Broad Agency Announcement

N01-CO-47010-16

Novel Technologies for Noninvasive Detection, Diagnosis and Treatment of Cancer

Issue Date:	***October 21, 2003***
Due Date:	***January 21, 2004***
Issuing Office:	Treatment, Biology, and Sciences Section
Contracting Officer:	Richard L. Hartmann rh75f@nih.gov 301.496.8620
Contact Point/Contract Specialist	Annmarie Keane ak155a@nih.gov 301.496.8620
Set-Aside:	No

It is requested that you send an electronic mail message to the Contract Specialist if you intend to respond to this BAA. In your message please indicate the name of the organization and the name of the Principal Investigator, plus a short description of the scientific fields encompassed by the response.

TABLE OF CONTENTS

Additional Documents and Forms in this BAA:

INTRODUCTION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA) (N01-CO-47010) entitled "Novel Technologies for Noninvasive Detection, Diagnosis and Treatment of Cancer." The Broad Agency Announcement is authorized by Federal Acquisition Regulation (FAR) 6.102. BAAs are used by agencies to fulfill their requirements for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. Proposals received as a result of the BAA will be evaluated in accordance with evaluation criteria specified herein through a peer review process. Proposals will not be evaluated against a specific Government need, as in the case of a conventional Request for Proposal (RFP), as they are not submitted in accordance with a common work statement.

In order to be considered for an award, the proposal must, at a minimum, present a detailed technical and cost proposal designed to meet the Technical Objectives described in this announcement. The proposal must be signed by an official authorized to contractually commit the submitting organization. ***It is expected that proposals will be submitted both by investigators new to the Unconventional Innovations Program (UIP), and by existing UIP contractors applying for renewal of existing projects.***

It is anticipated that multiple awards will result from this announcement. It is expected that these awards will be multi-year, cost-reimbursement, completion type contracts. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The maximum period acceptable for a research proposal is three (3) years. Awards are expected to be made on or about September 30, 2004. Negotiations are projected to commence approximately June 1, 2004. The NCI anticipates awarding 8 - 12 contracts based on technical merit, available funds, and programmatic balance. Program staff estimates the average total annual cost (direct and indirect costs) for these contracts to be $500,000 per contract. However, it is anticipated that the total costs for each award ***may vary substantially*** depending upon the scope and capacity of the technical objectives of the award.

Award documents will be tailored to the final negotiations with the selected offeror(s) and modified, as necessary, for the type of contractor organization, cost and/or fee arrangements, and other elements as negotiated prior to award.

Table of Contents

BACKGROUND AND TECHNICAL OBJECTIVES

This section presents the background and technical objectives the Government hopes to achieve under this BAA. Proposals submitted should be designed to achieve these objectives. NOTE: In contracts awarded as a result of this BAA, the Statement of Work

will be the Statement of Work proposed by the offeror and negotiated and accepted by the Government. **In preparing proposals, offerors are strongly encouraged to review the Proposal Instructions and Information and the Evaluation Factors for Award included in this BAA.**

OVERVIEW

Advances in the understanding of the genetic basis of cancer and related changes in the cell and local micro-environment have created the opportunity to define signatures that distinguish precancerous, cancerous, and malignant disease from one another, as well as the various diseases defined as cancer. Ongoing programs at the National Cancer Institute (NCI) to define the molecular signatures of cancer will also lead to the identification of new targets for therapeutics and prevention agents. The development of platform technologies that integrate non-intrusive sensing with intervention (treatment, prevention) in the individual based on defined signatures would revolutionize detection, diagnosis and treatment of cancer.

The Unconventional Innovations Program (UIP) is specifically soliciting projects to develop in vivo technology systems or systems components that will enable the sensing of defined signatures of different cancerous and precancerous cell types and/or their associated micro-environment in the living body in a way that is highly sensitive and specific, yet non-intrusive. **The highest priority is for systems that can either support or provide an integrated approach to sensing/detection, contrast enhancement, intervention (treatment), and monitoring in the living body.**

BACKGROUND

It has become clear that cancer is a set of diseases that result from changes in the genome and the expressed products of the genome. These changes result in alterations in the structure, physiology, and genetic/chromosomal stability of the affected cells, and they also stimulate changes in the local micro-environment. The path of scientific opportunity resulting from this fundamental observation can have a profound impact on the management and prevention of cancer. The NCI is putting in place programs that will both expand upon the fundamental observation of the genetic basis of cancer and transform the approaches to the prevention, detection, diagnosis, and treatment of cancer.

