54		SAIC-Frederick, Inc. A subsidiary of Science		1. Subcont	ract No.	2. Solicitation	No. 3.	. Date Issued		Page 1 of 36
From Science to	Solutions	Applications International Corpora	tion			S06-285	1	1/01/2006		
4. Maryland	Sales and	l Use Tax Direct Pay Permit No. 3	5.			Solicitation P) Solicitation			6. F	Requisition No. FF0537
7. Issued By	y:	Address Offer To:				8. Delivery D	ate: n/a			
SAI	IC-Frede	erick, Inc.				9. Place of De	livery: 1	n/a		
		Johnson Dr. Suite 250 Md. 21702				10. FOB: Des	stination			
	SOLICITATION									
11. To be tir marked to sh	mely, of now solid	fers must be received at the loc citation number.	ation	specified in	n Item 7	7 by 2:00 PM (ES	T) Janua	ary 9, 2007. P	ackag	ging shall be
12. FOR INFO	ORMATI	ON CALL: Name: Mr. S	Shann	on Jackson		Telephone 1	No. (301)	228-4022		
A. Soli B. Sup C. Des D. Pac E. Insp F. Deli G. Cor	Part I – The Schedule       OFFER/SUBCONTRACT CONSISTS OF:         A. Solicitation/Contract Form       Part II – Contract Clauses         B. Supplies or Services and Prices/Costs       I. Contract Clauses         C. Description/Specs./Statement of Work       Packaging and Marking         E. Inspection and Acceptance       Part IV – Representations, Certifications and Other Statements         F. Deliveries or Performance       K. Representations, Certifications and Other Statements         G. Contract Administration Data       M. Evaluation Factors for Award									
SCHEDULE										
ITEM NO.		SUPPLIES/SERVICE	ES			QTY.	UNIT	UNIT PR	ICE	AMOUNT
	See Se	ction B								
13. If this offer is accepted within <u>90</u> calendar days from the date for receipt of offers specified above, the offeror shall be required to furnish any or all items or services in accordance with the terms of the offer.										
14. DISCOUN	NT FOR I	PROMPT PAYMENT	1	10 CALENDAR	DAYS	20 CALENDAR DAY	8 30	CALENDAR DAYS	s .	CALENDAR DAYS
(In connection w be computed fro	with any di om the date	iscount for prompt payment, time shall e of invoice acceptance.)			%		%		%	%
15. ACKNOWLEDGMENT OF AMENDMENTS The offeror acknowledges receipt of amendments to the solicitation for offerors and related documents numbered and dated:			AMENDMI NO.	ENT	DATE		AMENDMENT NO.		DATE	
16. Name and Address of Offeror       17. Name and Title of Person Authorized to Sign Offer										
18. Submission of a signed offer constitutes an understanding and unqua acceptance of all terms, conditions, obligations and statements made here reference) or as attached hereto.				19. Sig	gnature			20	. Offer date	
AWARD										
21. Accepted	21. Accepted As To Items Numbered:       22. Amount:       23. Accounting Data:				a:					
24. Name/Title	le of Perso	on Authorized to Sign-SAIC		25. Signatu	are of Pe	erson Authorized to	Sign-SA	IC		26. Award Date

INTRODUCTION	4
	-
PART I—THE SCHEDULE	4
SECTION B—SUPPLIES OR SERVICES AND PRICES/COSTS	4
B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES	4
B.2. TYPE OF CONTRACT	4
B.3. PRICES/COSTS B.4. ADVANCE UNDERSTANDINGS	4
D.+. AD VARCE CROEKSTATION (GS	Т
SECTION C—STATEMENT OF WORK	5
C.1. BACKGROUND	5
C.2. STRUCTURE OF THE NCCCP PILOT	6 9
C.3. PURPOSE AND OBJECTIVES OF THE PROGRAM	9
SECTION D—PACKAGING AND MARKING	14
SECTION E-INSPECTION AND ACCEPTANCE	14
SECTION F—DELIVERIES OR PERFORMANCE	15
F.1. PERIOD OF PERFORMANCE	15
F.2. DELIVERABLES	15
F.3. REPORTING REQUIREMENTS	17
F.4. SATISFACTORY PERFORMANCE	18
SECTION G-CONTRACT ADMINISTRATION DATA	18
G.1. CONTRACT REPRESENTATIVES	18
G.2. SUBCONTRACTOR REPRESENTATIVES	19
G.3. KEY PERSONNEL	20
G.4. INVOICE SUBMISSION	20
SECTION H - SPECIAL CONTRACT REQUIREMENTS	21
H.1. PUBLICATION AND PUBLICITY	21
H.2. PRESS RELEASES	21
H.3. SALARY RATE LIMITATION LEGISLATION PROVISIONS	21 21
H.4. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE H.5. ORGANIZATIONAL CONFLICT OF INTEREST	21
H.5. ORGANIZATIONAL CONFLICT OF INTEREST H.6. PROHIBITION ON SUBCONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES	22
H.7. INSURANCE REQUIREMENTS AND CERTIFICATES	22
PART II—SUBCONTRACT CLAUSES	23
TART II—SUBCONTRACT CLAUSES	20
SECTION I—SUBCONTRACT CLAUSES	23
I.1. GENERAL CLAUSES FOR A NEGOTIATED TIME & MATERIALS SUBCONTRACT	23
I.2. ADDITIONAL TERMS & CONDITIONS	24
PART III—LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS	32
SECTION J-LIST OF SUBCONTRACT ATTACHMENTS	32
PART IV—REPRESENTATIONS, INSTRUCTIONS AND EVALUATION FACTORS	32
	20
SECTION K-REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	32

SECTION L— INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS	32
L.1. GENERAL INFORMATION	32
L.2. QUESTIONS	32
L.3. INSTRUCTIONS TO OFFEROR	33
L.4. RFP POINT OF CONTACT	33
L.5. RFP ATTACHMENTS	34
SECTION M — EVALUATION FACTORS FOR AWARD	34
M.1. BASIS FOR AWARD	34
M.2. POTENTIAL AWARD WITHOUT DISCUSSIONS	34
M.3. EVALUATION FACTORS	34

# **INTRODUCTION**

GOVERNMENT RELATIONSHIP: This contract is awarded by the SAIC-Frederick, Inc., a subsidiary of Science Applications International Corporation, under its contract with the National Cancer Institute at Frederick. The provisions and clauses contained herein are influenced by and reflect the relationship of the parties in that contract which was awarded and is administered under the provision of the Federal Acquisition Regulation (FAR). There is no privity of contract between the Seller and the Government.

# PART I-THE SCHEDULE

# SECTION B—SUPPLIES OR SERVICES AND PRICES/COSTS

### **B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

Independently, and not as an agent of SAIC-Frederick, Inc., the Subcontractor shall furnish services, qualified personnel, materials, equipment, facilities not otherwise provided under the terms of this Subcontract, as needed, to facilitate a NCI Community Cancer Centers Program (NCCCP) pilot research initiative that will explore the development of a national network of community-based cancer centers.

The focus of the pilot will be to research how best to accomplish the following:

- a) increase accruals to NCI-sponsored clinical trials, especially for underrepresented and disadvantaged populations;
- b) develop new or expanded programs to increase outreach to the uninsured, underrepresented, and disadvantaged populations for prevention, screening, treatment, follow-up care, palliative care, survivorship plans, and end-of-life care;
- c) increase knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG<sup>TM</sup> for community hospital settings, and increase implementation of electronic medical records and exploration of the application of electronic medical records in the provision of cancer care;
- d) increase knowledge of infrastructure requirements, policies and procedures, costs, and other issues (e.g. collaborations or contracts necessary for biospecimen collection, annotation and storage) required for implementation of the *First-Generation Guidelines for NCI supported Biorepositories (FGGs)*, thus enabling community hospitals to participate in biospecimen initiatives that will advance the NCI's research agenda.

### **B.2. TYPE OF CONTRACT**

It is anticipated that a resulting subcontract will be issued on a time and material basis, which provides for the procurement of supplies and services on the basis of fully burdened direct labor rates and requisite materials that may be billed at cost (see Federal Acquisition Regulation 16.601). The subcontractor may not exceed the established estimated cost without the advance, written approval of the Contracting Officer.

# **B.3. PRICES/COSTS**

The total not to exceed amount of this Time & Materials subcontract is <u>\$ TBD</u>.

### **B.4. ADVANCE UNDERSTANDINGS**

- a. Items to be Furnished to the Contractor: <u>\$ TBD</u>.
- b. Pre-award Expenses: <u>\$ TBD</u>.
- c. Travel Costs: <u>\$ TBD</u>. Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this subcontract shall not exceed the amount specified in each order without prior written approval of the Contracting Officer. Additionally, travel will be reimbursed in accordance with the Federal Travel Regulations (FTR). Funds may be requested to cover the cost of one trip per year for the Principal Investigator or Pilot Project Leader to attend a two-day meeting at the National Cancer Institute in Bethesda, Maryland.

(End of Section B)

# SECTION C—STATEMENT OF WORK

# C.1. BACKGROUND

### C.1.a. National Cancer Institute (NCI)

The NCI is the primary agency for conducting the nation's cancer research efforts. The NCI sponsors many programs including its NCI Cancer Centers Program, which supports major academic and research institutions throughout the United States, and sustains broad-based, coordinated, interdisciplinary programs in cancer research. These institutions are characterized by scientific excellence and capability to integrate a diversity of research approaches to focus on the problem of cancer, through basic research, population sciences research, and translational and clinical research. The Cancer Centers Program primarily supports infrastructure, and success requires the presence of ongoing research supported by other mechanisms. A majority of centers also provide clinical care and service for cancer patients. In addition, those NCI-designated cancer centers that are Comprehensive Cancer Centers have extensive ancillary, cancer-related activities, such as outreach, education and information dissemination. Through all of these activities combined, the NCI-designated cancer centers play an important role in their communities and serve to influence standards of cancer prevention, diagnosis, and treatment. While the NCI Cancer Centers Program makes significant contributions to advances in cancer research that are key to understanding, preventing, and treating this disease, only 16% of patients in the United States who are diagnosed with cancer have access to NCI-designated cancer centers, most often because of their location, but also, at times, because of research priorities, insurance participation, or financial screening requirements and other factors that limit access. This effort will examine a concept that would expand the capacity and accessibility of prevention, treatment, and follow-up care to more community-based locations.

### C.1.b. Future of Cancer Care

As of July 2006, the NCI Cancer Centers Program has grown to support 61 major academic and research institutes throughout the United States. At these facilities, medical science's rapidly mounting knowledge of the genetics of people and of the disease is being translated into a new era of "personalized medicine," in which tests and treatments will be designed for the individual based on a complete knowledge of his or her tumor profile. As personal molecular profiles and targeted interventions move from the theoretical and experimental to standard practice, cancer care will increasingly depend on highly advanced technologies and multi-agent, highly specific prevention and treatment regimens. NCI-designated cancer centers will be at the forefront of this transition. Yet, for most Americans, especially senior citizens and minorities who bear a heavy burden of cancer, an NCI-designated cancer center may be too far away, too far removed from their family and other support systems, or simply out of reach – for reasons that may be economic or personal. Thus, the majority of cancer treatment in this country takes place in community-based, private practice, oncology settings. For individuals in regions with high healthcare disparities, even the current community-based practice may be out of reach.

In an effort to bring important scientific advances, at their earliest stages of development and the highest level of innovative multispecialty care, to all patients, NCI is launching a community cancer care pilot project – the NCI Community Cancer Centers Program (NCCCP). The NCCCP pilot will explore methods and structures to bring state-of-the-art oncology care and early phase translational science to the hospital-based community cancer center setting, utilizing linkages with other NCI-sponsored research programs (e.g., Community Clinical Oncology Program (CCOP), Community Networks Program (CNP), Cancer Centers Program), as well as with local, state and federal agencies and private sector-sponsored research activities, and with the developing program of the Cancer Expert Corps. The NCCCP pilot will do so with the clear-cut goals of expanding access to cancer prevention, screening, treatment, survivorship follow-up, and end-of-life care, as well as increasing participation in early phase clinical trials, and reducing healthcare disparities.

The NCCCP pilot has the potential to advance key NCI and Department of Health and Human Services initiatives, such as the collection of biospecimens for NCI-sponsored research (e.g., The Cancer Genome Atlas); adoption of electronic medical records; the use of telemedicine to improve research, clinical care and access; and the advancement of a de facto biomedical internet called the cancer Biomedical Informatics Grid (caBIG<sup>TM</sup>, <u>https://cabig.nci.nih.gov/</u>). This could lead to a nationwide repository of data on screened patients, high-risk patients on prevention trials, cancer patients actively being treated, and cancer survivors. In addition, each NCCCP pilot site will demonstrate a commitment to coordinated multi-modality cancer care by having a physician program director who will coordinate medical, surgical, and radiation oncology, and the provision of multi-specialty patient care and clinical research.

### C.1.c. Trends in Community-based Cancer Care

Over the past thirty years, there have been a number of advances in the provision of cancer care in community settings. An increasing number of well-trained cancer physicians practice in these settings, and state-of-the-art technology is more readily

available. The Community Clinical Oncology Program (CCOP), now in its twentieth year, has made primarily phase III clinical trials available to many patients through community hospitals and physician practices across the country.

