

# Broad Agency Announcement

**N01-CO-57035-48**

## National Cancer Institute (NCI) Best Case Series (BCS) Program: Prospective Research Projects

Issue Date: **December 6, 2005**

Due Date: **March 20, 2006 by 2:00pm (Local Time)**

Issuing Office: Office of Cancer Complementary and Alternative  
Medicine, <http://cancer.gov/cam>

Contracting Officer: Richard L. Hartmann [rh75f@mail.nih.gov](mailto:rh75f@mail.nih.gov)  
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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 topic planned for study.**

**All questions related to this BAA must be received by March 1, 2006, via electronic mail (email) to the Contract Specialist, John R. Manouelian, at the following email address: [manouelj@mail.nih.gov](mailto:manouelj@mail.nih.gov)**

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## **INTRODUCTION:**

This announcement is to solicit proposals in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA) (N01-CO-57035-48) entitled " NCI Best Case Series (BCS) Program: Prospective Research Projects." 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. This proposal must be signed by an official authorized to contractually commit the submitting organization.

It is anticipated that one (1) award will result from this announcement. It is expected that this award will be a multi-year, fixed price or cost-reimbursement, completion type contract. 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 two (2) years, although many projects are expected to be of shorter duration. An award resulting from this announcement is expected to be made on or about August 1, 2006. The NCI anticipates awarding one (1) contract based on technical merit, available funds, and programmatic balance. Program staff estimates the average total cost (direct and indirect costs) for this contract to be up to \$350,000.

## **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 the contract 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:**

The focus of the BAA is to solicit projects that enhance the state of the science on cancer treatment. The NCI BCS Program is designed to seek out alternative approaches to cancer treatment and this BAA will support prospective research projects utilizing therapies identified through this program.

## **Background and Program Objective:**

For several decades, the NCI has been researching and conducting clinical trials involving anti-tumor treatments for cancer. For the most part, this research was conducted in absence of the study of *unconventional regimens*. In September 1990, the Congress of the United States requested the Office of Technology Assessment (OTA) [now defunct (closed on 9/25/1995)] to review the status of various unconventional cancer treatments. Following the OTA Report recommendations, the NCI identified two strategies to generate interpretable data: the preparation of a best case series and conducting a pilot clinical trial (Hawkins & Friedman, 1992).

The NCI BCS Program was established under the Cancer Therapy Evaluation Program (CTEP) during 1991-1992. The preparation of a BCS in the 1990s involved the retrospective identification of patients who benefited from treatment with an unconventional modality. Criteria for inclusion were, and remain, documentation indicating:

1. diagnosis and stage of cancer with available pathologic slides for review
2. tumor measurements showing a reduction in tumor size
3. no concurrent therapy with known anti-tumor effect
4. list of medications, previous therapies, and responses to therapy
5. course of unconventional therapy
6. therapy administration technique that can be easily duplicated.

The NCI Division of Cancer Treatment and Diagnosis (DCTD) conducted the review of early BCS submissions. In response to positive reviews, Phase II trials were considered. If the alternative modality was associated with an improved quality of life, increased survival (versus tumor reduction) or it was suggested that the modality be given with standard therapies, a prospective pilot randomized trial was recommended. At present, cases meeting the strict criteria for the NCI BCS Program undergo further review by the Director, Office of Cancer Complementary and Alternative Medicine (OCCAM) of NCI; pathologic diagnosis and radiographic findings are then evaluated by NIH consultants. The results of these reviews are summarized and, if sufficient evidence is available, presented to an expert panel of advisors in the Drug Development Group (DDG) of the CTEP. The DDG provides advice to the Director, OCCAM, NCI, regarding the appropriateness and relative priority for NCI-initiated prospective research. The Director, OCCAM incorporates this advice into decisions about whether existing OCCAM funds will be expended, or supplemental funds requested, to support prospective research and the appropriate mechanism for supporting such research.

Through two BAAs (N01-CO-57035-48 and N01-CO-57034-48), the OCCAM is soliciting projects both to develop complete BCS submissions to the NCI and to support further research into the topics that have been successfully submitted and reviewed by NCI and that the NCI decides warrants further study with NCI resources. **The highest priority is for projects that provide evidence of a strong interdisciplinary**

**partnership between a practitioner of the specific unconventional therapy (that is the subject of the investigation) and researchers with experience in clinical cancer research.**

Through several OCCAM outreach activities, the level of interest in the NCI BCS program has increased steadily. However, the number of completed series has remained low. Furthermore, of those series that have been completed and assessed for NCI initiated support, few have resulted in funded research projects. Examples include:

1. The Kelly-Gonzalez regimen which resulted in a supplement to a NCI Cancer Center for a phase II trial and;
2. A prospective outcomes monitoring and evaluation project in a homeopathic clinic in Calcutta, India.