The Definition of Signatures

The first step in the path of scientific opportunity will come with the development of a new scheme for distinguishing between various cancers as well as between normal and precancerous, cancerous, and malignant cells of any particular cancer. Given the fundamental molecular basis of cancer, the NCI has targeted the definition of the molecular signatures of cancer as one of the extraordinary opportunities in cancer research. Definition of the molecular signatures of cancers will require both the knowledge of the complete set of genes in the genome as well as technologies to support comprehensive molecular analysis of the genes and gene products. To this end, the NCI

has launched several initiatives focused on the definition of signatures including the Cancer Genome Anatomy Project (CGAP), the Innovative Molecular Analysis Technologies (IMAT) Program (http://otir.cancer.gov/tech/imat.html), and the Early Detection Research Network (http://edrn.nci.nih.gov)

The Need for Early Detection

Currently, the diagnosis of cancer is usually subsequent to the detection of a palpable tumor mass or a significant mass resolvable by anatomical imaging. The detection and diagnosis of the tumor is frequently many years after the earliest stages of cancer development. Although we know that early detection improves the outlook for success in patient treatment, we are extremely limited in our capabilities to identify the earliest stages of cancer as they emerge. Diagnosis is most frequently accomplished through physical removal of a portion of a suspect mass from the patient followed by pathological characterization. To derive the greatest benefit from the new molecular classification scheme, technologies must be developed to support the identification of the molecular signatures of cancer cells and related features of emerging cancers and to exploit those signatures/features by the development of new therapies. The ultimate goal is to develop a new generation of treatments that are precisely targeted to the cancer cells and that can be used instead of or in conjunction with surgical intervention and certainly instead of the harsh chemotherapeutic regimes currently employed. Knowledge of the molecular signatures and related features that are associated with the specific stages of progression from normal to precancerous, malignant, and metastatic for various cancers should allow the identification of the earliest set of changes in each cancer that correlates with a poor prognosis and the need for intervention.

Targets of Prevention and Treatment

Ongoing programs at the NCI to identify the molecular profiles of cancers and their various stages will lead to the identification of new targets for therapeutics and prevention agents. Information on NCI's ongoing and emerging initiatives for "Molecular Target Drug Discovery for Cancer" can be found at ***(http://cancer.gov/initiatives/grp-target.html)*** . The opportunity exists to base the discovery and development of new therapeutic/intervention agents or combinations of agents on the interference with specific molecular targets in premalignant and malignant cells and in the tissues surrounding the malignancy that sustain its growth and spread. New agents or combinations of agents will be developed that are both specific for cancers bearing particular molecular signatures and less general toxic for other body tissues. Clearly, the greatest benefit would be gained from intervention delivery vehicles that would target the agents to cells bearing cancer signatures or to the microenvironment of such cells. Development of technology platforms that support the non-intrusive detection of cancer signatures in the patient and serve either as the intervention delivery vehicle or as the homing beacon for the intervention delivery vehicle would make this possible.

Table of Contents

TECHNICAL OBJECTIVES

Program Objective. The UIP is seeking proposals that represent the highest potential for revolutionary breakthroughs in the development of in vivo technologies to enable the non-intrusive sensing of cancer signatures in the living body integrated with capabilities for monitored intervention. An in vivo system approach including detection, imaging contrast enhancement, treatment and post treatment monitoring is desired. **For the purposes of this solicitation non-intrusive is intended to mean that the system will be minimally disruptive to the living system, causing minimal or no discomfort, pain, or loss of function to the living host. This includes systems that might be introduced by such minimally disruptive means as, but not limited to, ingestion, inhalation, single or limited numbers of injections, or implantation. It is intended to exclude support for the development of analysis tools that require biopsies and phlebotomy for acquisition of specimens.**

The NCI is issuing this BAA as a demonstration of its commitment to the exploration of high risk approaches. Selected projects will be based on sound scientific, medical, and engineering principles, but priority will be given to entirely novel approaches or approaches likely to yield significant improvements in the current art. Projects are expected to project innovation beyond the range of research traditionally supported through the NIH investigator-initiated research support process and existing NCI programs. Proposals must contain a section that addresses both the level of innovation and technical risk associated with the project, and ongoing research by the applicant or in the community related to the proposed approach. An overview of UIP can be found at http://otir.nci.nih.gov/tech/uip.html and abstracts for all contracts awarded under UIP can be found at http://otir.cancer.gov/tech/uip_awards.html.

Solicitation Objective. In this BAA, the UIP is specifically soliciting projects to develop technology systems or systems components that will enable in vivo sensing of defined signatures of different cancerous or precancerous cell types or their associated microenvironment in the body in a way that is highly sensitive and specific, yet non-intrusive. In addition to in vivo sensing, the ideal system will provide imaging contrast enhancement, perform targeted drug delivery, and monitor the outcome of the intervention. **The highest priority is for in vivo systems that can integrate sensing/detection, imaging contrast enhancement, and intervention.** In vivo technologies of interest include those that allow for the:

- Nonintrusive detection of small foci of cells with signatures indicative of the early development of cancer integrated with interventions that would eliminate or limit the expansion of cells possessing such signatures prior to the development of a significant tumor burden.
- Nonintrusive early detection of cancer cells integrated with interventions that would both eliminate or limit the expansion of cells possessing signatures associated with any of the various stages of cancer development thereby eliminating or limiting the development of a significant tumor burden.