Consistent with recent trends in many medical specialties, an increasing number of cancer services are being provided in physician offices and/or "stand-alone" locations on and off the traditional hospital campus. There has also been an increase in "niche" medical specialty companies, including a number of national oncology specialty companies offering infusion and radiation therapy in multiple locations across the country. These developments have made cancer services more widely available, especially for insured patients. However, this "open environment of care" has not enabled the provision of the coordinated multi-disciplinary approach to care that has been a hallmark of the care provided at the leading cancer centers in the United States. Additionally, there is a high volume of patients seen in these settings who are eligible for participation in clinical trials, yet accrual rates are low, often because it is time consuming and costly for physicians in private practice to offer clinical trials.

Evidence suggests that cancer patients diagnosed and treated in a setting of multi-specialty care and clinical research may live longer with their disease, have a better quality of life, and have a greater chance of cancer cure. Thus, care of cancer patients today requires a focus on the full continuum of cancer care, including risk assessment, prevention, screening, treatment, follow-up care, palliative care, and appropriate end-of-life care. Accrual of patients to clinical trials ensures that advances in cancer research are made and are available to all patients in the community, including those who are underrepresented and disadvantaged.

A comprehensive model of care offering the full range of services is difficult to provide in a fragmented system of care, and care is not available equally to all in a community. Major reports on healthcare access mandated by Congress and the Administration over the past five years provide evidence that this nation's fragmented healthcare system fails to provide adequate information and access to effective cancer prevention, diagnosis, and treatment services in an equitable and timely manner. This is particularly evident among racial/ethnic minorities, people of lower socioeconomic status, residents of rural areas, and members of other underserved populations for whom the unequal burden of cancer continues to be documented through the nation's cancer surveillance networks. In the future, the greatest risk factor determining mortality from cancer may actually be access to optimal care.

For the future, cancer care is becoming more dependent upon highly specific prevention and treatment regimens, enabled by telemedicine, information technology and the biospecimen initiatives sponsored by the NCI. A fragmented system of care does not easily offer a platform for the provision of this level of care. A fragmented system of care is a major obstacle to the rapid translation of newly discovered biomarkers (diagnostics) and the sophisticated, molecularly-targeted therapies of the future. Through the development of the NCCCP, a highly organized, informatics-based, cancer care system that is linked to clinical research will create many benefits, by increasing the speed of novel therapy approvals and thereby significantly increasing the speed of drug discovery, reducing the cost of the drug approvals process, and markedly increasing the availability of treatment options for all patients.

# C.2. STRUCTURE OF THE NCCCP PILOT

### C.2.a. Overall NCCCP Pilot

The NCCCP pilot will incorporate key NCI initiatives into the examination of a model for hospital-based community cancer care to include increased accrual in clinical trials including early phase clinical trials, programs to reduce healthcare disparities, enhancements to healthcare informatics initiatives, and evaluation of biospecimen-dependent scientific initiatives. There is interest in exploring the following special areas of interest that could serve to enhance the model:

- Models for effective linkages with NCI-designated cancer centers or academic medical research institutions that would support the program goals;
- New community models to address healthcare disparities;
- Whether selecting a site that is part of a national health system might speed the replication of a successful model;
- Effective linkages with state-sponsored cancer initiatives;
- The potential benefit of participation in healthcare information technology initiatives such as a RHIO (Regional Health Information Organization) or similar initiative;
- Working with providers to examine the potential for the development of new reimbursement models for cancer prevention, screening and treatment;
- Models for survivorship plans that would support the overall goals of the program;
- Programs in locations where the population has significant hardships affecting access to healthcare;
- Exploration of the benefit of linkages with the NCI-sponsored Cancer Expert Corps, a program under development, to bring cancer expertise to locations where there is a gap in a needed service;

- The value of a knowledge exchange network for community hospital-based cancer providers;
- Models for co-investment with the NCI to broaden the effective reach of the NCI research programs;
- Models of multidisciplinary cancer care that incorporate the continuum of services including early detection, prevention, therapy, survivorship follow-up and end-of-life support programs; and
- Working with providers that have developed successful approaches for accrual of patients into NCI-sponsored clinical trials. NCCCP pilot sites are not expected to encompass all areas of special interest.

### C.2.b. Pilot Sites

A hospital-based community cancer center model, which is often effectively aligned with physicians in private practice, is the only platform for sponsoring a model of cancer care for a comprehensive approach to cancer care to be organized and made available to all patients in the community, including those who are underrepresented and disadvantaged. Working with hospital-based community cancer programs meeting baseline criteria as outlined in this Request, the NCCCP pilot activities will allow for the exploration of the necessary programmatic components required for a successful model of care, and how these programs can effectively incorporate organized components for risk assessment, prevention, screening, treatment, follow-up care, palliative care, and appropriate end-of-life care for all in the community it serves. The success of a comprehensive and multidisciplinary model of quality patient care depends on communication and interaction among the medical and clinical support staff in a cancer program.

For this pilot project, approximately six organizations with hospital-based community cancer programs will be selected with funding for three years, based on criteria specified in this Request. It is intended that there will be different locations and community settings in the pilot group representing a range of organizational models, expertise, and geographies, and serving different, racial, ethnic, and socioeconomic groups.

Health system organizations will be considered as a subset of the awarded sites because the NCI wants to promote rapid expansion of improved cancer care, using the NCCCP pilot model. Health system participants, with multiple acute care hospitals in different geographic markets, would help accelerate progress toward pilot goals because many of them already have knowledge transfer methods in place, and have developed best practices for clinical programs, quality-of-care, and meeting the needs of the underserved.

### C.2.c. Clinical Trials

The NCCCP pilot will examine ways to expand clinical research and to offer the availability of earlier phase clinical trials to more patients in the community setting, including those who are underrepresented and disadvantaged. Only those hospital-based community cancer centers that have accrued 25 patients or more to clinical trials for the past three years will be eligible. It is anticipated that during the pilot there will be an increase in accruals to all clinical trials, including treatment, prevention and behavioral trials, and with a key focus on multi-modality trials and NCI-sponsored trials. NCCCP pilot sites will work to increase their capability to offer phase II trials and to develop protocols for the referral of patients to phase I trials at NCI-designated cancer centers or academic medical research institutions. NCCCP pilot funding for clinical trials will be approved to provide infrastructure support at the pilot sites to expand clinical trials, not for the trials themselves. Funding and oversight for clinical trials at the NCCCP pilot sites will continue to be provided through the existing trial sponsors (e.g., NCI programs, the pharmaceutical industry).

### C.2.d. Community Initiatives to Address Healthcare Disparities

Ideally, to effectively address cancer healthcare disparities across the full continuum of cancer care, including risk assessment, prevention, screening, treatment, follow-up care, palliative care, and appropriate end-of-life care, it is recognized that a coordinated and broad-based community approach is required. These efforts should include primary care physicians, public health clinics, school-based programs, social services, cancer physicians and cancer programs, hospitals, and other related community-based programs with an infrastructure to coordinate activities and track progress. Unfortunately, for a complex set of reasons, natural alliances among these organizations that are all committed to the health of community members are not easily formed and/or supported. Competition exists between organizations and institutions, and they have not always acted in partnership with community-based healthcare and social services organizations. This issue, along with limitations in resources and a large number of uninsured in the United States, contributes to many individuals having limited or no access to healthcare or to cancer care.

The NCI offers several programs to address these issues and recently has launched its Community Networks Program and its Patient Navigation Program to accelerate efforts to create and enhance linkages in support of the provision of optimal cancer care for those who do not have access to healthcare, and to expand the availability of clinical trials for the underrepresented and disadvantaged. For the NCCCP pilot to realize its goals, it will need the participation of organizations that understand and are committed to addressing these issues, and that are helping to create improved and sustainable models of partnership between

hospitals and community-based resources. Only community hospitals (and their cancer programs) that have demonstrated a track record of leadership and active involvement with community-based approaches to address the needs of the underserved and disadvantaged, and those with demonstrated healthcare disparities, will be eligible.

# C.2.e. An NCCCP Network

The NCCCP pilot activities will include the development of information linkages between the pilot sites, thus forming a network for exchange of knowledge. During the pilot, processes and communications tools will be recommended and established, so that progress on the many detailed elements of the NCCCP pilot can be reported, and best practices or proposed solutions can be shared. Facilitated sub-groups within the network of NCCCP pilot sites (e.g., information technology, biospecimens, clinical trials, survivorship plans) will be formed to advance work on many of the pilot components. Among the pilot sites there will be national experts or "thought leaders" in areas relevant to the pilot (e.g., multi-disciplinary cancer care, clinical trial accrual, healthcare disparities). Through the network and its communications/knowledge exchange infrastructure, pilot sites will be able to draw upon these resources, which will in turn contribute to the overall success of the pilot.

The pilot will also allow examination of the extent to which an NCCCP Network could serve as a vehicle for a highly organized, informatics-based, cancer care system that is linked to clinical research. Through one point of contact, the NCCCP could create many benefits, by increasing the speed of novel therapy approvals; thereby, significantly increasing the speed of drug discovery, reducing the cost of the drug approvals process, and markedly increasing the availability of treatment options for all patients.

Formal structures for sharing information and collaboration will be an enabler for accelerating advances in cancer research and improvements in cancer care. The caBIG<sup>TM</sup> program is a significant resource for this purpose. The pilot will include an exploration of approaches — including infrastructure and tools offered through caBIG<sup>TM</sup>, for the specific role and guidelines for a network. The pilot sites, along with appropriate expertise from NCI, will be asked to examine and test effective approaches, and develop recommendations on a proposed model for an NCCCP Network that could ultimately be integrated into a future NCI program or for a broader application across organizations involved in community-based cancer care and clinical research.

### C.2.f. Participation in Quality Improvement and Funding Initiatives

As programs are introduced to improve quality of cancer care or provide enhanced reimbursement for cancer treatment, it is contemplated that such programs could be supportive of the goals of the pilot and will be considered in consultation with the sites. It is anticipated that the pilot sites would be locations that could explore, individually and as a group, the benefit of such programs. For example, the American College of Surgeons is developing new standards for oncology, which upon their finalization will be reviewed by NCI and could be evaluated by the pilot sites for incorporation into a future NCCCP initiative. Another example would be the voluntary CMS 2006 Oncology Demonstration program or a successor CMS voluntary program.

### C.2.g. Participation in National or State-Funded Cancer Initiatives

There are a number of state cancer plans and programs, as well as national programs (e.g., Centers for Disease Control and Prevention, American Cancer Society), in existence or under development, that provide funding to support cancer prevention, screening, and treatment. Participation in these programs will further advance the goals of the NCCCP pilot and will be taken into consideration in the selection of pilot sites, so that an examination of the value of these complimentary programs toward the achievement of pilot goals can be studied.

### C.2.h. Quality-of-Care Study

The NCCCP pilot will include a quality-of-care study, such as one for colorectal cancer, which is the second leading cause of cancer deaths in the United States. Colorectal cancer would serve as a good indicator of quality of cancer care because it includes opportunities to improve care across the continuum from screening through treatment and long-term survivorship with new treatments emerging. Screening rates are lowest among the three cancers known to be unequivocally associated with mortality reductions through screening (breast, cervical, colon cancer). There are also challenges for any community seeking to address healthcare disparities since the evaluation of abnormal fecal occult blood tests and the performance of screening endoscopies both must be addressed through collaboration among and between various community healthcare providers (e.g., community health centers, physicians, community hospitals). The study to be launched during the pilot will include a screening component and the use of evidence-based guidelines for cancer treatment and follow-up care.

# C.3. PURPOSE AND OBJECTIVES OF THE PROGRAM

The purpose of a resulting procurement shall be to acquire support from a hospital-based community cancer center to provide a coordinated program to research how best to:

- a) increase accruals to NCI-sponsored clinical trials, especially for underrepresented and disadvantaged populations;
- b) develop new or expanded programs to increase outreach to the uninsured, and underrepresented and disadvantaged populations for prevention, screening, treatment, follow-up care, palliative care, survivorship plans, and end-of-life care;
- c) increase knowledge of infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG<sup>TM</sup> for community hospital settings, and increase implementation of electronic medical records and exploration of the application of electronic medical records in the provision of cancer care;
- d) increase knowledge of infrastructure requirements, policies and procedures, costs and other issues (e.g., collaborations or contracts necessary for biospecimen collection, annotation and storage) required for implementation of the *First-Generation Guidelines for NCI supported Biorepositories (FGGs)*, thus enabling community hospitals to participate in biospecimen initiatives that will advance the NCI's research agenda.

### C.3.a. Organization Baseline Requirements

The NCCCP pilot site shall provide all of the necessary services, qualified personnel, material, equipment and facilities required to perform the statement of work. Refer to the detailed information request list included as Attachment 2. Baseline requirements for pilot site consideration include:

### C.3.a.(i). Hospital Cancer Center Program Components

The organization will be a community-based hospital with a cancer program that incorporates medical, surgical, and radiation oncology under one administrative/medical structure. Private practice arrangements with physicians or groups can 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 program will be 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.

Required baseline components 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).

The organization will provide supporting material to demonstrate that it has staffing, technology, clinical programs, and expertise to offer quality cancer services, including an ongoing referral relationship for hospice services.

