PhD, MPH BMaP Co-Program Director National Cancer Institute Center to Reduce Cancer Health Disparities 6116 Executive Blvd., Suite 602 Rockville, MD. 20852

Phone: (301) 496-8589 Fax: (301) 435-9225

Email: cmoten@mail.nih.gov

#### **Review Considerations**

All proposals will undergo review for scientific and technical merit by a committee of NCI staff with expertise in the disciplines pertaining to cancer health disparities. Those proposed projects judged to be responsive to the intent of this initiative will be evaluated based on the review criteria below, and prioritized accordingly. Applications will be evaluated on the following review criteria, organized by the three planning phases:

#### PHASE 1: Core Services

BMaP Coordinator and Coordinating Committee (CC) Leadership: Do the qualifications and experience of the regional coordinator and proposed members of the CC provide strong scientific and administrative leadership that will help in achieving the objectives of building region-based BMaP hubs for cancer research and training?

Letters of Commitment from CC members and sponsoring institution: To what degree do the letters of commitment fully support the development of a strong BMaP region and help in achieving the overall BMaP objectives and priorities? What is the level of authority of leadership committed to the BMaP network?

Administrative, Communications and Dissemination, Community and Socio-Cultural Beliefs, Ethical, Legal and Policy, and Collection, Processing, Storage and Analysis of Biospecimens Cores: Are descriptions of the specific functions of each of the core services adequate for the proposed BMaP center to function effectively?

#### PHASE 2: Needs Assessment

Is the design and quality of the needs assessment methodology and measures adequate to identify the strengths, capabilities, needs and interest of the participating NCI-funded MI/CCP, CNP, PNRP and CURE programs, and thus, provide a basis for broader BMaP planning and priority setting? Are the qualifications and experience for each of the proposed participating individuals adequate? Is the plan for involving the CC appropriate and adequate?

### PHASE 3: BMaP Implementation Plan

Is the design and quality of each of the planning and priority-setting processes adequate to develop, implement, evaluate and support a BMaP hub? Are the qualifications and experience for each of the proposed participating individuals who would participate in the planning processes appropriate and effective? Is the plan for using the CC members effective? Are the process, criteria and plan for developing each of the core services and undertaking an elective opportunity adequate? Are the process and criteria for identifying and implementing the resource and infrastructure needs adequate? Is the proposed timeline and budget appropriate?

#### **Award Criteria**

In addition to the CRCHD General Guidance for ARRA Funded Administrative Supplements (see page 1), awards will be based on the following criteria: a) scientific and technical merit of proposed project; b) the adequacy to include both genders, minorities and their subgroups, and children as appropriate for the goals of the implementation plan; and c) availability of funds.

### **Authority and Regulations**

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourages the use of all tobacco products. In addition, Public Law 103-227, the Pro- Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

### **Inquiries**

Inquiries concerning the BMaP concept, application requirements and supplement and application process should be addressed to:

Mary Ann S. Van Duyn, Ph.D., M.P.H., R.D. BMaP Co-Program Director, Center to Reduce Cancer Health Disparities (CRCHD) National Cancer Institute

6116 Executive Boulevard, Suite 602 Rockville, MD 20852-8341

Phone: (301 451-4284 Fax: (301) 435-9225

Email: vanduynm@mail.nih.gov

Carmen P. Moten, Ph.D., M.P.H. BMaP Co-Program Director, Center to Reduce Cancer Health Disparities (CRCHD) National Cancer Institute

6116 Executive Blvd., Suite 602

Rockville, MD 20852 Phone: (301) 496-8589 Fax: (301) 435-9225

Email: cmoten@mail.nih.gov

LeeAnn Bailey, Ph.D.
BMaP Co-Program Director, Center to Reduce Cancer Health Disparities (CRCHD)
National Cancer Institute
6116 Executive Blvd., Suite 602, Rm 6032
Rockville, MD. 20852

Phone: (301) 496-7344 Fax: (301) 435-9225

Email: baileyl@mail.nih.gov