- Nonintrusive detection of residual tumor cells, recurring tumors, or metastatic cells at distant sites following the removal/treatment of an existing tumor coupled to interventions that would target and eliminate residual, recurring, or metastatic cells identified on the basis of their signatures prior to the development of a secondary tumor burden.

Cancer Signatures of Interest. Technologies proposed for development may target either the specific profiles of cell-associated molecular alterations that are being defined through other ongoing NCI programs (see above) or alternative compelling signatures of cancer. NCI has already committed to programs to define the molecular signatures of cancers and, therefore, will require non-intrusive approaches to sensing such profiles in the body. Cell-associated profiles defined through existing NCI programs will likely consist of the presence of specific protein molecules, protein functions, specific levels or forms of protein or RNA molecules, or specific alterations in the genomic DNA, but may ultimately also include other targets (e.g., glycoproteins, glycolipids, etc). Informative profiles will likely consist of multiple components (i.e., multiple proteins or expression profiles for multiple genes) rather than the presence or absence of an individual molecule.

Signatures based on alternative parameters (i.e., structure, physiology, ploidy, microenvironment) may also provide great value in early de novo detection of cancer or early detection of recurrence or metastases. Therefore, non-intrusive approaches to sensing alternative unique signatures of precancerous or cancerous cells may also be proposed. For systems that recognize signatures other than molecular signatures, the nature of the signature(s) should be clearly understood and the signature parameters well defined and quantifiable. Compelling background data should be presented to substantiate that the signature parameters targeted for detection will be reliably predictive of specific cancer stages and types, including the earliest stages of cancer and/or precancers. The reliably predictive nature of signatures comprised of other than molecular parameters will be assessed based on the content of the proposal, and any supporting data or references should be included in this section.

Targeted Systems Requirements. A critical feature of the ultimate technologies targeted in this program is multi-functionality. **The program is targeting the development of in vivo technologies that integrate the following capabilities:**

- highly specific recognition capabilities for the components of the signature (detection)
- recognition-dependent direct signal generation or generation of an indirect signal through chemical or physical means
- signal amplification (e.g., imaging contrast enhancement, etc.), as needed
- signal capture and interpretation tools (e.g., mathematical approaches to feature definition and extraction) for the investigator or clinician
- intervention (treatment, prevention) delivery to the site of signal detection
- monitoring the effectiveness of intervention

Individual projects may propose to develop the entire system or components of a system. If only a component is proposed, then there must be a discussion as to how the component would operate in a complete system, as defined above. Multidisciplinary teams are strongly encouraged. These multidisciplinary teams should bring together the physical, engineering, biomedical, biological, and computational science expertise needed to address the program objectives.

The proposed statement of work should outline a description of the final system, a technical research plan for the technology to be developed, and relevance of any components to be developed in the absence of the development of a complete system. Key to the program is the development of the capability for non-intrusive sensing of biomolecular or other signatures in living animals/patients. The highest priority will be given to in vivo technologies that can integrate the sensing of cancer signatures with controlled and monitored intervention (treatment, prevention), either directly on the same platform or through a complementary agent or device that targets intervention to the site of signal generation. High priority will also be given to systems components **if a vision is provided** as to the overall system to which the component could contribute, or the fundamental utility of the component for multiple potential technologies is clear. The following areas are specifically **EXCLUDED** from this solicitation but are suitable for support in other ongoing NCI programs:

- projects that target the definition of the molecular or other signatures of cancer
- correlative or validation studies to examine the value of particular signatures as diagnostic or early detection markers
- projects to develop in vitro molecular analysis technologies that will either support the discovery process defining the molecular signatures of cancer or require conventional ***biopsies or conventional phlebotomy*** specimens
- development of specific recognition reagents in the absence of the development of the sensing and signaling ***technology***
- development of particular intervention agents in the absence of the development of targeted, monitorable, delivery platform.

Innovation. The degree of innovation will be determined within one or more of the following contexts; 1. design and development a new in vivo system that integrates sensing/detection, imaging contrast enhancement, drug delivery, and monitoring of intervention, 2. scale up of Good Manufacturing Practices (GMP) quality production of an integrated in vivo system, 3. entry into pre-clinical or clinical trials of the in vivo system.

Table of Contents

PROPOSAL INSTRUCTIONS AND INFORMATION

The proposal must be signed by an individual authorized to bind the organization to a Government contract.

NAICS Code and Size Standard

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employees.

Proprietary Data

(1) Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of, or in connection with, the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets (on pages) [insert numbers or other identification of sheets/pages].

(2) Mark each sheet of data you wish to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal

Uniform Assumptions - Information for Preparing the Proposed Budget

(1) Programmatic Presentations and Meetings.