### C.3.a.(ii). Clinical Trials

There is great interest in advancing all appropriate clinical trials as part of the NCCCP pilot model. NCCCP pilot sites will have demonstrated experience participating in clinical trials (NCI-sponsored trials preferred), and an established research function to support clinical trials. Organizations must have accrued at least 25 patients to clinical trials during each of the past three years. During the pilot, all trials will be tracked to determine whether there has been an increase in the number of patients accrued to clinical trials, including those who are underrepresented or disadvantaged. It is

anticipated that during the pilot, there will be an increase in accrual to all clinical trials including treatment, prevention and behavioral trials, with specific interest to increase accrual to multi-modality trials and NCI-sponsored trials. NCCCP pilot sites will be expected to increase their capability to offer phase II trials and develop protocols for referral of patients for phase I trials to NCI-designated cancer centers or academic medical research institutions. NCCCP pilot funding for clinical trials will be provided for infrastructure support at the pilot sites to expand clinical trials, not for the trials themselves. Funding and oversight for clinical trials at the NCCCP sites will continue to be provided through the existing trial sponsors (e.g., NCI programs, the pharmaceutical industry).

### C.3.a.(iii). Healthcare Disparities and Community Outreach

A significant aspect of the pilot is the exploration of approaches to reduce healthcare disparities. For this pilot, a successful organization will devote direct financial and other resources for community outreach (e.g., health screenings, relationships with public healthcare clinics for cancer patients) and will have existing and formal relationships within its community organized to respond to the healthcare needs of those who do not have access to healthcare services. Organizations will have a strong track record of community outreach programs and will demonstrate that those screened for cancer will receive treatment if needed. It will not be sufficient to have referral or transfer arrangements in place.

A track record of developing public/private partnerships to address the needs of the uninsured and underrepresented and disadvantaged populations is preferred, along with evidence of organized and sustainable partnerships with regional and state public health departments or other NCI/NIH/HHS programs to address healthcare disparities. Information for the past three years should be provided. Electronic tumor registries are of interest and should be described.

In order to understand the community demographics and healthcare needs of the market served, the organization will provide information on the population and the racial/ethnic and socioeconomic make-up of the market, and a summary of any studies that have been conducted to examine the healthcare needs of the community.

### C.3.a.(iv). Information Technology

The organization will provide a technical description of the information technology systems and strategy in place at the institution. Programs with electronic health record systems (in whole or part, planned or implemented) are preferred. The organization will also have the capacity to devote staff time and expertise to assess the benefits, implications, and barriers to implementing the relevant infrastructure and components of NCI's caBIG<sup>TM</sup> program over the duration of the pilot. The organization will have information technology capability that will include plans for an electronic medical record, and a description of how such a record will provide an interface for physicians and facilitate multidisciplinary diagnosis and treatment.

### C.3.a.(v). Biospecimen Initiatives

The NCCCP pilot will not focus specifically on collecting biospecimens. The organization will have the commitment and capability to describe and assess the implementation requirements for the *First-Generation Guidelines for NCI supported Biorepositories (FGGs)* (http://biospecimens.cancer.gov/biorepositories/guidelines\_full\_formatted.asp) for a hospital-based community cancer program. The organization will have the capacity to devote staff time and expertise over the duration of the pilot to assess the implications, barriers, costs, necessary processes and procedures, and relevant infrastructure for implementation in a hospital-based community setting. Experience with biospecimen programs or initiatives should be described.

### C.3.a.(vi). NCI Funding

The NCCCP pilot seeks to create new programs that extend state-of-the-art cancer care into new geographic areas, and to involve patient populations that are not being adequately served. As such, only those organizations that have received less than \$3 million in annual NCI funding will be considered. Current NCI funding is not a requirement.

### C.3.a.(vii). Supplemental Funding

The success of a community-based cancer program will be enhanced by supplemental funding or in-kind services provided by the successful organization. Organizations are encouraged to provide supplemental funding to support the stated "*Purpose and Objectives for the Program*": increased accrual to clinical trials including minority recruitment, increased outreach to underrepresented and disadvantaged populations, support of the IT assessment, and support of the biospecimen guidelines assessment. In addition, there is interest in seeking sites where supplemental state funding is available to help support the goals of the pilot project.

It is anticipated that any award amount issued under a resulting subcontract will not provide full reimbursement of the subcontractor's costs incurred given the breadth of the pilot project expectations and the varied state of the organization's current capabilities. Given this, organizations must clearly demonstrate in their proposals a reasonable level of cost sharing borne by the organization in the pursuit of the pilot project objectives.

Cost sharing may take a variety of forms and may include, but is not limited to, reductions in actual labor costs, the application of outside funding of any appropriate source. The degree and source(s) of cost sharing must be clearly demonstrated in the technical and price proposals and must be demonstrated for the duration of the subcontract period.

### C.3.b. Organization Additional Capabilities/Expertise

As an integral part of the NCCCP pilot, there is interest in seeking organizations to assist with exploration and evaluation of the following areas. Organizations that meet the baseline requirements should also provide additional information in their response to the RFP on how their organization or cancer program has demonstrated experience or would be able to address any of the areas listed below. As it is not expected that NCCCP pilot sites will have expertise in all special interest areas, organizations should comment on the following areas that apply:

#### C.3.b.(i). Linkages with NCI-Designated Cancer Centers or Academic Medical Research Institutions

There is interest in seeking examples of effective affiliations between hospital-based community cancer centers and NCIdesignated cancer centers or academic medical research institutions, such as, but not limited to: models to support clinical trials so that patient accrual will increase in the community location; service as a resource to improve the quality of medical care at the pilot site, while at the same time recognizing and accommodating the private practice model for cancer care; and examples of protocols for referral in place for especially complex cancer cases, and for phase I clinical trials so that the most appropriate care is available for cancer patients. One of the desired goals of the pilot is to enhance scientific linkages between the community cancer center and the larger institutions, and specific interest would be given to existing affiliations that involve less than substantial financial relationships as part of the collaboration. The successful model could include telemedicine and other information technology linkages for supporting clinical trials, genetic counseling services, and for the operation of an institution-appropriate biospecimen resource that complies with the *First Generation Guidelines for NCI-supported biorepositories (FGGs)*.

The relationship between the pilot site and the NCI-designated cancer center or academic medical research institution would be a model that could be replicated at other hospital-based community cancer program locations.

# C.3.b.(ii). New Community-based Models to Address Healthcare Disparities/Participation in Community Health Coalitions

There is interest in new community-based models (over and above the baseline requirements) to address healthcare disparities and the needs of the community, and to identify examples of new approaches in which the community hospitals or health systems/corporations participate in, and provide leadership to, community-based approaches. One of the pilot goals is to seek broad-based and sustainable models that include public/private partnerships to address the unmet healthcare needs of the community, particularly those of the uninsured, and underrepresented and disadvantaged populations. A successful model will have health screening, an information technology component, will incorporate metrics and methods of evaluation, and will have demonstrated efforts to track and measure improved healthcare outcomes. The model should show evidence of being able to be replicated in other locations and must reflect a sustainable and ongoing commitment of direct financial resources to support the programs. Participation in NCI-sponsored healthcare disparities programs is also of interest.

#### C.3.b.(iii). National Health System Models in Multiple Markets

There is interest in promoting the rapid expansion of improved cancer care, using the NCCCP pilot model. Health system participants, with multiple acute care hospitals in different geographic markets, would help accelerate progress in achievement of pilot goals because many of them have developed successful strategies and methods for knowledge transfer, including infrastructure development and the adoption of best practices for clinical programs, quality-of-care, and programs to respond to the needs of the underrepresented and disadvantaged populations. For consideration, the health system would operate acute care hospitals in multiple markets, and would be organized with a governance structure that has operating control over its hospitals. It would have an infrastructure and management with authority to, and success in driving, clinical initiatives and improvements in quality-of-care and in addressing the healthcare needs of the uninsured, underrepresented, and disadvantaged populations within its communities.

Minimal requirements for the successful organization(s) will be a national/regional health system with at least three hospital-based cancer centers in different geographic markets, meeting the baseline criteria for the pilot, so that there is a demonstration of cancer program expertise within or across the health system. If a system has additional sites that meet the baseline criteria, they may be noted. A health system would demonstrate that it has management capability, programs, and infrastructure that have enabled the successful transfer of knowledge and best practices for clinical program development, quality of care, and outreach to the uninsured, underrepresented, and disadvantaged populations (e.g., evidenced-based care, a Congestive Health Failure initiative, a cardiac, orthopedic or cancer product line adapted

for a rural hospital, a required template or approach for community outreach) across organizations in different geographic locations. The health system will demonstrate that it has authority to oversee the participation and obligations of the specific cancer center locations participating in the NCCCP pilot.

In its proposal, the health system would propose a partnership of one *lead site* and up to three *developmental* cancer program locations in different markets for the pilot activities. The primary or lead site would meet all of the baseline requirements for the pilot, and the developmental locations must be able to meet the baseline, as well as the final program requirements, within the three years of the pilot. There is also interest in a health system with a presence in more rural locations, so that adaptation of the NCCCP pilot model to more rural settings could be examined during the pilot.

Funding for a health system organization would be provided for one pilot for oversight and implementation at its participating cancer centers. There will not be additional funding for the multiple locations within the pilot.

### C.3.b.(iv). State-Funded Cancer Initiatives

There is interest in seeking an NCCCP pilot organization that would have a hospital-based community cancer center in a state with a state-sponsored initiative that provides funding for cancer prevention, screening, and treatment. The organization would provide an overview of the state cancer program and highlight any particular areas of focus and metrics for evaluation that have been introduced or that are being contemplated. The organization would demonstrate participation in the state-sponsored cancer initiative or demonstrate active involvement in the development of a state plan. There is also interest in any state initiatives that have included discussions with payers relative to new models for payment for cancer prevention, screening, coordinated treatment, and follow-up.

#### C.3.b.(v). Special Locations with High Incidence of Cancer/Lack of Services

There is interest in giving additional consideration for a pilot site at a location with documented severe access problems or special hardships that place the population, especially the poor, at a greater risk due to lack of services.

#### C.3.b.(vi). Health Information Technology (IT) Initiatives

There is interest in giving additional consideration to locations in states or regions with information technology and telemedicine initiatives that would accelerate the advancement of NCI/HHS IT goals, particularly locations with a special focus on cancer health information technology. Experience participating in Regional Health Information Organizations (RHIOs) or similar initiatives should be described. Other areas of interest include creative efforts to provide electronic medical records to patients and information systems that include tracking systems and reminders for follow-up care.

### C.3.b.(vii). Survivorship Plans

The NCI has initiatives underway to incorporate survivorship plans into a comprehensive model for the delivery of cancer care (<u>http://dccps.nci.nih.gov/ocs/</u>). There is interest in learning about community-based efforts in this area.

#### C.3.b.(viii). Experience with Payer-Sponsored Clinical Initiatives

During the pilot, there is interest in examining the potential to develop new reimbursement models for cancer prevention, screening, and treatment. There is interest in organizations with expertise (clinical and financial) to enable the exploration of partnerships with large state-based insurers or business coalitions to consider new methods and payment incentives for improved coordination of cancer care models along the lines of the CMS disease management demonstration program. The organization should describe its relevant expertise, and its experience with payer-sponsored clinical initiatives. Participation of cancer center physicians in the voluntary CMS 2006 Oncology Demonstration program should be noted.

#### C.3.b.(ix). National or Industry Expertise

The pilot will allow the development and refining of a new program concept for hospital-based community cancer care. The organizations should fully describe, with supporting documentation (e.g., articles, reports), areas of program expertise and/or professional expertise with supporting credentials for key participants from their organization and note the availability of these resources to contribute to the concept refinement for this project. Some examples would include the following expertise: developing a multidisciplinary model of cancer care; creating comprehensive, effective, and replicable models of care that improve access to care and address healthcare disparities; developing and implementing joint programs with a state cancer plan; adapting clinical programs to rural settings; and/or achieving "benchmark" accrual rates for patients on clinical trials. It is intended that a range of national or industry "thought leaders" from the pilot locations be integrally involved in this pilot.

### C.3.b.(x). Experience with Clinical Care Networks

The pilot will also allow for the exploration of the concept of a knowledge exchange network and the role and purpose of information and telemedicine networks to support clinical or research activities. Organizations with relevant experience with such networks or activities should provide a description with information that could be relevant.

### C.3.b.(xi). Multidisciplinary Cancer Care

There is interest in exploring examples and models of the highest level of innovative integrated multi-disciplinary cancer care. Cancer programs that have developed a successful multi-disciplinary approach, or that have a plan underway, should describe their program and the documented or perceived benefits.

### C.3.b.(xii). Successful Approaches for Accrual of Patients to NCI Clinical Trials

There is interest in exploring successful initiatives with documented results for increasing accrual of patients to clinical trials, with a particular interest in NCI-sponsored clinical trials and recruitment of underrepresented and disadvantaged populations. The successful approach would be able to be replicated in other organizations. Programs with outstanding success should briefly describe the strategies employed and provide supporting data to document results. Experience with CCOP (Community Clinical Oncology Program) institutions, Cooperative Groups or other NCI-sponsored programs is preferred.

