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| AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | | | 1. CONTRACT ID CODE | PAGE OF PAGES 1 6 | |
| 2. AMENDMENT/MODIFICATION NO. Two | | 3. EFFECTIVE DATE May 22, 2007 | 4. REQUISITION/PURCHASE REQ. NO. QSI70122 | 5. PROJECT NO. (If applicable) | |
| 6. ISSUED BY National Cancer Institute Office of Acquisitions, PSAB 6120 Executive Blvd., Rm 6070 Bethesda, MD 20892-7194 (US Mail) Rockville, MD 20852-7194 (Express Mail) | | CODE | 7. ADMINISTERED BY (If other than Item 6) Same as block #6 | | CODE |
| 8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) | | | (X) | 9A. AMENDMENT OF SOLICITATION NO. RFQ-NCI-70048-NV | |
| | | | (X) | 9B. DATED (SEE ITEM 11) 04/24/2007 | |
| | | | | 10A. MODIFICATION OF CONTRACT/ORDER NO. | |
| | | | | 10B. DATED (SEE ITEM 13) | |
| CODE | | FACILITY CODE | | | |

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
 (a) By completing items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

| | |
|--------------------------|---|
| CHECK ONE | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| <input type="checkbox"/> | |
| <input type="checkbox"/> | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). |
| <input type="checkbox"/> | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: |
| <input type="checkbox"/> | D. OTHER (Specify type of modification and authority) |

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

This solicitation is hereby amended to answer questions received from an interested party. The questions and answers are on the amendment pages that follow. Attached to this amendment you shall find a amended Attachment I - Statement of Work and Attachment II - Baseline Capabilities for NCCP Pilot Sites.

The due date for proposals is now June 11, 2007 at 11 AM EDT.

All other articles remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| | | | |
|---|------------------|--|------------------|
| 15A. NAME AND TITLE OF SIGNER (Type or print) | | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) | |
| | | Caren N. Rasmussen | |
| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
| (Signature of person authorized to sign) | | (Signature of Contracting Officer) | |

Question 1:

Are the Community Cancer Centers addressing cancers in adults only, or will pediatric cancers be included? Should the medical oncologist have experience only in cancers affecting adults, or also affecting children?

Answer 1:

The NCCCP pilot sites will only be addressing adult cancers for the NCI.

Question 2:

The setting for these programs is described in different ways throughout the RFQ. Terms such as 'hospital-based community setting', 'hospital-based community cancer programs', 'hospital-based community-based cancer programs' are used in describing the settings. Can NCI provide a more descriptive overview of the types of settings the evaluator will likely be encountering for these programs?

Answer 2: - See Attachment II

Hospital Cancer Center Program Components

The organizations are community-based hospitals with cancer programs that incorporate medical, surgical, and radiation oncology under one administrative/medical structure. Private practice arrangements with physicians or groups may be included if the arrangements support the goals of the cancer center for patient care, research and outreach, and the requirements of the NCCCP pilot for the duration of the pilot. The programs are located in a distinct physical setting – that is a separate building, a separate wing, or a discrete hospital location containing most of the program components and staff – as dedicated space for a large percentage of the program activities. The sites include both urban and rural sites, and provide care to a wide range of groups, including African Americans, Asians, Hispanic Populations, and Native Americans. Required baseline components for a site include:

- A physician director, patient navigation support, at least one and preferably more multi-disciplinary disease specific planning committees (e.g., breast, colon, prostate) to improve the delivery of patient care and clinical outcomes;
- Demonstration of institutional support for an effective role for the physician director;
- A strong oncology practice leadership group committed to providing vision, oversight, and plans for growth and research support;
- Demonstration of the treatment of a minimum of 1,000 new cancer cases a year or for special circumstances related to disparities or high cancer incidence, 600 new cancer cases may be considered;

- New cancer cases reported from Cancer Registry Data, consistent with the reporting format of the American College of Surgeons Commission on Cancer (COC) for the National Cancer Data Base;
- Existing programs for cancer screening;
- A hospital unconditionally accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the College of American Pathologists (CAP) or JCAHO for laboratory services, and by the Commission on Cancer of the American College of Surgeons (ACoS).

Question 3:

Will all sites/pilot programs have electronic medical records available?

Answer 3:

All sites have some form of electronic medical records.

Question 4:

Can NCI provide us with a range of funding available so that we can effectively design an evaluation to meet their needs?

Answer 4:

No.

Question 5:

We recognize that NCI is on a tight timeline for this proposal because the programs will soon be on board. However, this is a fairly complex proposal to develop and design. Would it be possible for NCI to extend the deadline?

Answer 5:

New delivery date will be provided.

Question 6:

On page 19 of Attachment 1, NCI states that the option year will be from Months 37-42. Since this is a 4 year project, it should be months 37-48. Please verify how many months are in the final option award.

Answer 6:

The final option year is for 6 months; this reflects 3 months to receive all of the data, and another three months to write the report and brief NCI. Therefore, Option Year Three covers months 37-42.

Question 7:

In what format would the sites be able to deliver the survey data to the contractor? Will it be the contractor's responsibility to clean the data when it arrives or does NCI assume that the data delivered by the sites will be prepared for analysis?

Answer 7:

See Attachment I – Statement of Work, Task 2.5.

Question 8:

In general, how experienced are the sites in collecting and preparing data similar to what will be requested for this project?

Answer 8:

See Attachment I – Statement of Work, Task 2.4

Question 9:

To what extent will the contractor need to plan to provide technical assistance to the sites to handle IRB issues related to survey data collection?

Answer 9:

See Attachment I – Statement of Work, Task 7.3.7 and Task 7.3.8

Question 10:

NCI notes that the data to be collected by the sites will be a 'shared' responsibility between the contractor and pilot programs. However, the contractor is supposed to ensure a response rate of 70%. Since the contractor will not be collecting the data directly, can NCI provide details about the requirements being placed on the programs themselves for ensuring the high response rate and explain whether the programs are likely to need technical assistance in setting up their collection processes?

Answer 10:

See Attachment I – Statement of Work, Task 7.3.2

Question 11:

Will the pilot programs have a designated evaluation contact person who will be required to be responsive to the evaluation contractor's requests in a timely manner?

Answer 11:

See Attachment I – Statement of Work, Task 1.1.e

Question 12:

Does NCI expect the contractor to deliver one report for each pilot site, as well as a report that compares findings across sites, or is the expectation that the contractor will provide just a cross-site report for each set of annual site visits/case studies?

Answer 12:

See Attachment I – Statement of Work, Task 1.1.g., Task 2.7, and Task 3.4

Question 13:

A number of interviews are required at each site for the initial case study yet OMB approval is described as a task that occurs later in the project and only for the patient survey. Does NCI anticipate that the protocols for the case study will require OMB approval?

Answer 13:

See Attachment I – Statement of Work, Task 1.1.f.

Question 14:

The baseline case study is described to include 2-day site visits to each site. However, given the list of people to be interviewed and the fact that the lead evaluator for each site visit will likely need to be present for each interview, a 2-day visit doesn't seem like enough time, even when some interviews could be conducted by phone. This seems to be the case particularly when the major hospital systems are described and multiple sites within one program may need to be visited. Does NCI expect that only 2 days be spent at each site or is there flexibility in the time allowed for these visits?

Answer 14: -

The government requires that these activities can be accomplished in two full working days on site. There is not a requirement that the lead evaluator be present for each interview, and it is anticipated that interviews will be divided up on site based on team members' expertise so that simultaneous interviews can occur.

Question 15:

NCI specifies that there will be an 'evaluation oversight committee' for this project on their web-site describing the NCCCP. However, this committee is not referred to in the RFQ. What will be the relationship, if any, between the committee and the contractor? For example, should the evaluator plan on attending meetings in person of this committee? Would conference calls be scheduled that includes this committee and the contractor? Should time be allotted in order to allow for the committee's review and input, in addition to that provided by the NCI evaluation project officer?

Answer 15: -

The NCI Evaluation Project Officer approves all work consistent with the contract; however there is an oversight group that will provide guidance on the evaluation for the NCI. The Contractor should anticipate interaction with this group for at least the following activities: the evaluation contract "kick off" meeting; the review of the contractor proposal for Cross-Site Evaluation Metrics, Measures, and Data Collection Protocols and Contractor Requirements as noted in the RFQ; and the annual briefing for each year, including the final closeout briefing.

Question 16:

Who are the key stakeholders (if not this committee) for the evaluation and how will they be engaged (if at all) in the evaluation planning process described on page 15?

Answer 16:

See Attachment I – Statement of Work, Task 1.2.1

Question 17:

What will be the role of sites in finalizing the metrics, instruments, etc.? Will the contractor need to plan for numerous revisions to incorporate their changes?

Answer 17:

See Attachment I – Statement of Work, Task 1.2.o.

STATEMENT OF WORK

EVALUATION OF NCI COMMUNITY CANCER CENTERS PROGRAM PILOT STUDY

I. PURPOSE

The purpose of this project is to support a multi-phased evaluation of the NCI Community Cancer Centers Program (NCCCP) pilot study. In the base year of the evaluation the contractor shall develop and initiate implementation of the evaluation design for the project. In the first phase of the base year, the contractor will provide an initial site assessment of each sites' program including reporting relationships and location of the program within the organizational structure of the hospital, the role and structure of management, medical staff and key hospital services, the cost structure in support of the program, and informatics infrastructure within the institution. This information will be presented in the form of a logic map, of how these structures, and processes, are anticipated to affect program outcomes. The contractor also shall create a patient survey during this phase of the base year contract.

In the second phase of the base year contract, the contractor shall review and comment on the proposed evaluation metrics for the evaluation provided by the NCI evaluation project officer. This assessment will include a review of the appropriateness of the metrics for the evaluation questions, the feasibility of site implementation in a manner consistent with cross-site evaluation, and recommendations, if any, for alternatives.