In performance of the work, offerors are expected to attend semi-annual programmatic meetings. In preparing the proposal, offerors should include costs for attendance at two programmatic meetings per year. For the purposes of estimating costs, offerors should assume one three-day meeting will be conducted at/near Washington, D.C. and one three-

day meeting will be conducted at/near San Francisco, with attendance by the Principal Investigator as well as the senior investigators on each component project. In addition, a request for support for attendance by a single investigator at two programmatically relevant scientific meetings to present results from this project may be included.

(2) Reporting Requirements.

In performance of the work, the following reporting requirements should be assumed:

a. Quarterly Reports

1. Face page to include contract number, title, period of performance being reported, Contractor's name and address, telephone and telefax numbers and date of submission.

2. An executive summary, to include:

    - A statement of intended work for the reporting period;
    - A brief overview of the work that was completed for the reporting period and/or justification for intended work that was not completed or unintended work performed;
    - A brief overview of the activities that occurred during the current reporting period and any problems (technical or financial) that occurred during the current reporting period;
    - The advancements made in relation to any of the specific aims or milestones set forth in the Statement of Work;
    - A brief discussion of the relevance and impact any advances may have on cancer research, including near-term technology spin-offs; and,
    - A brief overview of competing research from other laboratories including important presentations of data, abstracts and publications; and the impact these data have or will have on the direction and progress of the contract.

3. A full description of:

    - The work performed during the reporting period;
    - The relationship between the accomplishments to the goals, objectives, and milestones of the Statement of Work; and
    - A full discussion of the results and their relevance; explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned.

4. A full description of data pertaining to:

    - The work performed during the reporting period;
    - The materials and methods pertaining to the work; and

- The relationship of the accomplishments to the goals, objectives, and milestones of the Statement of Work Problems encountered and their resolution.

5. Conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. Indicate if any of the results or conclusion have been publicly disclosed.

6. A summary of activities planned for the next reporting period.

7. Copies of manuscripts (published or unpublished) derived from research under the contract and copies of all abstracts, manuscripts, preprints and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period.

8. Full disclosure of intent to file patent applications in the U.S. or outside of the U.S. on materials, reagents, animals modes or procedures derived or established by the work supported under this contract; full disclosure of patent applications filed in the US or outside of the US as well as copies of patent applications.

9. A full disclosure of any efforts to transfer the technology or receipt of support from outside entities interested in future access, partnering, or license to the developing technologies.

10. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months. A Quarterly Progress report is not required for periods in which an annual or final report is due.

b. Annual Reports

This report shall document and summarize all work results for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. The initial report will be submitted for the first full twelve months of the contract performance including any fractional part of the initial month. Annual reports thereafter shall be submitted at 12 month intervals. An annual report shall not be required for the period when the final report is due.

c. Final Report

This report shall consist of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The final report shall be submitted on or before the last day of the contract performance period. An annual report shall not be required for the period when a final report is due.

Salary Limitations

Pursuant to Public Law, no NIH extramural funds may be used to pay the direct salary of an individual through this contract at a rate in excess the salary rate ceiling established in DHHS appropriation acts. This rate can be found at http://www1.od.nih.gov/oma/manualchapters/contracts/6030-1/.

Proposals must be in Two Parts

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions. **No formal page limit exists, but proposals should attempt to be direct and concise in presenting information which clearly describes the proposed project. Offerors should realize that the clarity of the presentation is important in communicating their project ideas to reviewers, and that a concise and well formulated proposal is usually more effective in that respect than a voluminous proposal that lacks effective distillation of ideas.**

Proposal Format

Your proposal should be organized according to the following outline.

Technical Proposal (Separate Volume)

This volume provides the detailed discussion of the proposed work necessary to enable an in-depth review of the specific technical and managerial issues. Specific attention must be given to addressing both risk and payoff of the proposed work and relevance to the specific technical objectives of the UIP as outlined in the BACKGROUND AND TECHNICAL OBJECTIVES section, above.

Title Page

The Technical Proposal Title Page is a form included as an attachment to this RFP. The form is specifically created to capture data that is needed by the NCI to monitor proposals and award contracts and grants. Also the form has specific field lengths for the requested data. A copy of the form showing the field lengths is included with this BAA.

Table of Contents Page

Provide a Table of Contents for the Technical proposal. Include as the beginning of the Table of Contents, a list of keywords associated with your concept.

Section One - Proposed Statement of Work ***(recommended limit – 3 pages)***

This section should outline the scope of work, specific technical tasks to be undertaken, specific decision points, and any deliverables to be provided during the reporting requirements specified in this BAA. The scope of work, the decision points, and the deliverables presented here must correspond to the details for these items provided in later sections of the proposal, notably the Technical Approach. A timeline should be presented with the statement of work. The timeline should include quantitative milestones, including the start and stop points for various technical aspects of the plan, timeline for completion of milestones and time line of essential decision points, especially "go/no go" decisions. This information should be presented in text as well as in chart format. The various tasks for individual projects should be integrated according to year. To the extent possible milestones should be quantitative in order to provide metrics against which the success of completion of the milestone can be evaluated. The offerors should also provide a clear statement of the anticipated product at the end of the contract period. This section should be clearly marked as a separate part of the proposal because it shall form the basis of the Statement of Work for a contract, if awarded. One separate IBM-compatible diskette containing this Statement of Work should be submitted with the original proposal. The Statement of Work may be submitted in any of the following formats: DOS/ASCII text file, WordPerfect document, Microsoft Word document or Adobe Acrobat file.