### C.3.c. Specific Tasks Required

The organization must work in collaboration with the NCI and SAIC-Frederick to establish an NCCCP pilot at their location. The oversight of this project should be accomplished by creating a NCCCP Pilot Project Team to include both medical and technical support. By the end of the pilot period, the organization will implement the components of the NCCCP pilot, in addition to the required baseline components, to include:

- i. A physician director will be in place with specific cancer expertise, administrative qualifications, and institutional support to serve as an effective director for the program with one administrative/medical structure. The physician director must have a broad scope of authority to oversee all aspects of the program. The director shall dedicate most of his or her time to the cancer program (including patient care responsibilities within the cancer program).
- ii. Ongoing support and regular meetings for at least four multidisciplinary, organ-site specific planning committees. A colorectal cancer multidisciplinary planning committee may be a priority if one does not exist since this may be a focus of evaluation during the pilot.
- iii. Increased use of evidence-based guidelines, standards and protocols (e.g., NCCN, ASCO, USPSTF, ACoS).
- iv. The development of a cancer center-specific medical staff credentialing program to support the patient care, quality research, and community outreach goals of the cancer center.
- v. Enhanced patient navigation support.
- vi. Increased outreach infrastructure and increased community partnerships to improve access for cancer screening and treatment; Expanded programs/linkages for cancer screening and treatment, and evidence of sustainability for outreach programs to address healthcare disparities.
- vii. A detailed pilot site-specific report with recommendations on IT infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG<sup>TM</sup> for community hospital settings to support NCI research goals; Implementation of electronic medical record and tumor registry; Participation in the development of a group report (input provided by all pilot sites) with recommendations.
- viii. A detailed pilot site-specific report with recommendations on the necessary infrastructure requirements, policies and procedures, cost and other implementation issues necessary for the establishment of a biospecimen resource that is compliant with FGGs for NCI-Supported Biorepositories. The resource would oversee the collection, annotation, storage, quality control, and tracking of informed consent of specimen contributors required for implementation enabling community hospitals to participate in biospecimen-dependent scientific initiatives that will advance the research agenda of NCI; Participation in the development of a group report (input provided by all pilot sites) with recommendations.
- ix. New or expanded linkages with NCI-designated cancer centers or academic medical research institutions appropriate to meet the objectives for the NCCCP pilot; Exploration of the resources and assistance of the Cancer Expert Corps, a

program currently under development, and/or linkages with expertise at NCI-designated cancer centers for more specialized training or access to more specialized services with a special focus on reducing healthcare disparities.

- x. Demonstration of increases in accrual rates to clinical trials over the pilot period, particularly to phase II trials, and a detailed report with a description of the methods/programs/strategies utilized to accomplish increased accruals. Accruals for the recruitment of minority patients will be tracked specifically, as well as ways to increase accrual to phase II trials and NCI trials, and appropriate referral of patients for phase I clinical trials.
- xi. Genetic and molecular testing on-site or through a formal specimen referral to approved laboratories.
- xii. New or expanded palliative care initiatives into the cancer program.
- xiii. New or expanded survivorship plans into model-of-care for NCCCP pilot sites to ensure that an appropriate plan is developed for cancer patients (from initial diagnosis to discharge) and to ensure appropriate follow-up and monitoring.
- xiv. Results of a quality-of-care study, such as one for colorectal cancer.
- xv. NCCCP Network recommendations for incorporation into the future program to include recommendations for all four of the key areas of the pilot.
- xvi. For Health Systems, each *developmental* location will have achieved all baseline and subcontract requirements, such as distinct location. There will be a "tool kit" developed with effective strategies and methods for successful knowledge transfer of cancer program key components; If applicable, demonstration of the transfer of knowledge to rural settings.

(End of Section C)

# SECTION D—PACKAGING AND MARKING

Any deliverables required under this subcontract, shall be packaged, marked, and shipped in accordance with commercial standards, or as specified herein. At a minimum, all deliverables shall be marked with the subcontract number and Subcontractor name. The Subcontractor shall guarantee that all required materials be delivered in immediate usable and acceptable condition.

(End of Section D)

# SECTION E—INSPECTION AND ACCEPTANCE

- A. The Contracting Officer or a duly authorized representative will perform an evaluation of the research services and acceptance of deliverables provided.
- B. Inspection and acceptance will be performed at the National Cancer Institute at Frederick (NCI-Frederick), Frederick, Maryland.

(End of Section E)

# SECTION F—DELIVERIES OR PERFORMANCE

### F.1. PERIOD OF PERFORMANCE

The period of performance shall begin with the subcontract award date and shall extend for three years.

# **F.2. DELIVERABLES**

The following shall be required of the organization:

### F.2.a. Clinical Trials

The organization will demonstrate an increase in accruals to clinical trials over the course of the pilot. Immediately upon award, a target rate that will reflect a "significant" increase will be established for each pilot site based on the baseline rate of accrual and other factors to be determined by SAIC-Frederick in collaboration with the NCI. Accrual of underrepresented and disadvantaged patients will also be tracked for improvement. During the pilot there should be an increase in accruals to all clinical trials including treatment, prevention, and behavioral trials with specific focus to increase accrual to multi-modality trials and NCI-sponsored trials. NCCCP pilot sites will increase their capability to offer phase II trials and develop protocols for appropriate referral of patients for phase I trials to NCI-designated cancer centers or academic medical research institutions. The organization will provide quarterly reports and a final report to include methods and strategies employed (and resources required) to achieve the required target rate, and those to increase accrual of underrepresented and disadvantaged patients. It is intended that the methods will be replicable for other community cancer programs and be able to be documented and developed into recommendations at the end of the pilot. The pilot sites will also develop a joint report on methods to increase accruals to clinical trials in community cancer centers, including the recruitment of underrepresented and disadvantaged patients. This joint report will be a deliverable from the group, and will be developed through a facilitated group work effort during the pilot. A framework for approaching this collection of information and development of a joint report will be established in year one.

### F.2.b. Healthcare Disparities

The organization will demonstrate a documented improvement in health screening activities and outreach to community members including those of different racial, ethnic, and socioeconomic status, and those who are underrepresented and disadvantaged. They will have a policy that all patients who are screened will be treated with appropriate follow-up care and will provide documentation that this policy has been implemented. Specifically, an increase in the number of prevention and screening programs and other early detection activities will be required. The organization will document increased partnering with local community organizations, government and non-government, and diagnostic and treatment services. A baseline will be set at the beginning of the pilot and tracked for improvement over the course of the pilot and incorporated into a final report. The organization will provide information on direct financial investment to outreach programs as a baseline and will demonstrate no diminishment of that financial support over the course of the pilot. A framework for examining the most effective methods for achieving improvements in the reach and effectiveness of these outreach programs will be established in year one. The pilot sites will develop a joint report that will be a collection of successful approaches for community cancer centers to improve outreach and address healthcare disparities.

### F.2.c. Information Technology

Throughout the pilot, the NCCCP pilot sites will work closely with the NCI and SAIC-Frederick staff responsible for  $caBIG^{TM}$  and develop a detailed report with recommendations on IT infrastructure requirements, necessary interfaces, and applicability of specific components of  $caBIG^{TM}$  for community hospital settings to support NCI research goals. Implementation and integration of electronic medical records and electronic tumor registry data into the cancer program activities at each pilot site will be completed by the end of the pilot if not earlier. The IT infrastructure will also support the biospecimen resource requirements as detailed in the FFGs for NCI-Supported Biorepositories.

### F.2.d. Biospecimen Initiatives

Throughout the pilot, the pilot sites will work with NCI and SAIC-Frederick staff for the review of the *First Generation Guidelines for NCI Supported Biospecimen Repositories (FGGs)* to complete a detailed report with recommendations on the necessary infrastructure requirements, policies and procedures, cost and other implementations issues, such as collaborations necessary for biospecimen collection and storage, required for implementation enabling community hospitals to participate in biospecimen initiatives that will advance the NCI's research agenda.

### F.2.e. Deliverables for Evaluation Contractor

Individual site performance will be determined by SAIC-Frederick by the evaluation of contract deliverables. To determine the effectiveness/success of the NCCCP pilot, a separate evaluation contract will be negotiated and managed by the NCI. The NCCCP pilot sites will collaborate with the NCCCP project team to develop a preliminary evaluation plan to include both quantitative and qualitative data analysis. The actual evaluation to be completed by the NCI evaluation contractor will be based on the data provided by SAIC-Frederick, which will be the deliverables provided by the NCCCP pilot sites.

Beginning in year one, certain components of the NCCCP pilot will be finalized through this evaluation contractor and with the participation of all of the pilot sites. This work will include, but not be limited to, the establishment of a framework and metrics to address specific more complex issues, such as: a quality-of-care study for prevention and treatment for a specific cancer, such as colorectal cancer; a framework for conducting a qualitative data analysis of approaches to the multi-disciplinary care of cancer patients (*a pre- and post-patient-satisfaction survey will be completed as part of the evaluation utilizing a common survey instrument*); and a framework and recommendations for an NCCCP Network. This evaluation will continue throughout the pilot period and will extend to the end of the pilot.

### F.2.f. Program Component Deliverable Summary

Program Component	Deliverable
A physician program director with cancer expertise with the program under an administrative/medical structure.	A position description and CV of physician program director that demonstrates that the physician director has a broad scope of authority to oversee all aspects of the program and that the director shall dedicate most of his or her time to the cancer program (including patient care responsibilities). A description of his or her time commitment, and an organizational chart showing the reporting relationships and the span of authority.
Ongoing support and regular meetings for at least four multidisciplinary, organ-site specific, planning committees. A colorectal cancer multidisciplinary planning committee may be a priority if one does not exist, since this may be the focus of evaluation during the pilot.	Minutes of multi-disciplinary meetings, quarterly reports, and final report of process improvement/ accomplishments/issues resolved.
Increased use of evidence-based guidelines, standards and protocols (e.g., NCCN, ASCO, USPSTF, ACoS). The development of a cancer center specific medical staff credentialing program to support the patient care, quality research,	Documentation of use of guidelines and reports on improved compliance with guidelines. A process for credentialing of medical staff for the cancer center shall be approved by the organization
and community outreach goals of the cancer center. Expanded patient navigation support.	and its medical staff and implemented. Documentation of expansion of patient navigation program, and how it meets the needs of the patients served by the cancer center. The Patient Navigation staff including educational background and experience will be described. Quarterly progress reports will include an update and report on patient navigation including the type of staff dedicated to these efforts (e.g., nursing, social work).
Increased outreach infrastructure, expanded programs/linkages for cancer screening and treatment, and evidence of sustainability for outreach programs to address healthcare disparities.	Documentation of increased services, partnerships and a description of effective methods that led to success. Participation in the formal program evaluation.
A detailed report with recommendations on IT infrastructure requirements, necessary interfaces, and applicability of specific components of caBIG <sup>TM</sup> for community hospital settings to support NCI research goals. Implementation of electronic medical record and tumor registry. Participation in the development of a group report with recommendations.	Individual and group report to be completed. Implementation of electronic medical record and tumor registry.

Program Component	Deliverable
A detailed report with recommendations on the necessary infrastructure requirements, policies and procedures, cost and other implementations issues such as collaborations necessary for biospecimen collection and storage, required for implementation enabling community hospitals to participate in biospecimen initiatives that will advance the research agenda of NCI. Participation in the development of a group report with recommendations.	Individual and group report completed.
Linkages with NCI-designated cancer centers or academic medical research institutions appropriate to meet the objectives for the NCCCP pilot. Exploration of the resources and assistance of the developing Cancer Expert Corps program and/or linkages with expertise at NCI-designated centers for more specialized training or access to more specialized services with a special focus on reducing healthcare disparities.	All relevant relationships will be noted and described including how these relationships assist the NCCCP pilot in the achievement of pilot goals. New or expanded relationships established during the pilot will be included in quarterly progress reports.
Demonstration of increased accrual rates to clinical trials, particularly in earlier phase trials and a detailed report with a description of the methods/programs/strategies utilized to accomplish increased accruals. Accruals for NCI trials and minority recruitment will be tracked specifically.	Documentation of an increase in accruals to NCI- sponsored clinical trials and for minority recruitment. A report on effective methods that led to success. Participation in the formal program evaluation.
Genetic and molecular testing on site or through a formal specimen referral to approved labs.	A description of the in-house program with the credentials of the staff person or a copy of an affiliation agreement or contract with a description of the service.
Increased referrals to hospice.	Increased number of referrals based on volume and baseline and increase in patients receiving hospice program benefits with an increased Length of Stay in primary hospice receiving program referrals.
Expansion of palliative care initiatives into the cancer program.	A full description of the palliative care plan, program, and staffing.
Incorporation or expansion of <i>survivorship plans</i> into model-of- care to ensure that an appropriate plan is developed for patients (from initial diagnosis to discharge) and to ensure appropriate follow-up and monitoring for cancer patients.	A description of the program integrating survivorship plans and a report on the status of implementation.
Results of a quality-of-care study, such as for colorectal cancer. NCCCP Network recommendations for incorporation into the future program.	Full compliance with study and results reported. Participation in the network development activities over the course of the pilot – see F.2.e.
For Health Systems	For developmental locations, each location will have achieved all baseline and subcontract deliverables, such as distinct location.
	Provision of a "tool kit" for effective strategies and methods for successful knowledge transfer of cancer program key components. If applicable, transfer of knowledge to rural settings. Participation in the formal program evaluation.