In the third phase of the base year contract, the contractor shall create an evaluation plan for the project, utilizing the information collected in the first two phases, that will outline in detail the qualitative and quantitative methods, measures, and data collection protocols that will guide the formal evaluation of the pilot program. Once the NCI evaluation project officer approves the revised plan, the contractor shall initiate the implementation of the evaluation design in the base year contract and continue evaluation activities throughout the optional years of the contract.

The purpose of the evaluation is to support a process assessment and an impact assessment of the implementation, operations, and performance of the NCCCP pilot sites that are hospital-based cancer programs. The process assessment will evaluate the implementation experience of the specific NCCCP pilot sites, and, through individual site assessments and comparative research, assess the feasibility, best practices, relationship to NCI-designated Cancer Centers and other community resources and replicability potential of the NCCCP model (and its program components) to support cancer research and improved cancer care delivery (see Background section of this SOW for a description of the NCCCP model). The objectives for this part of the evaluation involve the development by the contractor of specific evaluation protocols to assess the acceleration of early phase translational science in hospital-based community settings through a program designed to enhance clinical trial participation by physicians and patients, bio-specimen collection and reporting, and connectivity of community-based programs to the Cancer Biomedical informatics grid (ca-BIG™). The contractor shall also develop evaluation protocols to assess the site's abilities to create an infrastructure and effective programs to reduce healthcare disparities, including the implementation of patient

education initiatives, patient navigation programs, community outreach programs and community partnerships with other healthcare providers. Similarly, the evaluation contractor shall develop methods and protocols for assessing how the pilot sites are incorporating enhanced health information technology (i.e., electronic medical records) into the NCCCP model to enhance both research and care delivery program objectives. The evaluation contractor also shall conduct a site replicability assessment to include: the role of hospital executive level management support necessary to assure an effective NCCCP program, the role of the medical staff to determine which factors support an effective NCCCP program, and a detailed assessment of the hospital and cancer program implementation and operational resource costs (fixed and variable) that are necessary to support an effective NCCCP program. These requirements are described in detail in subsequent sections of this Statement of Work.

The impact assessment will involve care delivery objectives that involve enhancing the delivery of evidence-based cancer screening and therapies through improved multidisciplinary care planning and care coordination across primary care, surgery, medical oncology, and radiation oncology. The evaluator will also assess the impact of the pilot sites to improve physician participation and accrual rates to clinical trials especially among minority individuals.

The contractor shall design and conduct the evaluation of this pilot project. The 12 month base contract will support the developmental tasks within this contract, including activities leading to the preparation of the evaluation design and implementation plan, the development of a cross-site patient survey, patient survey administration procedures, and an OMB clearance package for the survey. The contractor shall also initiate implementation of the evaluation plan in the base year contract. The option periods of the contract will involve the implementation of the evaluation plan, the baseline and follow-up patient survey, data analyses, and report preparation and briefings related to the evaluation of the pilot project. The option periods will include the collection and analysis of primary evaluation data by the contractor to support qualitative assessments of the NCCCP program, as well as a review of data collection protocols and secondary data provided by the NCI evaluation project officer to examine select evaluation issues suitable to quantitative assessment that pertain to the programmatic objectives of NCCCP pilot study described in this statement of work.

The contractor will collect primary data from two sources: interviews and site visits. Secondary data will come from the NCI project officer and include data from the participating NCCCP pilot sites' claims/billing, medical records data systems, patient survey data collection systems, other administrative data systems (e.g. financial or specialized baseline data protocols adopted by the sites), and pilot site feasibility and/or quality improvement projects necessary to establish common baseline or follow-up information on key NCCCP program components. These requirements are described more fully in this statement of work.

This evaluation project offers a unique opportunity to capitalize on a multi-hospital system site pilot initiative that examines how hospital-based community cancer programs can improve upon the NCCCP program model to enhance community participation in clinical research, evidence-based care delivery, and reducing health disparities. The challenge for the evaluation contractor will be to develop and implement a evaluation

plan that maximizes the ability of the government to learn from these pilot sites and inform decisions on the continued development and/or expansion of the NCCCCP at NCI.

II. BACKGROUND – THE NCCCCP MODEL

Since 1973 the National Cancer Center Program has grown from 8 to 61 major academic and research institutions throughout the United States to expand innovative cancer research and, in each of their regions, deliver the latest evidence-based therapy to cancer patients who need it. However, despite the substantial investment in research and clinical care delivery associated with this expansion, their services account for only about 16 percent of cancer treatment in America. Approximately 84 percent of cancer treatment takes place in community oncology settings. Cancer patients have a variety of personal and economic reasons for not accessing NCI-sponsored cancer centers, most often because of their location, but at times due to research priorities, insurance participation, or factors that limit participation.

The NCI Community Cancer Centers Program (NCCCCP) is a model program designed to bring state of the art oncology care to the community, including the earliest phase translational science, to all cancer patients, utilizing linkages with other NCI-sponsored research programs (e.g., Community Clinical Oncology Program, Community Networks Program, and Cancer Centers Program). It is characterized by improvements in the research infrastructure in community settings to support increased participation in clinical trials (especially early phase trials), collection of bio-specimens for NCI-sponsored research (e.g., the Cancer Genome Atlas), adoption of electronic medical records for care delivery and research, and integration into the ca-BIG™. The NCCCCP model is also characterized by cancer care delivery innovations to increase adherence to evidence-based therapy throughout the cancer care continuum, including cancer prevention, screening, treatment, survivorship and end-of-life care. These innovations include but are not limited to improved multidisciplinary team management and improved coordination of care. Because of its community-based structure, the NCCCCP model emphasizes the need to reduce health disparities through improved patient education and navigation programs, community outreach programs and partnerships with other healthcare providers.

The NCCCCP pilot study will explore the development of a national network of hospital – based, community-based cancer centers and how this model could impact the advancement of the NCI goals cited below. For this pilot study, ten organizations with hospital-based community cancer programs will be selected. In order to study different approaches to knowledge transfer, best practice sharing, and replicability, two of these ten pilot sites will involve multi-hospital system sites that include three distinct developmental programs in distinct geographic markets (see task 1.1.d for a description of these sites). These developmental programs will be included as part of the individual multi-hospital system sites. The pilots will be diverse, representing a range of organizational models, expertise, and geographies, and serving different racial, ethnic, and socio-economic groups.

The NCCCCP model is complex, encompassing a variety of research and cancer care delivery improvement goals. Therefore, not all pilot sites will be working on the same projects. The evaluation contractor will limit its evaluation activities to the core program

model components and the relevant hospital components essential to support the cancer program common to all participating pilot sites. Common to all sites will be the ability to demonstrate improvement in the following major study areas:

- Increased physician participation and accruals to NCI-sponsored clinical trials, especially early phase trials and minority participants who are either traditionally underrepresented in clinical research or represent disadvantaged populations
- Increased knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of the caBIG™ for hospital-based community-based cancer programs.
- Increased knowledge of infrastructure requirements, policies and procedures, costs, and other issues (e.g., collaborations or contracts with necessary for biospecimen collection, annotation, and storage) required for implementation of the NCI Best Practices for Biospecimen Resources, formerly First Generation Guidelines for NCI supported Biorepositories -FGGs), thus enabling community hospitals to participate in biospecimen collection and reporting initiatives that will advance the NCI's research agenda.
- Reduce disparities in cancer care delivery through demonstrated improvement in patient education, patient navigation programs, and community outreach.
- Improve the quality of care throughout the cancer care continuum by:
 - Improved multi-disciplinary team care and improve methods of care coordination to increase delivery of evidence-based care for prevention, screening, treatment, follow-up care, palliative care, survivorship care planning, and end-of-life care.
 - Measurable quality improvement in a specific cancer site, such as colorectal cancer, which will include a screening, component and use of evidence based guidelines and measures for cancer diagnosis and treatment.
- Increased hospital executive management support and improved coordination of related hospital services that are required to improve cancer care and clinical research in support of an effective NCCCP program.

Another core NCCCP program activity will be pilot sites' activities designed to determine how enhanced information technology applications (e.g., electronic medical records) can be incorporated into the NCCCP model to achieve the aims of the program in each of these study areas.

Another core activity in the pilot program that will be assessed by the evaluation contractor is the connection of the pilot sites to community based cancer programs and resources, especially as it relates to reducing cancer disparities in research and care delivery, linkages to NCI-designated cancer centers, and effective linkages with state-sponsored cancer initiatives to enhance the objectives of the NCCCP program.

Finally, the evaluation contractor shall assess the cost, feasibility and sustainability of the NCCCP model. This assessment shall include an assessment of the implementation and operational direct and indirect costs of the NCCCP program model and the cost implications for continuing the existing sites or expanding the program to new sites at the

end of the NCCCP initial pilot phase. These requirements are described in detail in the base contract evaluation requirements below.

III. Base Contract Period – Contractor Task Requirements

The Contractor shall provide the necessary personnel, materials, equipment, support and supplies to accomplish the tasks described below. The Contractor shall complete the analysis within the specified time and submit a written report of the findings to NCI. All work done under this contract shall be performed and is subject to the project officer's approval.

TASK 1. Base Contract Period Tasks. The base contract period shall be 12 months from the date of award. Contractor requirements are organized into four distinct phases during the base contract period, which are reflected as subtasks in this statement of work.