**References:**

Office of Technology Assessment, 1990, Unconventional Cancer Treatments, OTA-H-405, NTIS order #PB91-104893 available at:  
[http://www.wws.princeton.edu/~ota/ns20/alpha\\_f.html](http://www.wws.princeton.edu/~ota/ns20/alpha_f.html)

Hawkins, M.J. & Friedman, M.A. (1992). National Cancer Institute's evaluation of unconventional cancer treatments. *Journal of the National Cancer Institute*, 84(22), 1699-1702.

The NCI Best Case Series Process, Presentation by Dr. Jeffrey White, Mary McCabe, RN, and Dr. Michael Hawkins, June 11, 1999, available at:  
<http://cmbm.org/conferences/ccc99/transcripts99/f2.html>

White, J.D. (2002). Complementary and alternative medicine research: a National Cancer Institute perspective. *Seminars in Oncology*, 29(6), 546-551.

White, J.D. (2002). The National Cancer Institute's perspective and agenda for promoting awareness and research on alternative therapies for cancer. *Journal of Alternative and Complementary Medicine*, 8(5), 545-550.

Lee, C. (2004). Translational Research in Cancer Complementary and Alternative Medicine: The National Cancer Institute's Best Case Series Program. *Clinical Journal of Oncology Nursing*, 8(2), 212-214.

**Internal analyses of barriers and challenges:**

Staff analyses of the BCS process identified several barriers to successful submission of BCS materials and subsequent research activities. The major barriers include:

1. The difficulties in preparing the documentation: Although many CAM practitioners express interest in the program, it is extremely challenging for them to put together a series on their own without additional staff or expertise.
2. Lack of funding support: Interested academic researchers do not have available funding support to assist in the development of BCS.
3. Research Expertise: When a BCS submission is completed and positively reviewed, practitioners alone do not have the resources and/or expertise to conduct the follow-up research. NCI staff have tried to seek out potential partners but the search is challenging and is repeated anew for each series.

### **Technical Objectives:**

#### Program Objective:

This BAA is intended to provide a mechanism to solicit, initiate and support prospective research projects on selected topics identified via the NCI BCS Program. It is also intended to foster collaborative activities between CAM practitioners and more traditional cancer researchers.

#### Solicitation Objective:

Topics eligible under this BAA are alternative cancer therapies for which patient documentation is available and for which the intervention is available for prospective investigation. This BAA requests collaborative projects, which would pair a cancer investigator with a CAM practitioner. It is anticipated that such collaborations will result in:

- a) more timely and appropriately prepared BCS proposals submitted to the NCI,
- b) creating a trusting partnership between those who would (and could) do follow-up research and practitioners with expertise using specific unconventional approaches, and
- c) attracting experienced cancer investigators with a strong interest in researching specific unconventional interventions and the commitment in carrying the research forward.

### **Phase II Objectives:**

A prospective research project justified on the basis of results from the findings of a completed review of a case submission to the NCI BCS Program. The interventions for which there are completed case series through the NCI BCS Program and for which this solicitation applies are as follows:

- Homeopathic therapy of cancer as practiced by Dr. Prasanta Banerji (P. Banerji Homeopathic Research Foundation, Calcutta, India).
- Insulin Potentiation Therapy as practiced by Dr. Steven G. Ayre (Burr Ridge, IL) and Dr. Ross Hauser (Oak Park, IL).
- Macrobiotic Lifestyle Modification as taught by the Kushi Institute (Becket, MA)

Summaries of the cases involved in these reviews may be obtained by submitting a Request for Access to an OCCAM Data Set. This request can be obtained by contacting the OCCAM ([ncioccam-r@mail.nih.gov](mailto:ncioccam-r@mail.nih.gov); 301-435-7980).

It is anticipated that this contract will result in a completed research project within two (2) years. For clinical trials, this includes:

- an approved (NCI, IRB, FDA) protocol
- an accrual plan
- data analysis
- dissemination plan for the research results that include publication in a peer-reviewed, scientific journal.

## **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**

#### **Salary Limitations:**

Pursuant to Public Law, no NIH extramural firms 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 the following url:

<http://www1.od.nih.gov/oma/manualchapters/contracts/6030-1/6030-1.pdf>

#### **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 NCI BCS Program 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 BAA. 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, milestones 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, and a timeline for the successful completion of particular milestones. This information should be presented in text as well as in chart format. One separate PC format-compatible diskette or CD 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: WordPerfect document or Microsoft Word document.

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.

**Section Two - 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 OCCAM's experience in facilitating BCS development and subsequent initiation of a collaborative clinical trial with a CAM practitioner, 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 represent 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 Three - Offeror's Qualifications (*recommended limit -2 pages*):**

This section should present a discussion of the offeror's qualifications for leading the research effort proposed, including a record of prior and current related research projects.