# F.3. REPORTING REQUIREMENTS

### F.3.a. Quarterly Progress Reports

Organizations shall submit timely and thorough quarterly reports (template to be provided upon award) and shall include but not be limited to information such as:

- Specific progress on the four pilot components (Clinical Trials, Disparities, IT, Biospecimens)
- Management and Administrative update
- Program Changes or Adjustments in Scope
- Publications

### F.3.b. Final Report

Organizations shall submit a Final Report (template to be provided upon award) documenting and summarizing the results of the entire subcontract period of performance. This report shall include but not be limited to the following:

- Executive Summary
- Results of the four pilot components (Clinical Trials, Disparities, IT, Biospecimens)

### F.3.c. Report Submissions

Copies of all reports identified in this document shall be submitted electronically to the following individuals:

NAME	EMAIL ADDRESS		
Shannon Jackson	sjackson@mail.ncifcrf.gov		
Joy Beveridge	jbeveridge@ncifcrf.gov		
Beth Baseler	B_baseler@ncifcrf.gov		
Maureen Johnson, PhD	johnsonr@dea.nci.nih.gov		
Donna M. O'Brien	obriendo@mail.nih.gov		

If the Subcontractor becomes unable to deliver the required studies described above, the Subcontractor shall give the SAIC-Frederick, Inc. Contracting Officer immediate written notice of anticipated delays with reasons therefore.

# F.4. SATISFACTORY PERFORMANCE

Satisfactory performance shall be based on performance of the work described in Section C, and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of all deliverables, including data.

(End of Section F)

# SECTION G-CONTRACT ADMINISTRATION DATA

### G.1. CONTRACT REPRESENTATIVES

### G.1.a. SAIC-Frederick Contracting Officer

The following individual is designated as the SAIC-Frederick Contracting Officer and is authorized to conduct business, negotiate, award, and modify this subcontract.

ADDRESS	SAIC-FREDERICK CONTRACTING OFFICER	CONTACT INFORMATION
SAIC- Frederick, Inc.	Mr. Shannon Jackson	Phone: 301-228-4022
P.O. Box B, Building 1050		Fax: 301-228-4037
Frederick, MD 21702		Email: sjackson@mail.ncifcrf.gov

### G.1.b. SAIC-Frederick Contracting Officer's Technical Representative (COTR)

The following individual is designated as the COTR and is authorized to provide technical guidance and otherwise represent SAIC as stated herein:

ADDRESS	CONTRACTING OFFICER REPRSENTATIVE	CONTACT INFORMATION
SAIC- Frederick, Inc.	Joy Beveridge	Phone: 301-846-1623
P.O. Box B		Fax: 301-846-7514
Frederick, MD 21702		Email: jbeveridge@ncifcrf.gov

The Contracting Officer's Technical Representative is responsible for: (1) monitoring the subcontract technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by the subcontract; and (5) assisting in the resolution of technical problems encountered during performance.

### G.1.c. NCI Project Manager (PM)

The following individual is designated as the NCI Project Manager (PM) and is authorized to provide technical guidance. Only the SAIC Frederick Contracting Officer can authorize changes that effect delivery, price, terms or other material aspects of this subcontract.

ADDRESS	NCI Project Manager	CONTACT INFORMATION
31 Center Drive, MSC 2590	Maureen Johnson, Ph.D.	Phone: 301-402-0320
Building 31 / 11A19		Fax:
Bethesda, MD 20892		Email: johnsonr@dea.nci.nih.gov

# **G.2. SUBCONTRACTOR REPRESENTATIVES**

### G.2.a. Subcontractor Representative

The following individual(s) is/are the designated representative of the vendor. This will be the Official authorized to negotiate and sign this Subcontract:

ADDRESS	REPRESENTATIVE NAME	CONTACT INFORMATION
		Phone:
		Fax:
		Email:

### G.2.b. Subcontractor Invoice Representative

The following individual(s) is the designated representative to submit invoices and provide information related thereto:

ADDRESS	REPRESENTATIVE NAME	CONTACT INFORMATION
		Phone:
		Fax:
		Email:

### G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this subcontract, the following individuals are considered to be essential to the work being performed hereunder, and shall not be re-assigned, removed or substituted without the concurrence of the Contracting Officer (examples are provided):

NAME	TITLE	
	Principal Investigator/Pilot Project Leader	
Physician Director		
	Chief Information Officer	
Chief of Pathology		
	Administration Leader for Cancer Center	

### **G.4. INVOICE SUBMISSION**

**G.4.a.** Invoices shall be prepared in accordance with the SAIC-F Invoice Instructions for Time and Materials Subcontracts, which is provided as Subcontract Attachment 2:

An original and one (1) copy to the following designated representative:

SAIC-Frederick, Inc. Accounts Payable Attn: Ms. Leasa Mercer P.O. Box B Frederick, MD 21702

- G.4.b. Inquiries regarding payment of invoices should be directed to the attention of Shannon Jackson at 301-228-4022.
- **G.4.c.** To expedite payment of invoices, it is essential that the Subcontractor provide sufficient data, as defined in the invoice instructions that will support payment of all costs being billed.
- **G.4.d.** Invoices are payable net 30 days after receipt of a proper invoice. Payment shall be considered made on the date on which a check for such payment is dated.
- **G.4.e.** Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, incorporated in this subcontract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:
  - Acquisition, by purchase or lease, of any interest in real property;
  - Non-expendable Equipment
  - Special re-arrangement or alteration of facilities;
  - Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property that are usable for purposes other than research, such as office equipment and furnishings, and pocket calculators);
  - Travel to attend general scientific meetings, whether at domestic or foreign locations;
  - Consultant expenses; and
  - Subcontracts

(End of Section G)

# SECTION H - SPECIAL CONTRACT REQUIREMENTS

### H.1. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal Funds from the National Cancer Institute, National Institutes of Health, under Contract No. NO1-CO-12400. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the United States Government.

# H.2. PRESS RELEASES

The Subcontractor must seek advanced, written approval from the SAIC-Frederick contracting officer prior to the issuance of any press release, regardless or media, related to this subcontract.

The subcontractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources in accordance to Public Law 109-149, Title V, Section 506

# H.3. SALARY RATE LIMITATION LEGISLATION PROVISIONS

- H.3.a. Pursuant to Public Law(s) cited in paragraph B., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this subcontract at a rate in excess of the applicable amount shown for the fiscal year covered. Direct salary is exclusive of overhead, fringe benefits and general and administrative expenses.
- H.3.b. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multiple year contract, it may be subject to unilateral modifications by SAIC-F if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts in accordance with PL 109-149, General Provisions, Section 204

Effective January 1, 2006, this amount is \$183,500 or \$88.22 per hour (based on 2,080 hours per annum) and will remain at this level until such time as the Executive Level I is increased. See the web site listed below for Executive Level I rates of pay: <u>http://www.opm.gov/oca/PAYRATES/index.htm</u>

### H.4. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is <u>Htips@os.dhhs.gov</u> and the mailing address is:

Office of Inspector General Department of Health and Human Services TIPS HOTLINE P.O. Box 23489 Washington, D.C. 20026

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (http://www3.od.nih.gov/oma/manualchapters/management/1754).

# H.5. ORGANIZATIONAL CONFLICT OF INTEREST

During the performance of this Subcontract, the Subcontractor is prohibited from engaging in similar work or services adverse to the interests of SAIC-Frederick, Inc./NCI. The Subcontractor also certifies that no services rendered under any agreement during the term of this Subcontract will be adverse to the interest of SAIC- Frederick, Inc./NCI. The Subcontractor also certifies that no financial, contractual, organizational, or other interest exists relating to the work under this agreement that would constitute an Organizational Conflict of Interest or otherwise cause the Subcontractor to be unable or potentially unable to render impartial assistance or advice, impair objectivity in performing the work, or create an unfair competitive advantage for any entity wherein the Subcontractor has an interest. The Federal statutes and regulations concerning conflict of interest carry criminal penalties for violation. The Subcontractor is personally responsible for identifying any such conflict of interest, or any relationship or actions that might give the appearance that a conflict of interest exists or could reasonably be viewed as affecting the Subcontractor's objectivity in performing the work under this agreement. By signature the Subcontractor certifies the understanding of the above and that no Organizational Conflict of Interest exists that would affect this Subcontract. The Subcontractor also indemnifies or otherwise holds harmless SAIC-Frederick, Inc./NCI should an Organizational Conflict of Interest become apparent (not previously disclosed) during the life of this Subcontract.

# H.6. PROHIBITION ON SUBCONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Subcontractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Subcontractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Subcontract.

# H.7. INSURANCE REQUIREMENTS AND CERTIFICATES

The Subcontractor must provide Certificates of Insurance, proving:

- a) Commercial General Liability coverage
- b) Errors & Omissions coverage
- c) Professional Liability coverage
- d) Property Damage coverage
- e) Automobile Liability coverage
- f) All Risk coverage
- g) Worker's Compensation coverage
- h) Foreign Workers' Compensation coverage (including Defense Base Act coverage)

The Certificate of Insurance shall certify that the Subcontractor is insured for the period of performance of this Subcontract. Further, the Certificate of Insurance shall name SAIC-Frederick, Inc. as "*Additionally Named Insured*". The subcontract number and name of the project shall be included in the block naming SAIC-Frederick, Inc. as Additional Named Insured.

If at any time the period of performance of this Subcontract the insurance coverage lapses or is cancelled, the Subcontractor will immediately notify SAIC-Frederick, Inc.

(End of Section H)

# PART II—SUBCONTRACT CLAUSES

# SECTION I—SUBCONTRACT CLAUSES

# I.1. GENERAL CLAUSES FOR A NEGOTIATED TIME & MATERIALS SUBCONTRACT

Where the words "Contracting Officer" or "Government" appear, it shall be understood to mean "SAIC-Frederick, Inc. Contracting Officer" or "SAIC Frederick, Inc." (buyer) provided; however, that such substitution in no way supersedes or diminishes any rights or responsibilities of the Government under public law, Federal Acquisition Regulations, or in the terms of the prime contract, including, but not limited to, the right to review, audit, and approve any records or procedures of the Subcontractor. Where the word "Contractor" appears, it shall be understood to mean "Seller" and where "Contract" appears, it shall be understood to mean "Order."

### I.1.a. Federal Acquisition Regulation (FAR)

This subcontract incorporates the following FAR clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <u>http://www.arnet.gov/far/</u>.

Clause	Date	Clause Title	
52.202-1	Jul-04	Definitions (Over \$100,000)	
52.203-3	Apr-84	Gratuities (Over \$100,000)	
52.203-6	Sep-06	Restrictions on Subcontractor Sales to the Government (Over \$100,000)	
52.203-7	Jul-95	Anti-Kickback Procedures (Over \$100,000)	
52.203-12	Sep-05	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)	
52.209-6	Sep-06	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$30,000)	
52.215-1	Jan-04	Instructions to Offerors—Competitive Acquisitions	
52.215-2	Jun-99	Audit and Records - Negotiation (Over \$100,000)	
52.215-19	Oct-97	Notification of Ownership Changes	
52.222-21	Feb-99	Prohibition of Segregated Facilities	
52.222-26	Apr-02	Equal Opportunity	
52.222-35	Sep-06	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over \$100,000)	
52.222-36	Jun-98	Affirmative Action for Workers with Disabilities	
52.222-37	Sep-06	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Over \$100,000)	
52.222-50	Apr-06	Combating Trafficking in Persons	
52.223-6	May-01	Drug-Free Workplace	
52.223-14	Aug-03	Toxic Chemical Release Reporting (Over \$100,000)	
52.225-13	Feb-06	Restrictions on Certain Foreign Purchases	
52.227-2	Aug-96	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)	
52.227-14	Jun-87	Rights in Data—General	
52.232-7	Aug-05	Payments under Time-and-Materials and Labor-Hour Contracts	
52.232-9	Apr-84	Limitation on Withholding of Payments	
52.232-23	Jan-86	Assignment of Claims	
52.242-1	Apr-84	Notice of Intent to Disallow Costs	
52.242-13	Jul-95	Bankruptcy (Over \$100,000)	
52.243-3	Sep-00	Changes - Time-and-Materials and Labor-Hours	
52.244-2	Aug-98	Subcontracts	
52.244-6	Sep-06	Subcontracts for Commercial Items	
52.245-5	May-04	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)	
52.245-9	Aug-05	Use and Charges	
52.249-14	Apr-84	Excusable Delays	

### I.1.b. Department of Health and Human Services Acquisition Regulation (HHSAR).

This subcontract incorporates the following DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION HHSAR 48 Chapter 3 clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <u>http://www.hhs.gov/oamp/dap/hhsar.html</u>

Clause	Date	Clause Title	
352.202-1	Jan-01	Definitions	
352.215-1	Jan-04	tructions to Offerors—Competitive Acquisitions	
352.232-9	Apr-84	/ithholding of Contract Payments	
352.270-5	Apr-84	Xey Personnel	
352.270-6	Jul-91	ublications and Publicity	
352.270-7	Jan-01	Paperwork Reduction Act	

# **I.2. ADDITIONAL TERMS & CONDITIONS**

### I.2.a. GOVERNMENT RELATIONSHIP

This Order is made by SAIC-Frederick, Inc., a Subsidiary of Science Applications International Corporation, under its contract with the National Cancer Institute at Frederick (NCI-Frederick). The provisions and clauses contained herein are influenced by and reflect the relationship of the parties in that contract, which was awarded and is administered under the provision of the Federal Acquisition Regulation (FAR). There is no privity of contract between the Seller and the Government.