Task 1.1 Phase 1 – Pilot Site Evaluability Assessment Contractor Requirements

a. Initial Contract “Kick-off” meeting. Within two weeks of award, the contractor shall meet with the NCI project officer and other NCI officials in Bethesda Maryland for a “kick-off” meeting to review the work plan and requirements for the contract. The contractor and the government shall clarify any issues regarding the scope and timing of activities in the contract. The NCI evaluation project officer shall provide the contractor with a draft set of evaluation metrics to be used in the evaluation of the NCCCP pilot program. The contractor shall provide the NCI evaluation project officer a draft written summary of issues discussed at the kick-off meeting and what, if any, implications they have for clarifying the scope of work and the timing of evaluation activities within one week after the conclusion of the meeting. The contractor shall incorporate any revisions recommended by the NCI evaluation project officer.

b. The contractor shall assess the pilot site program models and determine which elements of their programs are suitable for evaluation according to the metrics provided by the NCI evaluation project officer (see task 1.1.a above). The evaluation contractor shall assess the evaluation metrics and data elements to determine if the metrics need revision, if alternative metrics are more appropriate, and if additional data elements may be needed to support the metrics for evaluation purposes. For example, the contractor may be aware of standardized measures that have already been tested and deployed widely by other programs that may be more suitable for the pilot study. Moreover, certain national programs may provide performance metrics that could be selected as national performance measures for the project. These include, for example, the American College of Surgeons Commission on Cancer quality initiative and the Medicare Physician Voluntary Reporting Program. Of particular importance will be the ability to select measures that enable the identification of a denominator population and the ability to track information over time. It also may be important to select measures where a baseline performance can be established early in the pilot study, so that pre/post evaluation designs may be considered and site progress tracked over time.

To assist in the assessment of the metrics, the contractor shall conduct two-day site visits to each of the pilot sites in the NCCCP program. The contractor shall assume there will be ten pilot sites with two of the sites consisting of multi-hospital system sites. One system will have a lead site and two developmental sites in different regions of the country and the second hospital system will also have three locations in different regions of the country with two lead sites and a third site which is three smaller cancer programs within a two hour driving radius which will integrate into one regional cancer program. The site visit plan for the system sites is described in more detail below. Assessing the two multi-hospital system sites will be especially challenging since the contractor needs to determine for which evaluation questions these sites should be examined as a system (across geographic distinct developmental programs) and for which research questions the programs should be treated as unique sites. Also, to the extent applicable, the contractor shall assess measures and metrics of performance already implemented at the sites, especially in the areas of clinical trial accrual, bio-repository collection and reporting, and effectiveness of care in cancer screening or treatment. It also may be important to select measures where a baseline performance can be established early in the pilot study, so that pre/post evaluation designs may be considered and site progress tracked over time.

c. The second purpose of the evaluability assessment is to systematically document the pilot site programs from an intervention and evaluation perspective relevant to each of the NCCCP components in order to help develop specific hypotheses pertinent to the NCCCP model that are subject to qualitative and quantitative evaluation. The contractor shall help develop these hypotheses for sites individually and collectively. The pilot site evaluability assessment will include both semi-structured interviews and case studies at each pilot site with the pilot program as the unit of analysis. This phase will include the development of program "logic maps" that diagram in detail the underlying program structures, processes, and outcomes at each site that are pertinent to the NCCCP objectives. This review shall include the ability of the pilot sites' information and data collection systems to support timely collection and reporting of these measures during the three-year pilot effort.

For program elements under development (e.g., new data collection systems or referral agreements between community hospitals and ambulatory care practices to enhance the coordination of cancer screening, diagnosis, and treatment services), the contractor shall evaluate the timing of their operational status during the pilot phase-in to adapt appropriate evaluation methods to the length of operations of the program component. The evaluation contractor shall develop specific testable hypotheses for each program that cover both the core elements of the NCCCP model at each site.

d. The contractor shall develop a protocol for conducting these site visits, interviews, and assessment. This shall include the case study methodology, list of evaluation questions for both the interviews and the case studies, program mapping methodology, and an evaluation work plan. The report shall include the theoretical framework utilized by the contractor to evaluate behavioral and organizational innovation and change in the NCCCP and clearly describe how this framework is applied in the interview/case study approach. This protocol shall include the proposed scheduling, evaluation methods, interview guides, as well as the topic areas that will be covered for each site. The

contractor shall have specific cancer (e.g., medical oncology), managerial/financial, healthcare informatics and organizational health services research expertise to serve on the team that conducts, the site visits. The contractor's protocol shall include but not be limited to a "kick-off" meeting with top leadership from the hospital, the PI and key leadership from the cancer program, and with one group of patients/caregivers. The patient/caregiver interviews shall be used to gather feedback on the quality and organization of the program. As part of this semi-structured interview process, the contractor will work with the sites to arrange a one-hour interview of one group of patients and caregivers to elicit patient input about the cancer program. The contractor shall explore the patient experience in the cancer program as well as exploring the reasons why this program was selected over other cancer program options.

For the two health systems pilots, the contractor shall visit the lead sites for two days and each developmental location in the pilot for one day. There will also be an additional half-day of interviews planned for the PI and key staff from the system headquarters. To reduce the travel and logistics expense for these system site visits, health system staff shall be present at the lead site location for a half-day.

For specific planning purposes, one system will have one lead site and two developmental sites all in different regions of the country. The system staff will be interviewed at the lead site location. The second system will include two lead sites and one developmental site with three smaller cancer programs, within a two hour driving radius, which plan to migrate into one NCCCP cancer program as part of the pilot (this one developmental site will need to have drive time factored into the schedule). For travel and logistical planning, it should be assumed that there will be a geographic range of sites (14 individual and system locations) as follows: one in the Northeast, two in the Middle Atlantic, two in the Southeast, five in the Midwest, two in the South/Southwest, one in the Mountain states, and one on the West Coast.

The list of pilot site representatives to be interviewed includes but is not limited to the following:

One-hour interviews:

- NCCCP Principle Investigator
- Hospital CEO and COO
- Hospital Medical Director
- Physician Director for Cancer Program
- Hospital CFO and/or relevant finance staff to address costs
- Hospital Vice President or Director of Community Outreach (or equivalent title)
- Hospital CIO
- Administrative Director and Nursing Director for Cancer Program

Half hour interviews:

- Hospital Chief of Surgery
- Hospital Chief of Pathology
- Hospital Chief of Radiology
- Hospital Vice President of Patient Care (Nursing)
- Director of the Operating Room

- Hospital Director of Pharmacy
- Hospital Director of Research/staff responsible for trials, IRB and consent policies
- Chief of Radiation Oncology
- Key Medical Staff in the Cancer Program - key cancer surgeons, medical oncology group leaders (note: may be more than one medical group). It is anticipated that there will an acceptable sample size of cancer center physicians interviewed.
- At least one Chair of a Multi-disciplinary disease specific committee
- Social Work Director for Cancer Program
- Lead Patient Navigator
- Key Survivorship/Palliative care Team leaders
- Key referring physicians
- A hospital governing body representative
- Community partners in outreach activities (e.g. an FQHC Director)
- NCI-designated Cancer Center or Academic Research Institute representative (not mandatory for baseline but for follow up)
- CCOP Principle Investigator if outside cancer program
- Representative from other research network relationships
- Representative from State Cancer Plans if applicable
- Representative from local survivorship groups (e.g. Reach for Recovery, Lance Armstrong, Koman)
- Director and Medical Director of the Hospice

Patient/Caregiver one-hour interview:

- Patient/Caregiver group

Health System half day interview

- Health System COO
- Health System Principle Investigator
- Health system lead disparities key staff person
- Other health system key personnel

These interviews are intended to assist the contractor in determining the current state of the program and the critical issues that impact the program and which should be incorporated into the evaluation and which will be the basis for the follow up site visits. The contractor shall develop an approach to conducting interviews that balances the need for effectiveness and efficiency, and includes the consideration of phone interviews for very selected informants (e.g., cancer center representatives and community advocates), and group interviews for support departments and services such as patient navigation, social work, pharmacy and finance and accounting). However, it is expected that most interviews of key leadership and program staff (e.g., hospital CEO) will be one-on-one, one-hour interviewing.

There may need to be longer sessions with leadership of the hospital or the Cancer Program such as for financial and cost related information. The contractor shall use these interviews to provide a variety of perspectives on the cancer program and they will

include those in the cancer program, in the hospital, in the cancer medical community, in the referring medical community, in community organizations working with the cancer program on outreach to the underserved and survivorship, in cancer research partnerships (NCI Centers/CCOPs, etc), and State Cancer Plans. These interviews also shall be used to assess issues related to data collection (e.g. cost data) to aid the contractor in the development of a data request for the NCI Evaluation Project Officer.

e. The contractor shall submit the draft evaluability protocol to the NCI evaluation project officer within 4 weeks of contract award. Based on the comments received by the NCI evaluation project officer, the final protocol for the site evaluability assessment shall be submitted 6 weeks from the date of award. The contractor shall schedule and conduct the site visits between 9 and 16 weeks after contract award. For communications involving the site visits and interviews, there will be a designated pilot site contact to coordinate the logistics of meeting dates and interview schedules. All other communications shall be coordinated through the NCI project officer.

f. OMB approval will not be required for the site visits because there will be less than 9 sites with similar questions. There are three very different types of NCCCP hospitals (1) hospitals that are part of a system of hospitals (2 sites), (2) Native American sites (2 sites), and (3) neighborhood hospitals (6 sites). The questions and the interviewees will be different for each type of hospital. As a consequence, none of the site interview protocols will be identical, and in no case will more than 6 sites receive a similar interview protocol or interview list.

g. The final site assessment report shall be submitted 18 weeks from the date of award and shall incorporate revisions made based on the comments from the NCI evaluation project officer and NCI staff. The contractor shall provide reports for each individual sites as well as a report that compares findings across sites. The contractor shall provide a copy of these reports to the pilot sites and the prime contractor for the pilot sites once the NCI evaluation project officer approves the report.