Section Two - Innovative Claims ***(recommended limit – 2 pages)***

This section should succinctly describe the innovation, novelty, and benefits of the proposed approach relative to the current state-of-art and alternate approaches. Note: In order for the approach to be considered innovative, the approach must be described within the context of the goals of the UIP and must comply with the requirements for a technology system as described in Targeted Systems Requirements, above.

Section Three – Potential Contribution to the UIP ***(recommended limit – 3 pages)***

This section should address the potential for contribution to the technological objectives of the UIP as outlined in the BACKGROUND AND TECHNICAL OBJECTIVES section. The following should be specifically addressed:

a. The ultimate anticipated utility of the technology in meeting the Solicitation Objectives listed in the TECHNICAL OBJECTIVES section.
b. The potential for contribution to resolving the anticipated Targeted Systems Requirements listed in the TECHNICAL OBJECTIVES section.

c. The potential to revolutionize the state-of-the-art in cancer detection, diagnosis and treatment and the feasibility of the overall approach with regard to implementation for cancer research and care objectives. The offeror should specifically address the potential for contribution to an ultimate platform for non-intrusive sensing in the body of signatures identified as associated with cancer or the genesis/progression of cancer, as well as the potential ***to integrate*** with capabilities for controlled and monitorable interventions appropriate for cancers as listed in Targeted Systems Requirements. Proposals targeting sensing of molecular profiles of cells should address the types of molecular species (i.e., protein, DNA, RNA) the technology will be able to sense, capabilities for sensing intracellular versus membrane bound cellular components, ongoing efforts to develop the profiles, and the predictive nature of the profile. Proposals that are based signatures on other than molecular should discuss the nature of the signatures, justify the choice of the signature parameters, and present compelling data that the signature parameters targeted for detection will be reliably predictive of specific cancer stages and types, including cancers at the earliest stages of growth or metastasis and/or precancers. The reliably predictive nature of signatures comprised of other parameters will be assessed based on the content of the proposal, and any supporting data or references should be included in this section.

The relevance of the proposal to this solicitation and program will be judged on the basis of the justification provided in the proposal. Note: Contribution and relevance to the NCI Novel Technologies for Noninvasive Detection, Diagnosis and Treatment of Cancer program receives the highest weighting in the evaluation criteria. The proposal can not receive a high score on the Technical Approach if it is deemed to have low contribution and relevance to the program.

Section Four - Detailed Technical Plan ***(recommended limit – 25 pages)***

This section should include a description of the specific technical steps to be taken, rationale, technical challenges likely to be encountered, alternative approaches that might be considered, and justification of approach. Given the level of innovation sought in the UIP, it is anticipated that proposals will carry substantial technical risk. Proposals should outline a technical plan with clearly defined quantitative milestones of progress and key decision points. Areas of highest technical risk should be identified and discussed, as well as potential alternative approaches. Specific milestones should be measures of the success in overcoming the technical risk in the areas identified. The technical plan should correspond to the milestones presented in the Statement of Work. In addition, identified technical risks and critical decision points should have corresponding milestones in the Statement of Work. This section should address the plans for identifying collaborators or partners to provide any additional expertise/components required for the complete envisioned system. This section should also discuss and reference competing approaches and ongoing or previous research by the applicant or in the community related to the approach. The potential superiority of the proposed approach and/or product should be clearly stated.

Section Five - Offeror's Qualifications ***(recommended limit – 2 pages)***

This section should present a discussion of offeror's qualifications for leading the research effort proposed, including record of innovation.

Section Six - Project Team and Management Plan ***(recommended limit – 5 pages, excluding CV's and letters of commitment)***

It is anticipated that the complexity of the overall systems targeted as the final products of the UIP will require that expertise from a variety of disciplines be engaged in the development process. Proposals should address the breadth of expertise required for completion of the project, capabilities of the team, and plans for recruiting additional expertise. Multidisciplinary teams are strongly encouraged. ***. These multidisciplinary teams should bring together the necessary physical, engineering, biomedical, biological, and computational science expertise needed to address the program objectives.*** The proposed management structure for the team and choice of project team leader(s) should be discussed. This section should include a discussion of the composition of the project team with regard to breadth of required expertise. This section should also address the programmatic relationship of team members; the scientific and technical expertise of team members as it relates to the proposed project; the task responsibilities of team members; the teaming strategy among the team members; and the key personnel along with the amount of effort to be expended by each person during each year. Any agreements that enable the collaboration of participating individuals or institutions should be detailed in this section. Letters of commitment should be provided for such agreements. The proposal should include an organizational chart detailing the roles and responsibilities of the individuals proposed under the project. Include in this section of the proposal a detailed listing of the time commitments of the Principal Investigator(s), Co-Investigator(s) and other Key Personnel. The Summary of Related Activities form is available for providing this information.