### I.2.b. GENERAL RELATIONSHIP

The Seller is not an employee of SAIC-Frederick, Inc. for any purpose whatsoever. Seller agrees that in all matters relating to this Order it shall be acting as an independent contractor and shall assume and pay all liabilities and perform all obligations imposed with respect to the performance of this Order. Seller shall have no right, power or authority to create any obligation, expressed or implied, on behalf of Buyer and/or Buyer's customers and shall have no authority to represent Buyer as an agent.

### I.2.c. DEFINITIONS

Buyer - SAIC-Frederick, Inc.

Seller - The party (contractor) receiving the award from SAIC-Frederick, Inc.

Prime Contract – The Government contract under which this Order is issued (see paragraph 1 entitled "Government Relationship").

NCI Government Contracting Officer –The NCI-Frederick person with the authority to interpret, modify, administer, and/or otherwise make decisions with regard to the Prime Contract". This term includes authorized representatives of the NCI-Frederick Contracting Officer within their delegated authority.

Contracting Officer – The SAIC-Frederick, Inc. person with the authority to enter into and administer Orders. The term includes authorized representatives of the Contracting Officer acting within their delegated authority.

Order - The contractual agreement between SAIC-Frederick, Inc. and the Seller.

Special Definitions – See paragraph 4 for the special definitions that apply in the use of the solicitation and award clauses of this Order.

### I.2.d. SOLICITATION AND AWARD CLAUSES - SPECIAL DEFINITIONS

FAR clauses included in this Order, including any solicitation document, shall be interpreted as follows:

Unless a purposeful distinction is made clear and the context of the clause requires retention of the original definition, the term "Contractor" shall mean Seller, the term "Contract" shall mean this Order, the term "Subcontractor" shall mean subcontractors of Seller at any tier, and the terms "Government", "Contracting Officer" and equivalent phrases shall mean SAIC-Frederick, Inc. and SAIC-Frederick's Contracting Officer, respectively. It is intended that the referenced clauses shall apply to Seller in such manner as is necessary to reflect the position of Seller as a contractor to SAIC-Frederick, Inc. to insure Seller's obligations

to SAIC-Frederick, Inc. and to the United States Government, and to enable SAIC-Frederick, Inc. to meet its obligations under its Prime Contract.

Full text of the referenced clauses may be found in the FAR (Code of Federal Regulation [CFR] Title 48), obtainable from the Superintendent of Documents, Government Printing Office (GPO), Washington, DC 20402 or online at http://www.arnet.gov/far/.

Copies of the clauses will be furnished by the Contracting Officer upon request.

### I.2.e. ENTIRE AGREEMENT

This Order, including all attachments and/or documents incorporated by reference by Buyer, shall constitute the entire agreement between Buyer and Seller. No other document (e.g., including Seller's proposal, quotation or acknowledgement forms) shall be a part of this Order, even if referred to, unless specifically agreed to in writing by Buyer. No right that Buyer has regarding this Order may be waived or modified except in writing by Buyer.

### I.2.f. ACCEPTANCE AND MODIFICATION OF TERMS

Acceptance of this Order by Seller may be made by signing the acknowledgement copy hereof or by partial performance hereunder, and any such acceptance shall constitute an unqualified agreement to all terms and conditions set forth herein unless otherwise modified in writing by the parties. Any additions, deletions or differences in the terms proposed by Seller are objected to and hereby rejected, unless Buyer agrees otherwise in writing. No additional or different terms and conditions proposed by the Seller in accepting this Order shall be binding upon Buyer unless accepted in writing by Buyer and no other addition, alteration or modification to, and no waiver of any of the provisions herein contained shall be valid unless made in writing and executed by Buyer and Seller. Seller shall perform in accordance with the Description/Quantity schedule set forth in this Order and all attachments thereto.

### **I.2.g. LEGAL CONSTRUCTION AND INTERPRETATIONS**

This Order shall be governed by and interpreted in accordance with the principles of Federal Contract Law, and to the extent that Federal Contract Law is not dispositive, and the state law becomes applicable, the law of the State of Maryland shall apply.

### I.2.h. COMPLIANCE WITH LAWS AND REGULATIONS

Seller shall submit all certifications required by Buyer under this Order and shall at all times, at its own expense, comply with all applicable Federal, State and local laws, ordinances, administrative orders, rules or regulations.

### I.2.i. GIFTS

Seller shall not make or offer a gratuity or gift of any kind to Buyer's employees or their families. Seller should note that the providing of gifts or attempting to provide gifts under government subcontracts might be a violation of the Anti-Kickback Act of 1986 (4 U.S.C. 51-58).

### I.2.j. MARYLAND SALES AND USE TAX

The State of Maryland has issued Direct Payment Permit #3, effective date August 29, 1996, to SAIC-Frederick, Inc. that will be issued to vendors of NCI-Frederick for purchases of goods and services. A copy of this Permit is available to vendors upon request. As a holder of a Direct Payment Permit, SAIC-Frederick, Inc. is authorized to make direct payment of sales and use tax to the State of Maryland. Accordingly, sellers that provide goods and services to SAIC-Frederick, Inc. are relieved from collecting sales tax from SAIC-Frederick, Inc. Therefore, sellers to SAIC-Frederick, Inc. shall not place a separate line item for tax on any invoice sent to SAIC-Frederick, Inc. Please note that the Permit is not to be used by sellers to make purchases free of sales tax, nor shall the Permit be transferred or assigned.

### I.2.k. BUYER FURNISHED DATA AND MATERIALS

Seller agrees that it will keep confidential and not disclose, disseminate or publish the features of any equipment, tools, gauges, patterns, designs, drawings, engineering data, computer programs and software or other technical or proprietary information furnished, loaned or bailed by Buyer hereunder (hereinafter collectively referred to as items/information), and will use such items/information only in the performance of this Order or, if authorized, other orders from Buyer, and not otherwise without Buyer's written consent.

All such items furnished, loaned or bailed by Buyer hereunder, or fabricated, manufactured, purchased, or otherwise acquired by Seller for the performance of this Order and specifically charged to Buyer, are the property of Buyer.

Upon completion, expiration or termination of this Order, Seller shall return all such items in good condition, reasonable wear only excepted, together with all spoiled and surplus items to Buyer, or make such other disposition thereof as may be directed or approved by Buyer. Seller agrees to replace, at its expense, all such items not so returned. Seller shall make no charge for any storage, maintenance or retention of such items. Seller shall bear all risk of loss for all such items in Seller's possession. Seller also agrees to use any designs or data contained or embodied in such items in accordance with any restrictive legends placed on such items by Buyer or any third party. If Buyer furnishes any material, for fabrication hereunder, Seller agrees: (i) not to substitute any other material for such fabrication with Buyer's prior written consent, and (ii) that title to such material shall not be affected by incorporation in or attachment to any other property.

### I.2.1. NOTICE OF DELAY

Seller agrees to immediately notify Buyer in writing of any actual or potential delay in Sellers performance under this Order. Such notice shall, at a minimum, describe the cause, effect, duration and corrective action proposed by Seller to address the problem. Seller shall give prompt written notice to the Buyer of all changes to such conditions.

### I.2.m. CHANGES AND SUSPENSION

Buyer may, by written notice to Seller at any time, make changes within the general scope of this Order in any one or more of the following: (a) drawings, designs or specifications; (b) quantity; (c) time or place of delivery; (d) method of shipment or packing; and (e) the quantity of Buyer furnished property. Buyer may, for any reason, direct Seller to suspend, in whole or in part, delivery of goods or performance of services hereunder for such period of time as may be determined by Buyer in its sole discretion. If any such change or suspension causes a material increase or decrease in the cost of, or the time required for the performance of any part of the work under this Order, an equitable adjustment shall be made in the Order price or delivery schedule, or both, provided Seller shall have notified Buyer in writing of any claim for such adjustment within twenty (20) days from the date of notification of the change or suspension from Buyer. No such adjustment or any other modification of the terms of this Order will be allowed unless authorized by Buyer by means of a written modification to the Order. Seller shall proceed with the work as changed without interruption and without awaiting settlement of any such claim.

### I.2.n. ADVERTISING

Seller agrees that prior to the issuance of any publicity or publication of any advertising that in either case makes reference to this Order, or to Buyer, Seller will obtain the written permission of Buyer with respect thereto.

### I.2.0. CONFIDENTIAL INFORMATION

Seller shall not at any time, even after the expiration or termination of this Order, use or disclose to any person for any purpose other than to perform this Order, any information it receives, directly or indirectly from Buyer in connection with this Order, except information that is or becomes publicly available, or is rightfully received by Seller from a third party without restriction. Upon request by Buyer, Seller shall return to Buyer all documentation and other material containing such information.

### I.2.p. INDEMNIFICATION

Seller shall indemnify, defend and hold harmless Buyer from and against any and all claims, liabilities, damages, losses, causes of action, lawsuits, costs and expenses, including reasonable attorneys' fees and litigation costs incurred in connection therewith and regardless of legal theory (hereinafter referred to as "claims"), occasioned wholly or in part by any act or omission of Seller or any of its lower tiers, or their employees, agents or representatives arising out of or relating to this Order. Notwithstanding the foregoing, Seller's obligations under this Section shall not apply to any claims that are finally determined by a court of competent jurisdiction to be occasioned solely by the negligence or willful misconduct of Buyer.

### **I.2.q. INFRINGEMENT INDEMNITIES**

Seller shall, at its expense, indemnify, defend, save and hold Buyer and its successors, affiliates, officers, directors, employees, agents, independent contractors and customers, and the officers, agents and employees of such customers (hereinafter collectively referred to in this section as "Buyer") harmless from and against any and all damages, liabilities, penalties, interest and costs awarded against and reasonable expenses, including without limitation attorneys' fees that result or arise out of or relate to, in whole or part, any claims, suits, proceedings, actions, causes of action and demands brought against the Buyer asserting that the deliverables, including without delivery, including without limitation all software, goods or services, or any part thereof, furnished under this Order, or the creation, delivery, use modification, reproduction, release, performance, display or disclosure, including without limitation resale or sublicensing thereof, constitutes an infringement of any patent, trademark, trade secret, copyright or other proprietary or intellectual property right or rights of privacy or publicity. In the event such goods or services or use thereof are enjoined in whole or in part, Seller shall at its expense and Buyer's option undertake one of the following: (i) obtain for Buyer the right to continue the use of such goods or services; (ii) in a manner acceptable to Buyer, substitute equivalent goods or services or make modifications thereto so as to avoid such infringement and extend this indemnity thereto; or (iii) refund to Buyer an amount equal to the purchase price for such goods or services plus any excess costs or expenses incurred in obtaining substitute goods or services from another source.

Notwithstanding this Section 17, should the deliverables or portion thereof be held to constitute an infringement and use as contemplated by this Order be enjoined or be threatened to be enjoined, Seller shall notify Buyer and immediately, at Seller's expense; (i) procure for Buyer the right to continue to use the deliverables or portion thereof with a version that is non-

infringing, provided that the replacement or modified version meets any applicable specifications to Buyer's satisfaction. If (i) or (ii) are not available to Seller, in addition to any damages or expenses reimbursed under this section, Seller shall refund to Buyer all amounts paid to Seller by Buyer under this Order.

### I.2.r. NON-WAIVER OF RIGHTS

The failure of Buyer to insist upon strict performance of any of the terms and conditions in this Order or to exercise any rights or remedies, shall not be construed as a waiver of its rights to assert any of same or to rely on any such terms or conditions at any time thereafter. Acceptance or payment of any part of the Order shall not bind Buyer to accept future shipments or performance of services nor deprive Buyer of the right to return goods already accepted or for which Buyer has made payment. Acceptance or payment shall not be deemed to be a waiver of Buyer's right to cancel or return all or any part of the goods because of failure to conform to the Order or by reason of defects, whether latent or patent, or other breach of warranty, or to make any claim for damages of any and all kind.

### I.2.s. INSURANCE REQUIREMENTS FOR WORK ON A GOVERNMENT INSTALLATION

If this Order entails effort on a Government installation, including any off-site buildings owned or leased by the Government, the Seller must provide and maintain the minimum amounts of insurance stated below.

At Buyer's request, Seller agrees to provide Certificates of Insurance evidencing that the required insurance coverages are in force and providing not less than thirty days written notice prior to any cancellation or restrictive modification of the policies.

Further, the required insurance coverages below shall be primary and non-contributing with respect to any other insurance that may be maintained by Buyer. The below required coverages and their limits in no way lessen nor affect Seller's other obligations or liabilities set forth in this Order.