Task 1.2 Phase 2 – Development of Cross-Site Evaluation Metrics, Measures, and Data Collection Protocols Contractor Requirements.

a. The development of interim cross-site evaluation metrics, measures, and data collection protocols shall occur after the completion of phase one of this contract. In this second phase of the evaluation, the contractor shall meet with the NCCCP prime contractor and program site representatives to review the specific metrics, measures and data collection protocols to guide the overall pilot study evaluation. This review shall educate the pilot sites on the rationale for the measures and data collection to support the evaluation and raise any additional issues to assist the evaluation contractor with their development of their recommendations to NCI regarding the development of a final evaluation design (see task 1.3 below).

b. The purpose of this phase is for the evaluation contractor to obtain feedback from the pilot sites on the timing and technical requirements so that the metrics and data collection plan is implemented uniformly across the pilot sites. This requires a clear understanding of the common metrics, measures, and data collection protocols necessary to support the

evaluation. These measures and data collection methods may be qualitative and quantitative in nature. The contractor's review shall be guided by the evaluability assessments completed in task 1.1 and resource availability at the sites, but also include additional information on potential metrics and measurement strategies that may not necessarily be deployed at any single site, but be available to the evaluation contractor.

c. The contractor shall assume that the following eleven areas and evaluation activities will be common across all pilot sites:

- Accruals to clinical trials, by phase and type of trial, and by population characteristics, including age, race, and ethnicity. Improved physician participation in trials and improved education for patients on the availability of trials and their advantages and disadvantages.
- What are the gaps in achieving best practices for bio-specimen collection and reporting of tissue specimens, and how well do the pilot sites close those gaps, either through enhancements in existing bio-repositories at the sites, or through pilots to test improvements in bio-specimen collection and reporting?
- Increased knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of the caBIG™ for hospital-based community-based cancer programs.
- Patterns of care for screening, diagnosis and treatment, including quality improvement initiatives in the use of evidence-based treatments at each phase of care.
- Multi-disciplinary care teams and their influence on improved coordination and continuity of cancer treatment and follow-up care. This includes more timely and appropriate referrals and communication among cancer specialists and between specialists and primary care physicians.
- The location of the NCCCP Program within the organizational and resource structure of the hospital including an assessment of the characteristics which contribute to improved quality of cancer care and clinical research (top management support, key organizational resources in support of the program (IT, Lab/Pathology, Operating Room, Community outreach programs, facilities, fund raising, etc.) and the extent to which there is the necessary support to achieve pilot goals.
- The medical staff model (private practice, employed physicians, contracts, oncology specialty companies, hybrid models, etc.) which supports the cancer program and how it influences improved cancer care and clinical research.
- Patient experience with care, including satisfaction with multi-disciplinary care. team communication, sense of emotional support and financial assistance, access to appointments and waiting time, and overall satisfaction with care.
- The creation of an infrastructure and effective programs to reduce, health disparities, including increasing cancer prevention and early detection procedures in communities with disparities, access to clinical trials, cancer treatment.
- Outreach to community and state cancer programs as well as linkages with NCI-sponsored programs like the National Cancer Center Program and CCOPs, and the ability to use these resources to enhance research and care delivery programs at the sites.

- The costs of implementing and operating NCCCP and the requirements needed to sustain existing sites and expand the program to other NCCCP sites.

d. For each research area described above, the contractor shall make recommendations to the NCI evaluation project officer to assure that the metrics, data collection protocols, and the timing of receipt of data, and analytical approach to evaluating the data support the investigation the following evaluation questions:

- (1) What changes in practice patterns, trial accrual, and adherence to evidence based practice are attributable to the NCCCP program?
- (2) What factors (e.g., NCCCP program components and related hospital organizational components) are associated with these changes?
- (3) What program changes and associated program elements of the NCCCP program are likely to be sustained or institutionalized within the existing sites? Which elements appear to be dependent on unique attributes of individual sites?
- (4) What is the potential for generalizing these results to similar community-based cancer programs that did not participate in the NCCCP pilot? What factors (e.g., funding, expertise, program infrastructure, program relationships within the hospital authority and resource structure, policy issues) are necessary to facilitate the expansion of the NCCCP to other community-based cancer programs?

e. The eleven evaluation areas and activities described above shall represent the minimum requirements for the evaluation contractor. The specific tasks and reports associated with these requirements are described in the remainder of this statement of work. The government may increase or modify these eleven areas depending upon the specific program characteristics of the pilot sites and the results of the contractor's evaluability assessment. In no case will these changes in scope exceed five additional projects. If so, the government shall prepare a change order for the contractor's review and negotiate a new scope and price for these changes.

f. Data collection activities to support the evaluation will be a shared responsibility by the contractor and the pilot sites. The contractor shall not be responsible for data collection for the following areas:

- Baseline and follow-up self-assessments and gap analyses of pilot site capabilities in the areas of clinical trial participation and accrual, bio-specimen procurement and reporting, IT capabilities for caBIG™ linkages, community-outreach and linkages with NCI cancer centers, and development of multi-disciplinary care teams and quality improvement program infrastructure, and overall baseline program components,
- Administrative data related to program costs, clinical trial participation (physicians and patients), patient demographics, health care encounters, health care claims or reimbursements,
- Clinical data on patients derived from medical records, either in paper form or electronically
- Survey data from patients and/or providers.
- Pilot study data generated by the sites in response to feasibility or quality improvement studies in the areas of ca-BIG™ integration, bio-specimen

collection and reporting, and quality of care.

g. The evaluation contractor shall have an opportunity to review data collection protocols and provide recommendations to the NCI evaluation project officer on their ability to support the work under this contract as well as evaluate the validity and reliability of the data received from the NCI evaluation project officer prior to initiating data analysis tasks. However, the NCI project officer shall make final decisions regarding the data made available for this evaluation.

h. The contractor shall not be responsible for obtaining Institutional Review Board (IRB) approval for the primary data collection protocols and data collection instruments used in this evaluation. The pilot sites, which are collecting the data, shall be responsible for preparing the justifications and supporting the IRB review and approval process at their own institutions. The evaluation contractor shall assume it will take 8 weeks to obtain IRB approval once final data collection protocols and survey instruments are provided to the sites by the government.

i. The evaluation contractor shall be responsible for collection of the following primary data:

- Qualitative data collected via interviews, documents, and observations at the sites to support the contractor's qualitative assessment of the program model. These data shall be specified in plans prepared for review and approval by the NCI evaluation project officer prior to initiation of data collection activities.
- Quantitative data related to the cost analysis of the NCCCP program, which shall be based on a data collection protocol prepared by the contractor and administered by the prime contractor for the sites.

j. Other aspects of the NCCCP model should also be assessed across sites, but the extent of variation in program development may be larger than in the clinical trial and clinical care arenas and the research methods inherently qualitative. For example, the contractor shall draw as much as possible from the experience of all sites in assessing the issues, processes, and recommendations concerning the collection of bio-specimen data and ability to achieve integration with ca-BIG™. The contractor shall also draw upon all sites in the evaluation of how to incorporate electronic medical records into the overall program design and how sites are planning to use EMRs to accomplish pilot research goals.

k. The evaluation contractor shall recommend the data necessary to measure the cost of the pilot site programs. A key evaluation question is the replicability of these models outside the specific sites and the resources that will be needed to sustain these programs over time. The contractor shall develop a data collection protocol and data collection plan to document the total implementation and operational costs of the program. The protocol shall take the following factors into account:

- Costs should be defined in terms of resource units and corresponding unit costs.
- Standardized categories of resource units that are applicable across site should be developed.

- Unit costs should be adjusted for cost conditions that vary by geographic location and healthcare delivery setting. Unit costs that are standardized against a national reference (e.g. Medicare fees) may be considered.
- Resource units and unit costs need to be developed for various types of resources that may not have an obvious market price, e.g. voluntary labor, contributed time, etc.
- Cost should include both fixed and variable costs.
- All relevant costs should be included, e.g., government expenditures and site cost sharing, cost of patient and/or community recruitment as well as delivery costs.
- When accounting for healthcare delivery services, list prices and or charges should be avoided. Actual payments or reimbursements should be used instead.
- The contractor shall work the NCI Evaluation Project Officer to determine the best sources of data of each cost element and to ensure comparability of these data across research sites, based on the assessment of site information collection capabilities.

l. The contractor shall develop a protocol for review and approval by the NCI evaluation project officer that describes these common metrics, measures and data collection protocols. This will include the proposed evaluation methods, NCCCP program areas addressed, meeting agenda with sites, possible metrics and measures for consideration by the sites, and research approach to reaching consensus among the sites. The key stakeholders for the evaluation are (1) the NCI, in consultation with the evaluation oversight committee, who will provide the evaluation metrics for review by the evaluation contractor (see task 1.1.a) and provide feedback on the contractor's final evaluation design protocol (see task 1.3); and (2) the pilot sites, who through their prime subcontractor will provide feedback on the contractor recommendations for metrics from the pilot sites (see task 1.2) This report shall be provided in accordance with the dates and times described in Task 2 of this statement of work.

m. Within 21 weeks of the date of award, the Contractor shall submit a written draft evaluation protocol for soliciting input from the pilot sites and their prime contractor on the metrics, measures, and data collection protocols for the comparative site evaluation. The draft protocol shall be informed by the evaluability assessment report and describe in detail the proposed NCCCP program elements suitable to comparative site evaluation, emphasizing the metrics, methods, and data collection protocols necessary for evaluating program performance. The protocol shall identify those evaluation tools that are potentially useable from existing site infrastructure and those that may require some modifications of existing pilot site data collection systems. The protocol also shall list other metrics, measures or data collection approaches not present at the sites that have been used successfully in similar program evaluations and could be considered in this evaluation. The plan also should include a detailed agenda for the meeting and identify the methods the contractor will use to reach consensus with the sites on common metrics, measures, and data collection protocols. The final evaluation protocol for phase II will incorporate revisions made based on comments from the NCI evaluation project officer and NCI staff.

n. Within 26 weeks of the date of award, the contractor shall convene a one-day meeting with the prime contractor and pilot site representatives to describe the evaluation metrics, answer questions of clarification from the pilot site representatives and reach consensus on the implementation requirements for sites to support these data collection requirements. The meeting shall be held in Bethesda, Maryland or a convenient and cost

effective location for the sites. The evaluation contractor shall be responsible for the meeting costs including reimbursement of travel and lodging expenses for one participant from each pilot site, and any meeting preparation costs, or travel, lodging, or per diem expenses associated with contractor staff attending the meeting. Sites may bring a second staff person at their expense and the health system pilot sites may want to propose additional staff at their own expense.

o. Within 28 weeks of award, the contractor shall provide a draft final report for phase II outlining in detail the proposed NCCCP program elements suitable for comparative evaluation, the metrics, measures and data collection protocols for each program element, and the timetable necessary for the pilot sites to adapt their information systems to accommodate these measures. Any concerns, risks, or evaluation barriers presented by specific pilot sites should be documented in the report. The NCI shall make the final decision on which metrics and instruments shall be used in the pilot evaluation. Therefore, while some modifications may be necessary in the metrics and instrumentation, the evaluation contractor shall not be involved in extensive and numerous revisions to the evaluation metrics and instruments based on pilot site input. The final evaluation plan for phase II will incorporate revisions made based on comments from the NCI project officer and NCI staff. The contractor shall have one-week turnaround to respond to comments received by the NCI evaluation project officer.