Section Seven - Facilities

This section should include a detailed description and documented availability of the facilities and equipment that would be used for the proposed effort. Submission of a floor plan detailing the workspace to be utilized under the contract is encouraged.

Section Eight - Technology Maturation ***(recommended limit – 2 pages)***

This section should address the plans and procedures for disseminating the resulting technology, including any plans for engaging commercial partners and support. Successful projects will have considered the future opportunities for disseminating the resulting technology. Offerors should discuss previous experiences with transitioning technology to fellow researchers, existing companies, or the formation of start-up companies. Offerors should provide plans for the recruitment of external support or commercial interest in the technology to be developed. For technologies very early in the research phase, a discussion of routes for future technology dissemination (e.g., potential

markets) should be included. This section should also include a discussion of near-term opportunities to transition technologies to independent development programs during the project period. Offerors should consider the potential for discoveries that could lead to spin-offs for near term technology applications en route to the long term technological goal. It is recommended that the offeror's technology management plan also include description of provisions for expanded access and development in the absence of external support or commercial interest. Detailed plans for the future will receive a higher rating than generalities.

Section Nine - Bibliography and Additional Supporting Documentation

The proposal may contain a brief bibliography of relevant technical papers and research notes (published and unpublished) that documents the technical ideas upon which the proposal is based. Proposals may include copies of not more than three (3) relevant papers.

Curriculum vitae for proposed personnel may be included in this section.

Section Ten - Resources Proposed

Provide in this section a detailed description of the proposed effort (labor-hours and categories) and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the your understanding of the project may be evaluated by the technical reviewers. It is requested that the Technical Proposal Cost Information/Summary of Labor and Direct Costs form be used as the format for presenting this information. Provide in this section a detailed TECHNICAL justification for the proposed resources. Provide in this section letters of commitment from proposed consultants.

Section Eleven - Animal Assurances/Human Subjects Assurance

a. If animals are proposed, include, in this section, a detailed plan for maintaining the animals under the contract in accordance to the requirements of NIH, PHS and AALAC. Provide the date of the last AALAC review and your Animal Assurance number. Address the 5 points dealing with vertebrate animal welfare as specified on pages 28-29 of the May 2001 electronic version of the PHS 398 application kit (http://grants.nih.gov/grants/funding/phs398/phs398.pdf).

- The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that an organization, whether domestic or foreign, bears responsibility for the humane care and

use of animals in PHS-supported research activities. This policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office for Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163.

- The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."
- No PHS award for research involving vertebrate animals will be made to an organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides certification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy.

b. If the proposal includes research involving Human Subjects, address the following in the proposal:

- Provide a copy of the DHHS Human Subjects Assurance Number if the proposed work involves Human Subjects.
- Address the timeline for approval by the Institutional Review Board of your organization.
- If human subjects are used, address the 4 points dealing with the use of human subjects in research, as well as the inclusion of women, minorities, and children, as specified on pages 18-28 of the May 2001 electronic version of the PHS 398 application kit (http://grants.nih.gov/grants/funding/phs398/phs398.pdf).
- Additional information is available from the Office for Human Research Protections (http://ohrp.osophs.dhhs.gov/index.htm).

Business Proposal (Separate Volume)

Face Page

The face page shall provide the following information:

The solicitation number;

The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

Names, titles, and telephone numbers, facsimile numbers, and electronic addresses, if available, of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office;

The total proposed cost; and

The submission date.

You are required to use the standardized face page developed for this solicitation. The face page is available as a pdf file suitable for viewing in adobe acrobat, and a Microsoft Word document for editing.

Section One - Budget Proposal

The business proposal must contain sufficient information to allow the Government to perform an analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit. The format should be in the Microsoft Excel Workbook provided with this BAA. The Excel spreadsheet may require amending to meet the specific requirements of your proposal. In addition to submission of the budget proposal in this section, you are requested to submit, with the ORIGINAL PROPOSAL ONLY, an IBM Compatible diskette containing the budget.