Seller agrees to purchase and maintain at its own expense the following insurance coverages with minimum limits as stated:

- (i) Statutory Workers' Compensation and Employer's Liability in an amount no less than \$1 Million per occurrence covering its employees, including a waiver of subrogation obtained from the carrier in favor of Buyer;
- (ii) Commercial General Liability in an amount no less than \$1 Million per each occurrence and \$2 Million in this Aggregate covering bodily injury, broad form property damage, personal injury, products and completed operations, contractual liability and independent contractors' liability. Buyer, its officers and employees shall be included as Additional Insureds and a waiver of subrogation shall be obtained from the carrier in favor of Buyer;
- (iii) Automobile Liability in an amount no less than \$1 Million Combined Single Limit for Bodily Injury covering use of all owned, non-owned, and hired vehicles. Buyer, its officers and employees shall be included as Additional Insureds on the policy;
- (iv) Professional Liability in an amount no less than \$1 Million per occurrence covering damages caused by any acts, errors, and omissions arising out of the professional services performed by Seller, or any person for whom the Seller is legally liable. To the extent that coverage for Seller's services are not excluded in (ii) above by virtue of being deemed not of a professional nature, this requirement does not apply.
- (v) All-Risk Property Insurance in an amount adequate to replace property, including supplies covered by this Order, of Buyer and/or Buyer's customer that may be in the possession or control of Seller. Buyer shall be named as a Loss Payee with respect to loss or damage to said property and/or supplies furnished by Buyer.

The required insurance coverages above shall be primary and non-contributing with respect to any other insurance that may be maintained by Buyer and notwithstanding any provision contained herein, Seller, and its employees, agents, representatives, consultants, subcontractors and suppliers, are not insured by the Buyer, and are not covered under any policy of insurance that the Buyer has obtained or has in place.

Any self-insured retentions, deductibles and exclusions in coverage in the policies required under this Article shall be assumed by, for the account of, and at the sole risk of Seller which provides the insurance and to the extent applicable shall be paid by Seller. In no event shall the liability of Seller be limited to the extent of any insurance or the minimum limits required herein.

### I.2.t. EXPORT CONTROL COMPLIANCE FOR FOREIGN PERSONS

Seller shall not, nor shall Seller authorize or permit its employees, agents or lower tiers to disclose, export or re-export any Buyer information, or any process, product or services that is produced under this Order, without prior notification to Buyer and complying with all applicable Federal, State and local laws, regulations and ordinances, including the regulations of the U.S. Department of Commerce and/or the U.S. Department of State. In addition, Seller agrees to immediately notify Buyer if Seller

is listed on any of the Department of State, Treasury or Commerce proscribed persons or destinations lists, or if Seller's export privileges are otherwise denied, suspended or revoked in whole or in part.

Under its contract with NCI-Frederick, Buyer conducts research activities that include export-controlled technology that cannot be readily segregated. Buyer may require Seller (including any lower tiers) to place restrictions on their work force performing onsite at SAIC-Frederick, Inc. to protected individuals as established under the guidelines of the Commerce Department Export Administration Regulations (EAR) and the State Department International Traffic in Arms Regulations (ITAR).

Contractors (including any lower tiers) may be required to disclose the status of personnel proposed to perform work onsite prior to award.

Contractors shall include in all agreements and related documents with lower tiers, notice to third parties that the export of any process, goods and/or technical data from the United States may require an export control license from the U.S. Government and that, failure to obtain such export control license may result in termination of Order, and/or criminal liability under U.S. laws.

### I.2.u. ASSIGNMENT

Neither this Order nor any interest herein may be assigned, in whole or in part, without the prior written consent of Buyer except that the Seller shall have the right to assign this Order to any successor of such party by way of merger or consolidation or the acquisition of substantially all of the business and assets of the Seller relating to the subject matter of this Order. This right shall be retained provided that such successor shall expressly assume all of the obligations and liabilities of the Seller under this Order, and that the Seller shall remain liable and responsible to Buyer for the performance and observance of all such obligations.

Notwithstanding the foregoing, any amounts due the Seller may be assigned in accordance with the provisions of the clause 52.232-23, Assignment of Claims.

In the event the prime contract of SAIC-Frederick, Inc. with the Government is succeeded by a successor contractor selected by the Government, this Order may be assigned to the successor contractor.

### I.2.v. DISPUTES

(A) If a decision relating to the Prime Contract is made by the NCI-Frederick Contracting Officer and such decision is also related to this Order, said decision, if binding upon Buyer under the Prime Contract shall in turn be binding upon Buyer and Seller with respect to such matter; provided, however, that if Seller disagrees with any such decision made by the NCI Contracting Officer and Buyer elects not to appeal any such decision, Seller shall have the right reserved to Buyer under the Prime Contract with the Government to prosecute a timely appeal in the name of Buyer, as permitted by the contract or by law, Seller to bear its own legal and other costs. If Buyer elects not to appeal any such decision, Buyer agrees to notify Seller in a timely fashion after receipt of such decision and to assist Seller in its prosecution of any such appeal in every reasonable manner. If Buyer elects to appeal any such decision of the NCI Contracting Officer, Buyer agrees to furnish Seller promptly of a copy of such appeal. Any decision upon appeal, if binding upon Buyer, shall in turn be binding upon Seller. Pending the making of any decision, either by the NCI Contracting Officer or on appeal, Seller shall proceed diligently with performance of this Order.

If, as a result of any decision or judgment whish is binding upon Seller and Buyer, as provided above, Buyer is unable to obtain payment or reimbursement from the Government under the Prime Contract for, or is required to refund or credit to the Government, any amount with respect to any item or matter for which the Buyer has reimbursed or paid Seller, Seller shall, on demand, promptly repay such amount to Buyer. Additionally, pending the final conclusion of any appeal hereunder, Seller shall, on demand promptly repay any such amount to Buyer. Buyer's maximum liability for any matter connected with or related to this Order which was properly the subject of a claim against the Government under the Prime Contract shall not exceed the amount of the Buyer's recovery from the Government.

Seller agrees to provide certification that data supporting any claim made by Seller hereunder is made in good faith and that the supporting data is accurate and complete to the best of the Seller's knowledge or belief, all in accordance with the requirements of the Contracts Disputes Act of 1978 (41USC601-613) and implementing regulations. If any claim of Seller is determined to be based on upon fraud or misrepresentation, Seller agrees to defend, indemnify, and hold Buyer harmless for any and all liability, loss, cost, or expense resulting there from.

Any dispute not addressed in paragraph (A) above, will be subject to paragraph (B) as described below.

(B) Buyer and Seller agree to first enter into negotiations to resolve any controversy, claim or dispute ("dispute") arising under or relating to this Order. The parties agree to negotiate in good faith to reach a mutually agreeable resolution of such dispute within a reasonable period of time. If good faith negotiations are unsuccessful, Buyer and Seller agree to resolve the dispute by binding and final arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association then in effect. The arbitration shall take place in the County of Frederick, State of Maryland. The arbitrator(s) shall be bound to follow the provisions of this Order in resolving the dispute, and may not award punitive damages. The decision of the arbitrator(s) shall be final and binding on the parties, and any award of the arbitrator(s) may be entered or enforced in any court of competent jurisdiction.

Seller hereby waives any immunity, sovereign or otherwise, that it would otherwise have to such jurisdiction and agrees that its rights, obligations, and liabilities hereunder shall be determined in the same manner and to the same extent as those of a private litigant under like circumstances.

All costs of the arbitration shall be shared equally between the Parties, but the Parties specifically agree that each Party shall bear the expense of any costs incurred by it for its own counsel, experts, witnesses, preparation of documents, presentations, and logistics related to the proceedings.

Pending any decision, appeal or judgment referred to in this provision or the settlement of any dispute arising under this Order, Seller shall proceed diligently with the performance of this Order.

### I.2.w. NOTIFICATION OF DEBARMENT/SUSPENSION

By acceptance of this Order either in writing or by performance, Seller certifies that as of the date of award of this Order neither the Seller, lower tiers, nor any of its principals, is debarred, suspended, or proposed for debarment by the Federal Government. Further, Seller shall provide immediate written notice to the Buyer in the event that during performance of this Order the Seller or any of its principals is debarred, suspended, or proposed for debarment by the Federal Government.

### I.2.x. QUALITY ASSURANCE/INSPECTION

All goods furnished and services performed pursuant hereto shall be subject to inspection and test by Buyer at all reasonable times and places, during the Order term, and in any event, prior to Final Acceptance as that term is defined in the Statement of Work. No inspection made prior to Final Acceptance shall relieve Seller from responsibility for defects or other to meet the failure requirements of this Order. In the event that goods furnished or services supplied are not in accordance with the Statement of Work and Schedule or other requirements. Buyer may require Seller to promptly correct, repair, replace or reperform the goods or services. The cost of correction, repair, replacement, or re-performance shall be determined under Section 7 of this Order. If Seller fails to proceed with reasonable promptness to perform the required correction, repair, replacement, or re-performance, Buyer may terminate the Order for default. If Seller is unable to accomplish the foregoing, then Buyer may procure such materials and services from another source or perform such services in-house and charge to Seller's account all costs, expenses and damages associated therewith. Buyer's approval of designs furnished by Seller shall not relieve Seller of its obligations hereunder.

### I.2.y. ORDER OF PRECEDENCE

In the event of an inconsistency or conflict between the Terms and Conditions and the Order issued, the inconsistency or conflict shall be resolved by giving precedence in the following order:

- 1) The Order including all terms and conditions and any provisions.
- 2) Specifications and/or drawings.
- 3) Other documents or exhibits when attached.

### I.2.z. TERMINATION

### **Termination for Convenience**

1) Buyer shall have the right to terminate this Order, in whole or in part, at any time, without cause, by providing written notice to Seller. Upon receiving notice of such termination, Seller shall:

- a) stop all work on this Order on the date and to the extent specified;
- b) place no further contracts hereunder except as may be necessary for completing such portions of the Order that have not been terminated; and

- c) terminate all contracts to the extent that they may relate to portions of the Order that have been terminated; and
- d) protect all property in which Buyer has or may acquire an interest and deliver such property to Buyer.

2) Within twenty (20) days from such termination, Seller may submit to Buyer its written claim for termination charges in the form prescribed by Buyer. Failure to submit such claim within such time shall constitute a waiver of all claims and a release of all Buyer's liability arising out of such termination. Under no circumstances shall Seller be entitled to anticipatory or lost profits.

3) Buyer reserves the right to verify claims hereunder and Seller shall make available to Buyer, upon its request, all relevant, non-proprietary books and records for inspection and audit (e.g. time cards and receipts). If Seller fails to afford Buyer its rights hereunder, Seller shall be deemed to have relinquished its claim.

### **Termination for Default**

1) Buyer may, by written notice of default to Seller, terminate the whole or any part of this Order, in any one of the following circumstances:

a) Seller fails to make delivery of the goods or to perform the services within time specified herein or any extension thereof; or

b) Seller fails to perform any of the other provisions of this Order in accordance with its terms and does not cure such failure within a period of ten (10) days after receipt of notice from Buyer specifying such failure; or

c) Seller becomes insolvent or the subject of proceedings under any law relating to the relief of debtors or admits in writing its inability to pay its debts as they become due.

2) If this Order is so terminated, Buyer may procure or otherwise obtain, upon such terms and in such manner as Buyer may deem appropriate, goods or services similar to those terminated. Seller shall be liable to Buyer for any excess costs of such similar supplies or services.

3) Seller shall transfer title and deliver to Buyer, in the manner and to the extent requested in writing by Buyer at or after termination, such complete or partially completed articles, property, materials, parts, tools, fixtures, plans, drawings, information and contract rights as Seller has produced or acquired for the performance of the terminated part of this Order, and Buyer will pay Seller the contract price for completed articles delivered to and accepted by Buyer and the fair value of the other property of Seller so requested and delivered.

4) Seller shall continue performance of this Order to the extent not terminated. Buyer shall have no obligation to Seller with respect to the terminated part of this Order except as herein provided.

### I.2.aa. SECURITY

Under its contract with NCI-Frederick, SAIC-Frederick, Inc. may be required to conduct, on persons performing work on Government Owned or controlled installations, individual background checks prior to the commencement of effort. As part of this process, information will be required to enable SAIC-Frederick, Inc. to conduct the appropriate background checks, including name (including any aliases), daytime phone number, SSN, date of birth, and country of birth. Individuals who are unable or unwilling to provide the required information and/or receive the required authorizations will not be allowed access to NCI-Frederick or any controlled premises.

Seller agrees to comply with the Information Technology (IT) systems security and /or privacy specifications set forth in the Agreement; the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems", and the DHHS Automated Information Systems Security Program (AISSP) Handbook, which may be found at the following websites: Computer Security Act of 1987: http://csrc.nist.gov/ispab/csa\_87.txt\_\_\_\_, OMB A-130 Appendix III: <a href="http://www.whitehouse.gov/omb/circulars/a130/a130appendix\_iii.html">http://www.whitehouse.gov/omb/circulars/a130/a130appendix\_iii.html</a>, DHHS AISSP Handbook : <a href="http://irm.cit.nih.gov/policy/aissp.html">http://www.whitehouse.gov/omb/circulars/a130/a130appendix\_iii.html</a>, DHHS AISSP Handbook : <a href="http://irm.cit.nih.gov/policy/aissp.html">http://irm.cit.nih.gov/policy/aissp.html</a>. The Seller further agrees to include this provision in any Order awarded pursuant to the Agreement. Failure to comply with these requirements may constitute cause for termination under Paragraph 26 of these Terms and Conditions.