Task 1.3 Phase 3 – Revised Evaluation Design Report Contractor Requirements

a. This phase of the evaluation project will commence after the completion of tasks 1.1 and 1.2 (phases one and two) of the base contract period. The contractor shall develop a final evaluation design and data collection protocol to guide the formal evaluation of the NCCCP pilot study. Based on the data collection in the first two phases of this evaluation, the contractor shall develop a detailed plan to evaluate the total NCCCP program and each individual NCCCP pilot site. The evaluation shall outline in detail the evaluation questions, the evaluation methods, metrics and expected outcomes for each of the core NCCCP objectives described above. The evaluation plan shall flow directly from the findings in phases one and two of this evaluation and address the entire key program elements of the NCCCP model. These include, but are not limited to, the following key evaluation questions:

- How effective is the NCCCP model in increasing accruals to NCI-sponsored clinical trials, especially early phase trials and participants who are either traditionally underrepresented in clinical research or represent disadvantaged populations? How effective were the sites in increasing physician awareness and participation in clinical trials?
- What are the issues, problems, and site recommendations in developing the knowledge, infrastructure requirements, necessary interfaces, and applicability of specific components of the Cancer Bio-informatics Grid (caBIG™) for hospital-based NCCCP models?
- What knowledge of infrastructure requirements, policies and procedures, costs, and other issues (e.g., collaborations or contracts with necessary for biospecimen collection, annotation, and storage) are required for

implementation of the NCI Best Practices for Biospecimen Resources in hospital-based NCCCP models? How can community hospitals participate in biospecimen initiatives that will advance the NCI's research agenda? What are the gaps in achieving best practices for bio-specimen collection and reporting of tissue specimens, and how well do the pilot sites close those gaps, either through enhancements in existing bio-repositories at the sites, or through pilots to test improvements in bio-specimen collection and reporting?

- What types of electronic medical record data collection and decision support systems best support the research and care delivery goals of the NCCCP? What is the potential for replicating these systems in other hospital-based, community cancer programs?
- What types of multi-disciplinary team-based care improve methods of care coordination? Which team-based models are most compatible with the NCCCP aims of increasing the delivery of evidence-based care for prevention, screening, treatment, follow-up care, palliative care, survivorship care planning, and end-of-life care? What quality of care measures and pilot site interventions were effective in increasing adherence to evidence-based cancer care delivery in cancer screening, diagnosis and treatment?
- What are the elements of management and broad organizational support that lead to an improved quality of cancer care and clinical research in support of pilot goals?
- Which interventions methods (e.g., improved patient education, patient navigation programs, community outreach and expanded community partnerships, transportation, access to insurance coverage) implemented at the pilot sites hold the most promise for enhancing the NCCCP objective to reduce disparities? How these programs further were enhanced when linked to broader state-based cancer care initiatives or collaborations with NCI programs such as the Community Network Program and the NCI-designated cancer centers or other providers/purchasers of cancer care (e.g., HRSA primary care clinics)?
- What extent does the NCCCP model duplicate, complement, or overlap with existing NCI-sponsored initiatives/programs that may have similar objectives (e.g., CCOPs, NCI-designated Cancer Centers)?
- Among multi-hospital system pilot sites, does being a member of a system that demonstrates a high degree of "systemness" enhance the operation of program components? In what ways does "systemness" influence the diffusion of best practices for cancer research and delivery and the goals of an NCCCP Program?

c. The contractor shall assess the program at three levels of inquiry; the overall program performance, specific program elements (e.g., multi-disciplinary team effectiveness), as well as the patient experience. Thus, the contractor shall develop a mail with telephone follow-up patient experience survey instrument, but will not be responsible for administering the survey. The survey shall include but not be limited to questions concerning overall satisfaction with care, multi-disciplinary care team communication,

knowledge of NCCCP services, emotional and financial support from the program, and access to appointments and waiting time. It is anticipated that many of the sites may have operational patient surveys that the contractor can select questions from for this survey. Pilot site surveys, if available, shall be provided within two weeks after award of the contract. The contractor also may propose other domains as required based on the results of the evaluability assessment in phase one of the base contract. The survey will be considered a key evaluation tool for the impact analyses, and therefore will be administered at the sites twice during the pilot program. (See task 7.2 of this SOW for more details on the survey requirements, deliverables and delivery dates).

d. The contractors shall also provide a Gantt chart detailing the timeline for the evaluation, noting when the collection of baseline data begins, intervention period, data collection milestones, and analysis and reporting writing period for the base contract and each option year.

e. Revised Evaluation Plan for the Pilot Study. Within 32 weeks of the date of award, the Contractor shall submit a written draft revised evaluation plan for conducting the evaluation requirements of this statement of work. The report should flow directly from the evaluability assessment report and the report on common metrics, measures and data collection protocols (tasks 1.1 and 1.2 of this statement of work) and describe in detail how the evaluation contractor will evaluate all components of the NCCCP model, both individually and collectively at the pilot sites. The evaluation design report shall include the discussion of the measures and metrics that were described in task 1.2 and shall discuss the following in detail:

- The research questions and study hypotheses to be addressed in the study.
- The qualitative measures that will be analyzed as part of this evaluation
- The quantitative utilization and administrative data that will be analyzed as part of this evaluation
- Evaluation method(s) to be used
- Variables' definitions that will be studied to answer the research questions.
- Analytical plan for addressing the study hypotheses, including plans for analyzing clinical trial accrual, health utilization, quality of care, and pilot site resource costs.
- Plans for addressing the special evaluation issues of the multi-system pilot sites
- Specific plans related to the evaluation of biospecimen collection, health information technology, and program integration with ca-BIG™.
- Strategies for addressing claims or utilization data challenges
- Proposed schedule

f. The evaluation plan shall outline the specific hypotheses associated with each evaluation question and describe the methods, measures, and data collection protocols necessary to answer each research hypothesis. These shall include both qualitative and quantitative methods and measures. Qualitative methods should include a description of the specific approach (e.g., comparative case study method; focus group) and how this particular method is appropriate for addressing the evaluation question. For hypotheses suitable for quantitative evaluation, the contractor shall describe the specific measures, data sources, and statistical approach used in the evaluation.

The evaluation design report shall clearly delineate these study milestones, due dates and personnel assignments. It should also identify all data required from the pilot sites and specify dates for submission of data requests. The final evaluation plan for phase II will incorporate revisions made based on comments from the NCI project officer and NCI staff. The final design report shall be submitted to the NCI project officer within 35 weeks of the date of award.

g. The evaluation design report shall clearly delineate these study milestones, due dates and personnel assignments. It should also identify all data required from the pilot sites and specify dates for submission of data requests. The final evaluation plan shall incorporate revisions made based on comments from the NCI project officer and NCI staff.

Task 1.4 Phase 4 – Contractor Requirements for Implementing the Evaluation Plan

a. Between months 9 and 12 of the base contract period, the contractor shall implement and conduct the NCCCP evaluation. All evaluation activities (e.g., contractor site visits, data collection schedules) shall be coordinated with the project sites through the NCI Evaluation Project Officer.

b. Monthly project reports will be sent to the NCI Evaluation Project Officer outlining any issues, problems, or other factors that may affect the timetable or success of the evaluation research. (See task 5.1)

b. At the end of the base contract period, the contractor shall prepare an annual evaluation report. This report should summarize the overall experience of the pilot program during the year with a focus on the sites' progress in answering key evaluation research questions in the project. The contractor will be expected to identify for NCI interim evaluation findings as appropriate. (See task 5.3)

TASK 2. Option Period One Contractor Requirements – Months 13 – 24 months after base contract award

The contractor shall implement the evaluation design as described in the evaluation design plan approved by the NCI project officer. These tasks include but are not limited to:

Task 2.1. Within one month of the award of the option contract, the evaluation contractor shall attend a one-day meeting in Bethesda, Maryland and provide NCI project leadership a detailed presentation on the interim findings and progress of the pilot sites in meeting the evaluation objectives. The evaluation contractor shall provide a copy of their PowerPoint presentation to the NCI evaluation project officer twenty days prior to the presentation for review and comment. The NCI evaluation project officer shall provide comments within five days of receiving the draft presentations materials and the contractor shall incorporate the project officer's changes and provide revised materials within five days of receiving the NCI recommendations.

Task 2.2. Within two months after the exercise of the option, the contractor shall provide to the NCI evaluation project officer a data evaluation plan that will describe their quality

control procedures for reviewing the secondary evaluation data submitted by the NCI evaluation project officer. This plan shall include the procedures used to assess the suitability of the data for analysis. These procedures will include but not be limited to edit checks, missing data checks, and consistency checks. The NCI evaluation project officer shall have two weeks to review the plan and provide comments. The evaluation contractor shall revise the plan based on the NCI project officer's comments and provide a final data evaluation plan within two weeks of receiving the NCI project officer's comments.