- The format must be used to submit the breakdown of all proposed estimated cost elements. List each cost element and sub-element for direct costs and indirect

costs, plus fee, if applicable. In addition, provide detailed calculations for all items. For example:

- For all personnel, list the name, title, rate per hour and number of hours proposed. If a pool of personnel is proposed, list the composition of the pool and how the cost proposed was calculated. List the factor used for prorating Year One and the escalation rate applied between years. Your proposal should be stated in the same terms as will be used to account for and record direct labor under a contract (i.e. percentage of effort is used for most faculty and professional employees at educational institutions). If percentages of effort are used, the basis to which such percentages are applied must also be submitted by the offeror.
- For all materials, supplies, and other direct costs, list all unit prices, etc., to detail how the calculations were made.
- For all indirect costs, list the rates applied and the base the rate is applied to.
- For all travel, list the individual trips.
- For each subcontract proposed, submit a separate Microsoft Excel Workbook, in the same format as described above

In preparing your budget proposal, the following should be considered:

1. The NCI views the funding of these contracts as high risk-high potential, similar to venture capital investments in the private sector with the contractor potentially receiving a substantial financial benefit for successful projects. Accordingly, the NCI does not consider the inclusion of Fee or Profit appropriate for these contracts.

2. If your proposal includes cost sharing, describe the cost sharing, the method of allocating funds, and the source of the shared funds.

3. The use of the provided Excel spreadsheet greatly facilitates the analysis and review of the proposed budget.

4. In performance of the work, offerors are expected to attend semi-annual programmatic meetings. In preparing the proposal, offerors should include costs for attendance at two programmatic meetings per year. For the purposes of estimating costs, offerors should assume one three-day meeting will be conducted at/near Washington, D.C. and one three-day meeting will be conducted at/near San Francisco, with attendance by the Principal Investigator as well as the senior investigators on each component project. In addition, a request for support for attendance by a single investigator at two programmatically relevant scientific meetings to present results from this project may be included.

Section Two - Budget Justification and Documentation

In this section, provide justifications and explanations of the proposed costs. This INCLUDES explanation of the processes by which extended costs were derived and a basis for why the proposed costs should be considered reasonable.

Submit, with the ORIGINAL PROPOSAL only, cost data supporting the costs proposed. This data includes:

- Verified salary documentation. Acceptable documentation includes any one of the following: 1) personnel action forms, or 2) most recent payroll register showing name, pay rate, and percent of effort if applicable, or 3) copy of pay stub. If the proposed positions have not been filled or are to be named or hired, then acceptable documentation includes the following: 1) letter of intent to hire including salary rate and title, or 2) position descriptions and salary scales or organizational wage table showing salary range and a copy of hiring policy, or 3) a comparable employee's payroll document.
- A detailed explanation of when employees receive salary increases and the methodology for determining the salary increase rate(s) and the salaries rates for proposed new employees.
- Vendor quotations, catalog prices, etc. that document the proposed material and supply costs.
- Supporting documentation of the reasonableness of proposed consulting costs, including documentation from the consultant that the proposed rate is the established consultant rate which the particular consultant normally bills for the work to be performed. Provide documentation which compares the rate proposed with rates for other consultants for similar work.
- DO NOT intermix subcontract and prime contract costs. Prepare each subcontract budget in a separate spreadsheet. The same cost documentation specified for the prime contract is needed for any subcontract. Subcontractors may submit the cost documentation directly to the Contracting Officer.
- Copies of negotiated indirect cost (IDC) rate agreements. If no current IDC rate agreement is in effect, specific documentation of the methodology for determining the proposed IDC costs. Include a description of the cost components of both base and pool costs. Additional guidance on indirect costs is available from the Division of Financial Services, Office of Contracts Management, NIH at http://ocm.od.nih.gov/dfas/idcsubmission.htm.

The information in this section must also be prepared and submitted for each proposed subcontractor.

Table of Contents

Section 3 - Additional Business Data

Total Compensation Plan

Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. Provide in this section a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

a) Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this

contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).

(2) The offeror's name and remittance address, as stated in the offer.

(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.

(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.

(5) The offeror's account number and the type of account (checking, savings, or lockbox).

(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

Facilities Capital Cost of Money

The following Clause is applicable if you are a commercial organization:

Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

Include in this section of the ORIGINAL PROPOSAL ONLY, a copy of the organization's most recent annual report.

Include in this section of the ORIGINAL PROPOSAL ONLY, a copy of the your (and any proposed subcontractor's) written travel policy. If you, or any proposed subcontractor, does not have a written travel policy, provide a statement to that effect.

Section 4 - Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, provide a subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation. A sample plan is included as an Attachment to this BAA.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged

individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this BAA.

Section Five - Representations and Certifications

Include in this section of the ORIGINAL PROPOSAL ONLY, the Representations and Certifications required by this particular acquisition. The Representations and Certifications can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer.

ADDITIONAL INFORMATION AND REQUIRED CLAUSES

LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND WITHDRAWALS OF PROPOSALS, PHS 352.215-10

Notwithstanding the procedures contained in the provision of this solicitation entitled Late Submissions, Modifications, and Withdrawals of Proposals, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government, and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in the Excel Spreadsheet provided as an attachment to this BAA shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Richard L. Hartmann
Contracting Officer
Research Contracts Branch
National Cancer Institute
EPS, Room 6064
6120 EXECUTIVE BLVD MSC 7193
BETHESDA MD 20892-7193

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

Table of Contents

PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified above in the PROPOSAL INSTRUCTIONS AND INFORMATION. Shipment and marking shall be as indicated below.