The Seller shall be responsible for properly protecting all information used, gathered, or developed as a result of the Agreement. The Seller shall establish and implement appropriate administrative, technical, and physical safeguards to ensure the security and confidentiality of sensitive Government information, data and/or equipment. Any Seller employee who may have access to sensitive information under this agreement shall complete the form entitled, "Commitment to Protect Non-Public Information – Contractor Agreement," which may be found at the following website: <u>http://irm.cit.nih.gov/security/Nondisclosure.pdf</u>. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the

Contracting Officer prior to performing any work under the Agreement. The Seller shall assure that each employee has completed the NIH Computer Security Awareness Training (<u>http://irtsectraining.nih.gov</u>) prior to performing any work under this contract.

The Seller shall maintain and submit to the Contracting Officer a listing by name and title of each individual working under this contract, who has completed the NIH required training. Any additional security training completed by Seller staff shall be included on this listing.

In addition, during all activities and operations on Government premises, the Seller shall comply with DHHS, including National Institutes of Health (NIH), rules of conduct. Should the Seller have questions concerning these requirements or need of procedural guidance to ensure compliance they may contact the cognizant SAIC-Frederick, Inc. acquisition representative.

### I.2.bb. TOBACCO USE AT THE NCI-FREDERICK

In accordance with the Department of Health and Human Services (HHS) directive, the NCI-Frederick campus is a tobacco free workplace. Use of tobacco in any form is prohibited on the entire NCI-Frederick campus. This includes personal vehicles while on NCI-Frederick property and all government vehicles, regardless of their location.

This policy applies to all employees, Government and Contractor, visitors, subcontractors, vendors and guests of the NCI-Frederick, and extends to all HHS owned or leased facilities and properties external to the NCI-Frederick campus where the sole tenant(s) are HHS and/or SAIC-Frederick employees.

### I.2.cc. PAYMENT AND INVOICING

Payment – Work accepted by Buyer shall be paid for in U.S. dollars (\$USD) within the negotiated terms upon receipt of proper invoice.

### I.2.dd. STANDARDS OF BUSINESS ETHICS

Seller, including all lower tiers are expected and required to comply fully with Buyer's standards of business ethics and conduct and to inform appropriate Buyer officials immediately of any illegal or unethical conduct in their dealings with Buyer's officers or employees. Copies of the Buyer's Code of Ethics and contacts for such reports are available on <u>www.saic.com</u> under Corporate Governance.

(End of Section I)

# PART III—LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

# SECTION J-LIST OF SUBCONTRACT ATTACHMENTS

The following are subcontract attachment(s) and will be made part of the subcontract upon award:

Attachment No.	Document Description	No. of Pages
1	Subcontractor's Price Proposal	TBD
2	Invoice instructions for Time & Materials Contracts	4

(End of Section J)

# PART IV—REPRESENTATIONS, INSTRUCTIONS AND EVALUATION FACTORS

At time of award, this Part (including RFP Attachments) shall be physically removed from the award document and incorporated by reference. Submission of a signed offer constitutes an understanding and unqualified acceptance of all terms, conditions, obligations and statements made herein (or by reference) or as attached hereto.

# SECTION K—REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The Representations and Certifications are provided as RFP Attachment 5. All relevant pages must be completed and submitted with the contractor's proposal.

(End of Section K)

# SECTION L— INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

# L.1. GENERAL INFORMATION

Original, signed proposals are due to the Point of Contact listed in Section G.1.C. not later than 2:00PM (EST) January 9, 2007. Electronic versions, to include facsimile, are not acceptable. *Late proposals will not be considered for award*.

Offerors shall provide an original of both technical and price proposals (marked as such) as well as 8 copies of each.

# L.2. QUESTIONS

Anticipated questions to the RFP have been included as RFP Attachment 6. Any additional questions regarding this RFP must be provided, in writing (via email), to the Point of Contact as specified in Section L.4 not later than 2:00PM (EST) November 17, 2006. Questions should be provided in one concise submission with references to the relevant section(s) of the RFP. The questions submitted will be collected and responded to as needed and will be posted for public viewing and may be incorporated as an Amendment to this RFP.

If deemed necessary or desired by the Contracting Officer, a second round of questions may be solicited.

### L.3. INSTRUCTIONS TO OFFEROR

Although discussions after receipt of offers may be conducted, SAIC-Frederick reserves the right to make an award without discussions. Given this, proposals should be complete and represent an organization's best and final offer. To be considered responsive to this request for proposal the offeror must provide/complete the following:

### L.3.a. Completion of blocks 13-20 on page 1 of this RFP

L.3.b. Completion of Section G.2. "Subcontractor Representatives" and Section G.3. "Key Personnel"

### L.3.c. Provision of a complete Technical Proposal

The offeror must provide proposals that clearly demonstrate their organization's current capabilities to meet each of the various requirements as established in Sections C.1. and C.2. Responses should be focused, succinct and free of extraneous data or information responding solely to the requirements contained in this RFP. Additionally, proposals should be formatted in such a way to clearly cross-reference the section of the RFP the proposal is making reference. *Technical proposals shall not indicate cost or price.* 

- L.3.c.i. The Table of Contents for the technical proposal is provided in Solicitation Attachment 1.
- **L.3.c.ii.** The specific information to be included in each section has been outlined (including page limitations and Appendices) in RFP Attachment 2.
- **L.3.c.iii.** Standard Cancer Center Information Summaries ensure consistency and thoroughness of evaluations of competing proposals. Templates are provided as RFP Attachment 3.

#### L.3.d. Provision of a complete price proposal

A resultant subcontract will be issued as a time and materials subcontract as described in Section B.3. As such, all prices for labor shall be proposed on an hourly basis and be inclusive of all cost elements (e.g., base labor rate, overhead, fringe). Additionally, price proposals shall include an estimated number of hours required by each labor category to advance the elements listed below. Any materials required should be clearly delineated with estimated costs and a rational provided for each category.

A price proposal should be submitted for each of the three years of the period of performance. In lieu of individual proposals for each of the years, offerors may elect to provide a price proposal for year one with a statement indicating a percentage of escalation to be applied equally to each element of the price proposal for subsequent years. Any assumptions used to develop the price proposal should be clearly indicated.

The approximate allocation of funding shall be as follows:

•	Healthcare disparities	40%
•	Information Technology	20%
•	Biospecimen Initiative	20%
•	Clinical Trials	20%

### Price proposals shall be formatted as prescribed in RFP Attachment 4.

**L.3.e.** Completion of Section K—Representation and Certifications provided as RFP Attachment 5.

### L.4. RFP POINT OF CONTACT

The Point of Contact for this solicitation is identified below.

Name:	Shannon Jackson
Address:	SAIC-Frederick, Inc.
	92 Thomas Johnson Dr. Suite 250
	Frederick, Maryland 21702
Email:	sjackson@mail.ncifcrf.gov

# L.5. RFP ATTACHMENTS

RFP Attachment No.	Document Description	No. of Pages
1	Table of Contents for Technical Proposals	1
2	Technical Proposal Information Requirements	6
3	Standard Cancer Center Information Summaries	5
4	Price Proposal Format	3
5	Representations and Certifications	15
6	Questions and Answers	5

The following are attached to this RFP and will be removed from the RFP before award:

(End of Section L)

# SECTION M — EVALUATION FACTORS FOR AWARD

### M.1. BASIS FOR AWARD

SAIC-Frederick will award approximately six subcontracts resulting from this RFP to the responsible organizations whose offers conforming to the RFP will be the most advantageous to the SAIC-Frederick, price and other factors considered. Although technical factors are of paramount consideration in the award of this subcontract, cost/price is also important to the overall subcontract award decision.

# **M.2. POTENTIAL AWARD WITHOUT DISCUSSIONS**

SAIC-Frederick reserves the right to award a subcontract without discussions if the Contracting Officer determines that the initial offers are fair and reasonable and that discussions are not necessary. Therefore, the offeror's initial offer should contain the offeror's best terms from a price and technical standpoint. However, SAIC-Frederick reserves the right to conduct discussions if later determined by the Contracting Officer to be necessary. SAIC-Frederick may reject any or all offers if such action is in the public interest; accept other than the lowest priced offer; and waive informalities and minor irregularities in offers received.

The assessment of the offers received in response to this RFP will be carefully considered against the needs of SAIC-Frederick and the NCI. This assessment is not intended to be a solely mechanical or mathematical analysis of an offer, but rather the product of both objective and subjective measurements and judgments of the source selection officials after consideration of the relevant information.

### **M.3. EVALUATION FACTORS**

The following evaluation factors shall be used to evaluate the prospective subcontractors:

- 1. Baseline Requirements
- 2. Additional Capabilities/Expertise
- 3. Key Personnel
- 4. Price/Supplemental Funding

Of the four evaluation factors listed above, factor four, Price, is considered to be a non-technical factor. The remaining three factors are considered to be technical evaluation factors.

Of the three technical evaluation factors listed above, factor one, Baseline Requirements, is considered to be more important than factors two and three, Additional Capabilities/Expertise and Key Personnel.

### M.3.a Evaluation Factor 1—Baseline Requirements

The following requirements, as further detailed in Section C, will be evaluated before other requirements and are considered baseline (minimal). Qualifications over and above the baseline will be taken into consideration along with supplemental expertise. Offerors should clearly demonstrate that their organizations' current ability meet or exceed these requirements in order to be considered further.

BASELINE REQUIREMENTS	REVIEW CRITERIA	
Hospital Cancer Center Program Components	The offeror demonstrates sufficient facility resources, medical expertise and leadership, cancer patient population and supporting programs, and specified accreditations, with the majority of program components located in a distinct physical setting.	
Clinical Trials	The offeror demonstrates experience with clinical trials and can support the expansion of clinical research efforts.	
Healthcare Disparities and Community Outreach	The offeror demonstrates that it is dedicated to address the unmet healthcare needs of its community.	
Information Technology	The offeror demonstrates that it has dedicated IT support to the cancer program, and is capable of addressing complex issues (e.g., interoperability, standards) inherent in collaborating with multiple pilot sites.	
Biospecimen Initiatives	The offeror demonstrates it has sufficient and laboratory/pathology expertise and services to actively participate in the pilot activities.	
NCI Funding <\$3M	The offeror has received less than \$3 million in NCI funding per year for the past three years.	
Supplemental Funding	The offeror demonstrates that it is willing and able to invest in the pilot activities to enhance its cancer program and ensure the successful fulfillment of the pilot components.	

### M.3.b. Evaluation Factor 2—Additional Capabilities/Expertise

The following capabilities, as further detailed in Section C, will be evaluated on the basis of best value. We anticipate that the successful pilot group will represent a range of capabilities within each of the areas outlined in Section C. Organizations should clearly demonstrate their key individuals' experience or capabilities related to the areas listed. Organizations should describe their current status, as well as plans underway to expand in any of these areas.

ADDITIONAL CAPABILITIES/EXPERTISE	REVIEW CRITERIA
Linkages with NCI-Designated Cancer Centers or Academic Medical Research Institutions	The offeror demonstrates existing relationships that effectively support clinical research and patient care, and that are directly related to the pilot mission.
New Community-based Models to Address Health Disparities	The offeror exceeds the baseline requirements, and demonstrates that it participates or leads a community-based infrastructure to support the needs of the uninsured, underrepresented and disadvantaged.
State-Funded Cancer Initiatives	The offeror demonstrates that it is active in supporting and developing state- funded/sponsored cancer programs.
Special Locations with High Incidence of Cancer/Lack of Services	The offeror provides statistics to support a high incidence of cancer or lack of services.
Health Information Technology Initiatives	The offeror exceeds the baseline requirements, and demonstrates that it has invested in additional initiatives.
Survivorship Plans	The offeror demonstrates that it has integrated survivorship plans into its cancer program.
Experience with Payer-Sponsored Clinical Initiatives	The offeror demonstrates that it has clinical and data collection expertise for successful participation in payer-sponsored clinical initiatives.

ADDITIONAL CAPABILITIES/EXPERTISE	REVIEW CRITERIA	
National or Industry Expertise	The offeror employs key individuals with unique expertise available to support the pilot mission.	
Experience with Clinical Care Networks	The offeror demonstrates such experience and relates it to the pilot mission.	
Multidisciplinary Cancer Care	The offeror demonstrates its success with the implementation of a multi- disciplinary model of cancer care that may be replicated at other centers.	
Successful Approaches for Accrual of Patients to NCI Clinical Trials	The offeror demonstrates its success with accrual to NCI trials, especially of underrepresented and disadvantaged patients.	
National Health System Models in Multiple Markets	The offeror exceeds the baseline requirements and demonstrates success in knowledge transfer, replication of clinical program development and quality of care "best practices," and healthcare programs targeted to the uninsured, underrepresented and disadvantaged.	

# M.3.c. Evaluation Factor 3— Key Personnel

The oversight of this project should be accomplished by creating a NCCCP Pilot Project Team to include medical, technical, and administrative support. The offeror has identified dedicated key personnel to include strong clinical, scientific and administrative leadership, as well as documented experience and expertise in the design, execution and management of cancer programs, and the conduct and management of clinical trials.

### M.3.d. Evaluation Factor 4—Price

As part of the best value assessment of offers, price will be considered and a determination of the fairness and reasonableness of the prices proposed must be reached.

(End of Section M)

(End of RFP)