Task 2.3 The contractor shall conduct one day training of the pilot sites' prime contractor's patient survey data collection administrators on the protocols for the survey. This shall include training on sample selection, survey administration and follow-up, handling of non-respondents, and the collection of the data for submission to the government in a form that will support the analytical activities of the contractor. The training shall include a conference call with pilot site representatives to inform them how the survey procedures will be implemented at the sites. The contractor shall provide all training materials to the NCI evaluation project officer within two weeks of the option year award date for comment and shall submit final training materials to the sites within one month of award. The training shall occur in Bethesda, Maryland within six weeks of option year award at a site selected by the government and the contractor shall only be responsible for the cost of the meeting preparation and materials and the cost of providing food and refreshments to meeting attendees.

Task 2.4. The contractor shall receive secondary data from the NCI project officer on a quarterly basis that include trial accrual, physician participation in clinical trials, health utilization data on cancer services provided by the pilot sites. All of the sites are Commission on Cancer Accredited which requires the submission of standardized data pertaining to hospital-based quality of care indicators. Most of the sites have experience with CMS and other pay for performance reporting. Many sites were participants in the CMS physician oncology demonstration. The contractor shall review these data for data quality and report to the NCI evaluation project officer any problems with data quality that would compromise the evaluation. The contractor shall use these data to monitor the pilot sites' progress in meeting evaluation objectives. These data also shall be used to prepare the evaluation contractor's annual report at the conclusion of the option period.

Task 2.5. The evaluation contractor shall receive from the NCI project officer the baseline patient survey data. Baseline assessments and reports shall be submitted electronically following predefined, uniform data collection templates. Quality controls will be in place so that the evaluation contractor can expect to receive cleaned data that is complete, consistent, and valid. These data shall be provided to the evaluation contractor four months after the award of the option. The contractor shall review these data for data quality and report to the NCI project officer any problems with data quality that might compromise the evaluation. The contractor shall submit a draft descriptive report based on the patient survey data seven months after award of the option period. This draft report should illustrate the variation in patient reported findings by site. The contractor shall revise the draft report based on the NCI evaluation project officer's comments and submit a final report within two weeks of receiving the NCI evaluation project officer's comments. These data shall also be used to prepare the evaluation contractor's annual report at the conclusion of the option period.

Task 2.6. The evaluation contractor shall conduct site visits to the pilot sites at month nine of the option period. The contractors shall update any modifications to the site visit protocol approved by the NCI project officer (see task 1.3) and submit them to the NCI project officer for review and approval at month seven of the option period. The NCI project officer shall provide comments within two weeks of receipt of the site visit protocols. The contractor shall have one week to revise the protocol based on the NCI project officer's comments and submit the final protocol to NCI. Once the protocol is finalized, the contractor shall make arrangements with the sites for the site visit. This notification shall be completed no less than one month prior to the scheduled visit.

Task 2.7 The evaluation contractor shall prepare a comprehensive annual report outlining the progress the pilot sites are making in meeting evaluation objectives. The report shall contain reports generated for each individual site as well as a report that compares findings across sites. The requirements for this report are described in task 5.3 of this statement of work.

TASK 3. Option Period Two Contractor Requirements – Months 25 – 36 after base contract award

The contractor shall implement the evaluation design as described in the evaluation design plan approved by the NCI project officer. These tasks include but are not limited to:

Task 3.1 Within one month of the award of the option contract, the evaluation contractor shall attend a one day meeting in Bethesda, Maryland and provide NCI project leadership a presentation on the interim findings and progress of the pilot sites in meeting the evaluation objectives. The evaluation contractor shall provide a copy of their PowerPoint presentation to the NCI evaluation project officer twenty days prior to the presentation for review and comment. The NCI project officer shall provide comments within five days of receiving the draft presentations materials and the contractor shall incorporate the project officer's changes and provide revised materials within five days of receiving the NCI recommendations.

Task 3.2 The contractor shall receive secondary data from the NCI project officer on a quarterly basis that include trial accrual, physician participation in clinical trials, health utilization data on cancer services provided by the pilot sites. The contractor shall review these data for data quality and report to the NCI evaluation project officer any problems with data quality that would compromise the evaluation. The contractor shall use these data to monitor the pilot sites' progress in meeting evaluation objectives. These data also shall be used to prepare the evaluation contractor's annual report at the conclusion of the option period.

Task 3.3 The contractor shall conduct site visits to the pilot sites at month nine of the option period. The contractors shall update any modifications to the site visit protocol approved by the NCI project officer (see task 2.5) and submit them to the NCI project officer for review and approval at month seven of the option period. The NCI project officer shall provide comments within two weeks of receipt of the site visit protocols.

The contractor shall have one week to revise the protocol based on the NCI project officer's comments and submit the final protocol to NCI. Once the protocol is finalized, the contractor shall make arrangements with the sites for the site visit. This notification shall be completed no less than one month prior to the scheduled visit.

Task 3.4 The evaluation contractor shall prepare an annual report outlining the progress the pilot sites are making in meeting evaluation objectives. The report shall contain reports generated for each individual site as well as a report that compares findings across sites. The requirements for this annual report are described in task 5.3 of this statement of work.

TASK 4. Option Period Three Contractor Requirements – Month 37 – Month 42 after base contract award

Task 4.1 Within one month of the award of the option contract, the evaluation contractor shall attend a one day meeting in Bethesda, Maryland and provide NCI project leadership a presentation on the interim findings and progress of the pilot sites in meeting the evaluation objectives. The evaluation contractor shall provide a copy of their PowerPoint presentation to the NCI evaluation project officer twenty days prior to the presentation for review and comment. The NCI project officer shall provide comments within five days of receiving the draft presentations materials and the contractor shall incorporate the project officer's changes and provide revised materials within five days of receiving the NCI recommendations.

Task 4.2 Within two months of the award of the option contract, the evaluation contractor shall receive from the NCI project officer the follow-up patient survey data. The contractor shall review these data for data quality and report to the NCI project officer any problems with data quality that might compromise the evaluation. The contractor shall prepare a final report based on the baseline and follow up patient survey data according to the analysis plan contained in the evaluation design plan (see task 1.3). These data shall also be used to prepare the evaluation contractor's draft final report three months after the award of the option contract.

Task 4.3 Within three months of the award of the option period, the contractor shall receive all final pilot site secondary data from the NCI project officer. These data include but are not limited to trial accrual, physician participation in clinical trials, health utilization data on cancer services provided by the pilot sites, and a report on the pilot sites quality improvement study. The contractor shall review these data for data quality and report to the NCI evaluation project officer any problems with data quality that would compromise the evaluation. The contractor shall use these data to prepare the evaluation contractor's final report at the conclusion of the option period.

Task 4.4 Final Report. Within five months after the conclusion of data collection, the contractor shall prepare a draft final report for the NCI outlining the successes and shortcomings in the sites meeting the program wide and site-specific study aims and evaluation hypotheses set forth by the contractor. Separate chapters should be prepared

for each of the eleven core activities described in task 1.2.c of the statement of work. Within each major study question, the contractor shall describe:

- Which study aims and hypotheses were successfully and unsuccessfully completed/achieved?
- What were the multi-hospital health system and programmatic/organizational characteristics that led to successful or unsuccessful completion of the study areas/hypotheses?
- What are the contractor recommendations for improving the NCCCP model or replicating it to other hospital-based community programs?

The NCI evaluation project officer shall provide the contractor comments within four weeks of receipt of the draft final report. The contractor shall revise and resubmit a final report within 15 days of receiving the NCI project officer's comments.

The final report shall be delivered to the NCI project officer in the formats specified by the NCI for electronic and paper, including (1) paper, bound, in the number of copies specified by the NCI project officer, and (2) paper, unbound, suitable for use as camera-ready copy. The report shall include a short synoptic summary of the evaluation and its findings that could be used for wider dissemination to NCI constituencies.

In addition, the contractor shall provide a 200-word abstract/summary of the final report for submission to the National Technical Information Service (NTIS).

All products from the survey, including the instrument, implementation procedures, data files and sampling design should be considered as deliverables, as well as all analytic files and related documentation. These should be submitted with the Final Report for this contract.

Task 4.5. Within six months of the award of the option contract, the evaluation contractor shall attend a one day meeting in Bethesda, Maryland and provide NCI project leadership a presentation on the final evaluation findings for the pilot project. This presentation shall include recommendations for continuation of the NCCCP model. The evaluation contractor shall provide a copy of their PowerPoint presentation to the NCI evaluation project officer twenty days prior to the presentation for review and comment. The NCI project officer shall provide comments within five days of receiving the draft presentations materials and the contractor shall incorporate the project officer's changes and provide revised materials within five days of receiving the NCI recommendations.

TASK 5. Project Administration Contractor Requirements

Task 5.1 Monthly Conference Calls. The Contractor shall participate in monthly conference calls during the second full week of the month with the project officer and NCI staff. These calls shall be scheduled no earlier than two business days prior to the submission of the monthly progress report (see task 5.2) and shall be used as a mechanism for discussing administrative and project issues as they arise. The Contractor shall submit an electronic version of the agenda 2-3 days prior to the call. A written summary of the conference call shall be submitted electronically by the Contractor 1-2

days after the call. The monthly conference calls can be anticipated to move to every other month after the NCI evaluation project officer approves the final evaluation design plan.

Task 5.2 Monthly Progress Reports. The Contractor shall submit monthly administrative progress reports outlining all work accomplished during the month. At a minimum, such reports shall cover the following items:

- Administrative activities during the month (in accordance with the Gantt chart and evaluation plan approved by the NCI evaluation project officer as described in task 1.3).
- Administrative activities planned for the forthcoming month.
- A brief discussion of substantive findings to date, if any.

Each monthly report shall be submitted within 7 days following the end of the month or 2 days prior to the monthly conference call (see task 5.1 above), whichever is sooner. Two copies of the progress report should be sent directly to the NCI project officer and one copy accompanying the Contractor's invoice. Invoices will not be processed without submission of a monthly progress report.