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

It is anticipated that the complexity and uniqueness of the two phases of the project will require that expertise from a variety of disciplines be engaged in the development process. Proposals should address the breadth of expertise required for the successful completion of the project, capabilities of the team, and plans for recruiting additional expertise, if needed. Multi-disciplinary teams are strongly encouraged. 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 Five – Facilities:**

This section should include a detailed description and documented availability of the facilities and equipment that would be used for the proposed effort

**Section Six - Bibliography and Additional Supporting Documentation:**

The proposal may contain a brief bibliography of relevant technical papers and research notes (published and unpublished) that document 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 Seven - Resources Proposed:**

Provide in this section a detailed description of the proposed effort (labor-hours and categories) and applicable rates, materials, subcontracts, travel, other direct costs, etc., and associated costs so that the your understanding of the project may be evaluated by the technical reviewers. It is requested that the [Breakdown of Proposed Estimated Cost and Labor Hours Form](#) be used as the format for presenting this information. Provide in

this section a detailed TECHNICAL justification for the proposed resources. Also, provide in this section letters of commitment from proposed consultants, if any proposed.

### **Section Eight - Human Subjects Assurance:**

If the proposal includes research involving Human Subjects, address or provide the following in the proposal:

- A copy of the DHHS Human Subjects Assurance Number,
- The timeline for approval by the Institutional Review Board of your organization.
- 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 11-13 of the September 2004 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://www.hhs.gov/ohrp/>)

### **Business Proposal (Separate Volume)**

**Face Page - The face page shall provide the following information:**

- The solicitation number;
- The name, address, telephone and facsimile numbers of the offeror and electronic mail 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, telephone numbers, facsimile numbers and electronic mail 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

### **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

shall include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, and fee/profit. The format used should be Microsoft Excel. In addition to submission of the budget proposal in this section, you are requested to submit, with the ORIGINAL PROPOSAL ONLY, a PC Compatible diskette or CD containing the budget.

**a.** 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:

1. 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.
2. For all materials, supplies, and other direct costs, list all unit prices, etc., to detail how the calculations were made.
3. For all indirect costs, list the rates applied and the base the rate is applied to.
4. For all travel, list the individual trips.
5. For each subcontract proposed, submit a separate Microsoft Excel Workbook in the same format as described above

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

1. If your proposal includes cost sharing, describe the cost sharing, the method of allocating fields, and the source of the shared fields.
2. The use of the provided Excel spreadsheet greatly facilitates the analysis and review of the proposed budget.
3. In preparing the proposal, offerors should include costs for attendance at one programmatic meeting per year. For the purposes of estimating costs, offerors should assume one three-day meeting will be conducted at/near Washington, D.C., with attendance by the Principal Investigator and one Senior Investigator.

## **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.

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

1. Verified salary documentation. Acceptable documentation includes any one of the following: 1) personnel action forms, or 2) the most recent payroll register showing names, pay rates, and percent of effort, if applicable, or 3) copies of pay stubs. If the proposed positions have not been filed 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 tables showing salary ranges and a copy of your organization's hiring policy, or 3) a comparable employee's payroll document.
2. A detailed explanation of when employees receive salary increases, the methodology used for determining the salary increase rate(s) and the salary rates for proposed new employees.
3. Vendor quotations, catalog prices, etc. that document the proposed material and supply costs.
4. Supporting documentation of the reasonableness of proposed consulting costs, including documentation from the consultant that the proposed rate is the established consultant rate that 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.
5. 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.
6. 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 is required. Include a description of the cost components of both the base and pool costs. Additional guidance on indirect costs is available from the Division of Financial Services, Office of Contracts Management, NIH, at <http://oamp.od.nih.gov/dfas/IdCSubmission.asp>

b. The information in this section must also be prepared and submitted for each proposed subcontractor. Subcontractors may prepare and submit cost data directly to the Contracting Officer.

### **Section Three - Additional Business Data:**

#### **a. 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 under these contracts. Please 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 the proposed 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, as well as 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.

1. 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.

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

3. Other (Labor Relations):

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

**b. Federal Acquisition Regulation Clauses Incorporated by Reference:**

1. **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the

agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

## 2. **Salary Rate Limitation in Fiscal Year 2005**

Offerors are advised that pursuant to P.L. 108-447, no NIH Fiscal Year 2006 (October 1, 2005 - September 30, 2006) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I\* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I\*. The salary rate

limitation set by P.L. 108-447 applies only to Fiscal Year 2005 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I\* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-447 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I\*."

**LINK TO EXECUTIVE SCHEDULE SALARIES:**

<http://www.opm.gov/oca/05tables/html/ex.asp>

**\*Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2005 Executive Level I Salary rates.

3. Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
4. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
5. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
6. Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

**c. 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.

**d. 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 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.

**e. Annual Report:**

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

**f. Travel Policy:**

Include in this section of the ORIGINAL PROPOSAL ONLY, a copy of your institution's (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 Four (Section K) - Representations and Certifications:**

Section Four (Section K) can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION FOUR (SECTION K) AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.