EXTERNAL PACKAGE MARKING

In addition to the address cited below, mark each package as follows:

"RFP NO. N01-CO-47010-16 Novel Technologies for Noninvasive Detection, Diagnosis and Treatment of Cancer

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

PLEASE NOTE - THE TECHNICAL PROPOSAL SHALL BE SENT IN SPLIT SHIPMENTS TO TWO LOCATIONS. PLEASE READ THE FOLLOWING INFORMATION CAREFULLY.

Submit the Original, 1 Electronic Copy, and 4 Full Color Copies, and 7 additional copies (either black and white or color) of the TECHNICAL AND BUSINESS PROPOSALS to:

If hand-delivered or delivery service

Annmarie L. Keane
Contract Specialist
Research Contracts and Acquisition Branch
National Cancer Institute
Executive Plaza South, Room 6056
6120 Executive Boulevard
Rockville, Maryland 20852

If using U.S. Postal Service

Annmarie L. Keane
Contract Specialist
Research Contracts and Acquisition Branch
National Cancer Institute
Executive Plaza South, Room 6056
6120 EXECUTIVE BLVD MSC 7220
BETHESDA MD 20892-7193

Submit 1 Electronic Copy, 5 Full Color Copies of the TECHNICAL PROPOSAL ONLY to:

If hand-delivered or delivery service

Michael Shatarsky
Special Review Referral and Resources Branch
National Cancer Institute
6116 Executive Boulevard, Room 8055
Rockville, Maryland 20852-7405

If using U.S. Postal Service

Michael Shatarsky
Special Review Referral and Resources Branch
National Cancer Institute
6116 EXECUTIVE BLVD MSC 7405, Rm 8055
BETHESDA MD 20892-7405

Table of Contents

EVALUATION FACTORS FOR AWARD

General

The Government will make awards to the responsible offeror(s) whose proposals provide the best value to the Government, cost and other factors considered, including the provisions of FAR 19.1103. For this solicitation, the technical proposal shall receive paramount consideration in the selection of the contractor(s). The evaluation will be based on the demonstrated capabilities of the prospective offerors in relation to the evaluation criteria as set forth herein. Each proposal must document the feasibility of successful implementation of the requirements of the BAA.

The estimated cost of an offer must be reasonable for the tasks to be performed, and, in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government.

All technical proposals will undergo evaluation by a peer review group also known as the Technical Evaluation Panel (TEP).

Final selection of awards will depend upon the availability of funds, scientific priority, and program balance which the NCI determines to exist at the time of award selection.

Offerors are reminded that the Technical Approach is evaluated within the context of "contribution and relevance to this program." For example, even though a proposal provides a clear, comprehensive technical plan for achieving a particular objective, if the plan is NOT within the context of the goals of this program, it will receive a low technical score regardless of the technical feasibility of the technical approach.

Technical Evaluation Criteria

The evaluation criteria are used by the Technical Evaluation Panel when reviewing the technical proposals. The criteria below are listed in relative importance with weights assigned for evaluation purposes.

Evaluation Factor		Weight
a.	Potential of the Proposed Concept for the Unconventional Innovations Program	40%
	• Level of innovation within the context of the goals of the Unconventional Innovations Program. • Potential for achieving the technical objectives as outlined in BACKGROUND AND TECHNICAL OBJECTIVES SECTION • Appropriateness of the signature to be recognized with regards to the objectives as outlined in BACKGROUND AND TECHNICAL OBJECTIVES SECTION , specifically addressing whether the signature is either molecular (DNA, RNA, protein) or another signature that is clearly understood, well defined and quantifiable,	

	reliably predictive of specific cancer stages and types, or the corresponding microenvironment, and suitable (ideally) for identification of the either earliest stages of growth or metastasis and/or precancers.	
b.	Technical Approach	30%
	• Merit of the technical plan within the context of the goals of the Unconventional Innovations Program • Appropriateness of the quantitative technical milestones and proposed time frame for completion. • Feasibility of the overall approach • Evidence of inclusion of all relevant disciplines	
c.	Offeror's capabilities	15%
	• Suitability of the Principal Investigator's training, record of innovation, time commitment and project leadership experience. • Suitability of the qualifications and time commitments of the members of the proposed project team. • Suitability of the proposed management structure. • Suitability and availability of the facilities and equipment. • Suitability of the multidisciplinary composition of the team	
d.	Plans and capability to accomplish technology maturation	15%
	• Suitability of the proposed plans for a path for dissemination of the resulting technology. • Suitability of the plans for identifying near-term technology opportunities and translating such technology opportunities to independent development programs.	

Table of Contents