Task 5.3. Annual Report. The contractor shall be expected to provide a draft annual report in the base contract period and in the first two option periods. The report shall summarize the overall experience of the pilot program during the year with a focus on the sites' progress in answering key evaluation research questions in the project. The report shall incorporate as appropriate, information from the following sources: quarterly project data provided by the NCI evaluation project officer, patient survey data, annual site visit assessments, and any site specific pilot study data or findings. Special attention will be given to perceived problems or barriers affecting site participation in evaluation activities, changes in evaluation timelines, and recommendations for how to ameliorate these barriers and problems to increase the success of the evaluation. Preliminary findings, if any, should be included in this report. The contractor will be expected to identify for NCI interim research findings as appropriate.

The contractor shall be expected to deliver the draft annual report to the NCI Evaluation Project Officer at the beginning of the 12-month of the base contract or each option period of the contract. The contractor shall provide a PowerPoint presentation to the NCI Evaluation Project Officer 5 days after the delivery of the draft annual report and travel to Bethesda Maryland to present their interim findings to NCI within 15 days of the receipt of the draft annual report. The contractor shall incorporate NCI recommendations following the presentation and submit the final annual report within 15 days following the presentation.

Task 5.4 Final Contract Close out Meeting. In option four of the contract, the Contractor shall prepare a final draft report according the requirements outlined in task 4.4 of this statement of work.

TASK 6. Project Meetings

The contractor requirements in this section of the statement of work refer to meetings not

otherwise specified in earlier tasks in this statement of work.

Task 6.1 Project Meetings with NCI Evaluation Project Officer and NCI NCCCP project staff. Because of the front loading of evaluation activities in the base year contract, the evaluation contractor shall meet with NCI staff face-to-face after the evaluability assessment (month three), cross-site comparison meeting (month six), and to present the final draft of the evaluation research design report (month nine). In each of the option periods, the contractor shall meet with NCI staff once a year in month six to provide interim updates on evaluation project activities. The Project Director shall attend these meetings and one other evaluation team member that shall be determined based on the content of the briefing. These will be one-day meetings at an NCI facility in Bethesda or Rockville, Maryland.

TASK 7. Primary Data Collection

The contractor requirements in this section of the statement of work refer to primary care data collection requirements not otherwise specified in earlier tasks in this statement of work.

Task 7.1 Site Visits in the optional contract periods. It is anticipated that the contractor will conduct periodic site visits as part of the formal evaluation of the NCCCP pilot study. At a minimum, these visits will be necessary to document the evolution of program implementation and operations to provide contextual data to interpret the success or failure of specific sites in meeting program objectives. The site visits also may be part of case study methods to formally evaluate specific NCCCP program elements that are only suitable to qualitative research methods. As part of their evaluation plan described in task 1.3 of this SOW, the contractor shall outline in detail the purpose of these evaluation site visits, how they relate to the evaluation objectives of this contract, the methods to be utilized, the length of the visits, and specific interview protocols and data collection protocols anticipated during these visits. The number and timing of these visits shall also be included in the evaluation plan. Team composition and size will be defined by the evaluation plan presented in task 1.3 of the base period, although it is expected that the size of the team and scope of the site visits will be lower in the first option period of the contract. The final evaluation plan for phase II will incorporate revisions made based on comments from the NCI project officer and NCI staff (see task 3.3).

Task 7.2 Patient Experience Survey

Task 7.2.1. Design of patient experience survey instrument. The contractor shall design a formal survey of patients who are participating in the NCCCP pilot study. This aspect will provide a comprehensive assessment of the patient perspective of the success and challenges in the NCCCP pilot study. The selected patients will provide a statistical representation of the patient experience at the ten sites. The selection criteria may include stratified random sampling based on certain site characteristics (e.g., volume of services delivered - low, medium and high). The contractor shall address the specific issues of sampling the multi-system pilot sites. The formal surveys to be conducted will include a mail survey with telephone follow-up to a maximum of 3,000 completed patient surveys (approximately 300 per site) for both the baseline and follow-up survey. The

contractor shall assume the pilot sites' prime contractor responsible for survey implementation will achieve a minimum 70 percent response rate.

a. The survey topics will include but are not limited to:

- a. Patient socio-demographic characteristics (race, ethnicity, age, income, education)
- b. Patient comorbidity and functional status (e.g., other health conditions, quality of life, activities of daily living)
- c. Current health care arrangements (e.g., insurance status, availability of current sources of care)
- d. Prior experience with cancer treatment (e.g., new patient or survivorship status)
- e. Overall satisfaction with NCCCP program participation
- f. Multi-disciplinary care team communication and care coordination
- g. Knowledge of cancer treatment, care planning, and follow-up care
- h. Access to care, appointments, and waiting time
- i. Perceptions of emotional support and financial assistance offered by the program
- j. Needs assessment of services and supports required by patients to assist in the management of cancer treatment.

b. The government may increase the number of survey domains or the number of surveys based on the assessment of related literature or findings from the first two phases of the evaluation contract. In no case will the increase in the scope of the survey domains exceed five additional survey domains and the numbers of completed patient surveys exceed 8,000. If the government increases the number of survey domains or the total number of patient surveys in a manner that results in an increase in workload, the government shall prepare a change order for the contractor's review and negotiate a new scope and price for these changes

c. The contractor shall design and pre-test a survey instrument that will address the topics mentioned above to establish validity and reliability of the instrument. It is anticipated that several of the sites will have operational patient surveys already in use and that the NCI evaluation project officer shall provide the contractor with recommended survey items. The contractor shall attempt to draw upon those instruments and items as appropriate in designing the survey for this pilot.

Task 7.3.2 Protocol for implementation of patient experience survey. The patient survey shall be administered by the pilot sites' prime contractor, not the pilot sites themselves.

The contractor shall develop a patient survey administration protocol that shall be used by the pilot sites' prime contractor to administer the patient surveys. The protocol shall provide the survey administration procedures, training of survey data collectors, and patient follow-up procedures for non-respondents, and procedures for transmitting the data to the evaluation contractor for assessing data quality and supporting analysis. The contractor shall train the pilot sites' prime contractor in administering the survey, based on the protocols established by the contractor. The training shall provide clarification as necessary for the pilot sites' prime contractor to assure their survey staff understands the protocols to assure quality control in administering the surveys. The protocols also shall be designed to enable the pilot sites' prime contractor achieve a 70 percent response rate. The achievement of a 70 percent response rate is a requirement of the pilot sites' prime contractor, not the evaluation contractor. However, the survey administration procedures developed by the evaluation contractor which the pilot sites' prime contractor uses, shall be consistent with past performance in achieving these response rates from surveys of program participants. These protocols shall be developed for both the baseline and follow-up survey.

Task 7.3.3 Data analytic plan for survey. The contractor shall describe how these data will be used in the program evaluation. This includes a detailed explanation of the proposed analyses based on the survey results and how these analyses will be supported by the survey design, survey response rates, the NCCCP project objectives.

Task 7.3.4 Patient experience survey delivery dates. The contractor shall deliver the survey content, protocol, and data analytic plan according the following schedule:

- a. Submit draft survey content, protocol, and data analytic plan within 12 weeks of base year contract award
- b. Pre-test an approved draft survey instrument and data collection protocols within 16 weeks of base year contract award
- c. Submit final instrument, protocols, and analytic plan within 20 months of base year award
- d. Training of pilot sites' prime contractor staff implementing the survey within 6 weeks of option period one contract award.

Task 7.3.5 Preparation of the OMB Package. The contractor shall prepare all documents for obtaining OMB approval of the survey and submit a draft clearance package within 24 weeks of base year contract award. The final survey instrument, protocols, analytic plan, and OMB approval documents will incorporate revisions made based on comments from the NCI project officer and NCI staff and be submitted within 26 weeks of base year contract award. The government may explore a clinical exemption for the patient survey and if approved, shall remove this task from the contract and negotiate a revised timetable and budget (if necessary) with the contractor.

Task 7.3.6 The contractor shall submit the final survey of patients to the NCI printing officer for clearance within one week of final OMB approval in month 12 of the base year contract award.

Task 7.3.7 The contractor shall provide a copy of the OMB approved patient survey and all OMB-approved survey administration protocols to the NCI evaluation project officer who will send them to the pilot sites' contractor.

Task 7.3.8 The pilot sites' prime contractor shall not be responsible to work directly with the sites in preparation of any IRB materials related to the patient survey. Any additional clarifications of the survey or survey administration protocols shall be accomplished through the evaluation project officer.

Task 8. Analyses and Reporting

The contractor requirements in this section of the statement of work refer to analyses and reporting not otherwise specified in earlier tasks in this statement of work.

Task 8.1. Option Period Site Visit Reports. The contractor shall provide a draft summary to the NCI project officer of the result of Phase III site visits within two weeks of the conclusion of the site visit. The site visit report will be based on the approved protocol (see section 4.1.2). After receipt of comments from the NCI project officer and NCI staff, the contractor shall make revisions and submit a final site visit report to the NCI project officer within two weeks of receipt of NCI comments.

Task 8.2. Final Evaluation report. The final report shall be prepared and delivered according the requirements set forth in task 4.4 of this statement of work. A draft report will be delivered in 20 weeks of the option year 3 contract award and based on input from the contractor's presentation to NCI staff (see meetings section 4.2.2), the contractor shall take these comments and make revisions with the final report due no later than 32 weeks after the option year 3 contract award.

All products from the survey, including the instrument, implementation procedures, data files and sampling design shall be considered as deliverables, as well as all analytic files and related documentation. These products shall be submitted with the Final Report for this contract.

Task 9. Key Personnel

The contractor shall designate the following key staff as key personnel for the contract:

- a. **Principal Investigator.** The contractor shall provide the services of a qualified principal investigator (PI), with the requisite time available to effectively manage the project. The PI shall be experienced in the management and direction of large-scale multi-site research and evaluation projects that involve both qualitative and quantitative tasks. He or she shall have the necessary interpersonal skills, competencies, and experience in working with project site directors and relevant hospital personnel to facilitate consensus and support for evaluation research in pilot programs or demonstration projects of similar structure and nature. He or she shall be capable of effectively communicating with individuals representing various

professional disciplines and service providers, as well as the hospital leadership, site directors, and staff of project sites participating in evaluation studies.

- b. Survey Director. The contractor shall provide the services of a qualified survey director for the project. This individual shall have experience in designing and/or overseeing the development of patient surveys, survey administrative protocols, OMB clearance packages, survey data editing, the development of analytical survey files, and the development of survey reports.
- c. Medical Oncologist Researcher and/or Consultant. The contractor shall provide for the services of a medical oncologist with specific clinical and/or organizational experience with cancer care research and/or delivery programs with experience in a community-based setting. This experience could include but not be limited to participation in clinical trials, clinical care, or health services research. He or she shall provide expertise to the evaluation team on clinical issues related to the evaluation research design and serve on the team that conducts the site visits. This individual could be employed by the contractor or as a consultant.
- d. Organizational health services researcher. The contractor shall provide for the services of a research scientist with expertise in logic mapping or related organizational assessment techniques and experience with qualitative assessments of the implementation and operations of complex health organizations. This experience could include but not be limited to case study evaluation of Medicare demonstration or pilot programs implementation or operations, organizational consulting in health organizations relevant to this procurement. This individual could be employed by the contractor or as a consultant.
- e. Any change in key personnel post award shall require approval by the NCI evaluation project officer.

SCHEDULE OF DELIVERABLES*

| Deliverable Number | Task Number | Deliverable | Due Date (from Contract Award) |
|--------------------|-------------|---|--|
| 1. | | Base Contract Period (12 months) | |
| 2. | 5.1 | Monthly conference calls | Monthly – second full week of the month* |
| 3. | 5.2 | Monthly progress reports | Monthly – first full week of the month* |
| 4. | 5.3 | Annual Evaluation Report | 48 weeks* |
| 5. | 1.1.a | Initial meeting-kick off | 2 weeks |
| 6. | 1.1.a | Meeting summary from Kick-off meeting | 3 weeks* |
| 7. | 1.1.e | Draft evaluability protocol | 4 weeks |
| 8. | 1.1.e | Final evaluability protocol | 6 weeks* |
| 9. | 1.1.f | Draft site assessment report | 17 weeks |
| 10. | 1.1.f | Final site assessment report | 18 weeks* |
| 11. | 1.2.1 | Draft evaluation protocol for | 20 weeks |

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| | | assessing with sites comparative metrics, measures, and data collection protocols | |
| 12. | 1.2.m | Final evaluation protocol for assessing with sites comparative metrics, measures, and data collection protocols | 22 weeks* |
| 13. | 1.2.n | 1 full day meeting with pilot sites and sites' prime contractor to review common metrics, measures, and data collection protocols | 26 weeks |
| 14. | 1.2.o | Draft final report for phase II | 28 weeks* |
| 15. | 1.2.o | Final phase II report | 30 weeks* |
| 16. | 1.3.e | Draft Final Evaluation Design Report | 32 weeks* |
| 17. | 1.3.g | Final Evaluation Design Report | 35 weeks* |
| 18. | 7.3.4 | Draft Survey & Data Analytic Plan | Draft 12 weeks/Final 16 weeks* |
| 19. | 7.3.4 | Final Patient Survey Instrument | 16 weeks* |
| 20. | 7.3.4 | Survey Pre-test protocol and training materials | Draft 16 weeks/Final 18 weeks |
| 21. | 7.3.4 | Final Survey analytic plan and protocols | Draft 20 weeks/Final 24 weeks* |
| 22. | 7.3.4 | OMB Survey Clearance Package | Draft 24 weeks/Final 26 weeks* |
| 23. | 7.3.6 | NCI Printing Office clearance package for survey instrument | 52 weeks |
| | | Option Period 1 – (12 months) | Due Date (from Option Period 1 Award) |
| 24. | 5.1 | Conference calls with NCI evaluation project officer | Every other month – second full week of the month |
| 25. | 5.2 | Progress reports | Every other Month – first full week of the month* |
| 26. | 5.3 | Annual Evaluation Report | 48 weeks* |
| 27. | 2.1 | PowerPoint presentation for NCI briefing on annual report | 3 weeks |
| 28. | 2.1 | Presentation to NCI staff on annual report in Bethesda, Maryland | 5 weeks* |
| 29. | 2.2 | NCCCP draft Data evaluation plan | 8 weeks |
| 30. | 2.2 | NCCCP final Data evaluation plan | 12 weeks* |
| 31. | 2.3 | Draft training materials for project site survey administrators | 2 weeks* |
| 32. | 2.3 | One day training for the pilot sites' prime contractor staff and /or with a | 6 weeks |

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| | | component for a telephone orientation for the sites on patient survey protocols | |
| 33. | 2.4 | Receipt of pilot site evaluation data | Quarterly |
| 34. | 2.5 | Draft descriptive report of the NCCCP sites based on baseline provider survey data | 30 weeks |
| 35. | 2.5 | Final descriptive report of the NCCCP sites based on baseline provider survey data | 34 weeks* |
| 36. | 2.6 | Submission of draft site visit protocol update (if necessary) | 28 weeks |
| 37. | 2.6 | Final site visit protocol | 31 weeks* |
| 38. | 6.1 | Project meeting with NCI staff in Bethesda, Maryland | 26 weeks |
| | | | |
| | | Option Period 2 – (12 months) | Due Date (from Option Period 2 Award) |
| | | | |
| 39. | 5.1 | Conference calls with NCI evaluation project officer | Every other month – second full week of the month* |
| 40. | 5.2 | Progress reports | Every other Month – first full week of the month* |
| 41. | 5.3 | Annual Evaluation Report | 48 weeks* |
| 42. | 3.1 | PowerPoint presentation for NCI briefing on annual report | 3 weeks |
| 43. | 3.1 | Presentation to NCI staff on annual report in Bethesda, Maryland | 5 weeks* |
| 44. | 3.2 | Receipt of pilot site evaluation data | Quarterly |
| 45. | 3.3 | Submission of draft site visit protocol update (if necessary) | 28 weeks |
| 46. | 3.3 | Final site visit protocol | 31 weeks* |
| 47. | 6.1 | Project meeting with NCI staff in Bethesda, Maryland | 26 weeks |
| | | | |
| | | Option Period 3 – (6 months) | Due Date (from Option Period 3 Award) |
| | | | |
| 48. | 5.1 | Conference calls with NCI evaluation project officer | Every other month – second full week of the month* |
| 49. | 5.2 | Progress reports | Every other Month – first full week of the month* |
| 50 | 4.1 | PowerPoint presentation for NCI briefing on annual report | 3 weeks |

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| 51. | 4.2 | Draft report on follow-up patient survey | 12 weeks |
| 52. | 4.2 | Final report on follow-up patient survey | 16 weeks* |
| 53. | 4.4 | Draft Final Report | 20 weeks |
| 54. | 4.4 | Final Report | 26 weeks* |
| 55. | 4.5 | Draft PowerPoint presentation for NCI presentation on final report in Bethesda, Maryland | 30 weeks |
| 56. | 4.5 | Presentation for NCI staff on final report and recommendations for the NCCCCP initiative | 32 weeks* |

* Note that all asterisked tasks must be separately priced in the option period bid.

III. PERFORMANCE PERIOD:

Performance period shall be from July 1, 2007, or date of award, whichever is later, for twelve months with three option periods.

IV. PAYMENT

Partial payments may be made for deliverables shown on pages 26-29 and marked with an asterisk after approval and receipt by the Government.

All other payments shall be made in arrears after services have been approved and received by the Government.

Optional Line Item 2

The NCCCCP pilot evaluation is designed to evaluate pilot projects individually and collectively in order to make recommendations for improving and replicating the NCCCCP model in other areas of the country. This RFP does not require the offeror to compare the pilot sites to other community cancer programs or other community-based cancer delivery arrangements not affiliated with the NCCCCP pilot sites. The offeror has the option to develop an optional quotation that addresses an approach for comparing the NCCCCP pilot sites to other appropriate organizations or delivery arrangements. For example, the offeror could consider a model that compares the integrated NCCCCP model with a less integrated cancer program with similar objectives (e.g., accrual to NCI-sponsored clinical trials, dissemination of new evidence-based treatments, or reducing health disparities). Alternatively, the offeror could propose an approach to compare the NCCCCP model to a different type of integrated care model (e.g., an health maintenance organization). The bidder may propose other desired comparison groups, such as NCI-sponsored programs with similar goals (e.g., CCOPs). Of particular interest to NCI are "passive comparative evaluation approaches" that enable the government to place the NCCCCP pilot experience in the context of secular trends in cancer research, cancer care delivery, and infrastructure development (e.g., adoption of information technology) that

assists placing the pilot experience and performance in the broader context of the cancer research and care delivery system.

If the offeror elects to develop an optional quotation, the quotation should be no more than six single spaced pages and outlines the comparison group, evaluation design (e.g., case comparison or passive monitoring), research questions, and appropriate data elements and analytical techniques. The offeror must clearly state how this comparative evaluation approach will add value to our understanding of the NCCCP model over the evaluation of the sites alone. The offeror also should include a separate business quotation for the comparative evaluation. This six-page quotation is not included in the 25-page limit and The project principal investigator must have necessary interpersonal skills, competencies, and experience in working with project site directors and staff to facilitate consensus and support for evaluation research in pilot programs or demonstration projects of a similar structure and nature. must be clearly marked as "Optional quotation for Comparative Evaluation".

The optional quotation is not evaluated for the purpose of determining contract award. However, the government reserves the right at its sole discretion to accept an optional quotation from the winning offeror, if proposed.

52.217-7 -- Option for Increased Quantity -- Separately Priced Line Item.

As prescribed in 17.208(e), insert a clause substantially the same as the following:

Option for Increased Quantity -- Separately Priced Line Item (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.