

**NATIONAL INSTITUTE OF MENTAL HEALTH, NIH
REQUEST FOR PROPOSAL - SOLICITATION COVER PAGE**

REQUEST FOR PROPOSAL NO:	NIMH-02-DM-0006
TITLE:	Measurement and Treatment Development Activities on Cognition in Schizophrenia
OMB No.: 0990-0115	PURCHASE AUTHORITY: Public Law 92-218 as amended; Note: The issuance of this solicitation does not commit the Government to make an award, or to pay any costs for the preparation and submission of a proposal.
ISSUED BY: Suzanne Stinson Contracting Officer Contracts Management Branch National Institute of Mental Health, NIH Neuroscience Center Building 6001 Executive Blvd., Rm. 6107 (MSC 9603) Bethesda, MD 20892-9603 E-mail: ss704b@nih.gov Phone (301) 443-4116 Fax at (301) 443-0501 Collect calls will not be accepted.	ISSUE DATE: February 12, 2002 DUE DATE: April 12, 2002 at 4:00 PM local prevailing time Note: The official Point of Receipt for the purposes of determining timely delivery is the Contract Management Branch, NIMH. If the Contracting Officer or Designee does not receive your proposal at the place and time specified, then it will be considered late and handled in accordance with PHS Clause 352.215-10 entitled "Late Proposals, Modifications of Proposals and Withdrawals of Proposals" located in this solicitation.
NO. OF AWARDS:	Estimated: One (1) award
PERIOD OF PERFORMANCE:	Two (2) years, beginning on or about September 30, 2002, with two (2) one (1) year options
SMALL BUSINESS/ 8(a) SET-ASIDE:	NOT A SET ASIDE, (NAICS Code 541720)
JUST IN TIME:	Yes
OFFER EXPIRATION DATE:	Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Attachment 5)
TECHNICAL PROPOSAL PAGE LIMITS:	No
AWARD WITHOUT DISCUSSIONS:	The Government reserves the right to make awards without discussions
POINT OF CONTACT:	Suzanne Stinson; voice (301) 443-4116; fax (301) 443-0501; E-mail ss704b@nih.gov <i>No collect Calls will be accepted.</i>

NOTE: OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE NIMH WEBSITE AT <http://www.nimh.nih.gov/grants/indexcon.cfm> and/or FedBizOpps at <http://www.fedbizopps.gov> FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.



National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

February 12, 2002

Dear Sir/Madam:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-02-DM-0006 entitled "Measurement and Treatment Development Activities on Cognition in Schizophrenia." Proposals are being solicited under Full and Open Competitive procedures.

It is expected that one (1) cost-reimbursement, completion contract will be awarded on or before September 30, 2002 with a base period of two (2) years, and two additional option periods of one (1) year each.

FOR PROPOSAL PURPOSES, THE OFFEROR MUST PROVIDE A TECHNICAL AND BUSINESS PROPOSAL (BUDGET) FOR THE BASE PERIOD AND THE OPTION PERIODS (TOTAL FOUR (4) YEARS). FURTHER, THERE ARE TWO (2) OPTION ITEMS (See SOW Attachment 2, item C.) WHICH WILL ALSO REQUIRE THE DEVELOPMENT OF INDIVIDUAL BUDGETS AND WHICH SHOULD BE INCLUDED IN THE BUSINESS PROPOSAL.

Special attention should be directed to the technical proposal instructions and business proposal instructions contained in **Attachment 4**.

The documents included with this electronic RFP package are as follows:

- I. Streamlined RFP:
 - A. Statement of Work (SOW) (**Attachment 1**)
 - B. Deliverables and Reporting Requirements (**Attachment 2**)
 - C. Evaluation Factors for Award (**Attachment 3**)
- II. Standard RFP Instructions and Conditions and Notice to Offerors (**Attachment 4**)
- III. Applicable RFP References/Forms/Web links (**Attachment 5**)
- IV. Proposal Intent Response Sheet (**Attachment 6**)

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition.

An official authorized to contractually bind your organization must sign your proposal. One (1) original and ten (10) copies of your technical proposal, and one (1) original and five (5) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN **4:00 p.m., local prevailing time, on Thursday, April 12, 2002**, at the following address:

If hand delivered or using overnight delivery service: If using U.S. Postal Service:

Attn: Suzanne Stinson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 6107 (MSC 9603) Rockville, MD 20852-9603	Attn: Suzanne Stinson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 6107 (MSC 9603) Bethesda, MD 20892-9603
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Your attention is further directed to the “Proposal Intent Response Sheet” contained in **Attachment 6**. Please complete this form and return it to this office or notify me at the following Internet address: ss704b@nih.gov on or before March 12, 2002. This will allow us to expedite preparations for the peer review of proposals.

IF THERE ARE ANY AMENDMENTS TO THIS SOLICITATION, THEY WILL BE AVAILABLE ON THE INTERNET at FedBizOpps at <http://www.fedbizopps.gov> and/or the NIMH HOME PAGE AT: <http://www.nimh.nih.gov/grants/indexcon.htm> . It is the offerors responsibility to monitor these websites for possible solicitation amendments.

This RFP does not commit the Government to pay any costs for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer (CO) is the only individual who can legally commit the Government to expenditure of public funds in connection with this proposed acquisition.

Any discussion of this RFP with any individual(s) outside the Contracts Management Branch, NIMH, may result in disqualification of the offeror and rejection of any proposal submitted.

Questions concerning any areas of uncertainty, which in your opinion require clarification or correction on the part of NIMH, must be furnished in writing to Suzanne Stinson, and marked “Offeror’s Questions, RFP No. NIMH-02-DM-0006”. You are requested to submit (preferably via e-mail) your questions to Suzanne Stinson (ss704b@nih.gov). It would be appreciated if you questions were received in the contracting office on or before March 22, 2002, to allow a reply to reach all prospective offerors before submission of their proposals.

Sincerely,

/s/

Suzanne Stinson
 Contracting Officer
 Contracts Management Branch, ORM
 National Institute of Mental Health, NIH

Attachments: 1-6

**ATTACHMENT 1
STATEMENT OF WORK
RFP No. NIMH-02-DM-0006**

Measurement and Treatment Development Activities on Cognition in Schizophrenia

A). Introduction

Despite treatment with the best current pharmacological agents, many patients with schizophrenia experience substantial long-term impairment and disability. Recent cross-sectional and longitudinal studies suggest that cognitive impairment, rather than “positive” symptoms (delusions and hallucinations) may be the major determinant of short- and long-term functional outcome in this disorder. Advances in understanding the specific behavioral aspects, systems-level neurobiology and neuropsychopharmacology of cognition are yielding new hypotheses to inform therapeutic approaches. Treatment development, however, is hampered by lack of scientific consensus regarding both the key cognitive impairments to be targeted and the selection of reliable and valid measurement tools to assess cognition as a dependent variable in treatment trials. Given these limitations, the Food and Drug Administration (FDA) has not yet been able to recognize cognition in schizophrenia as a valid treatment endpoint for industry-sponsored research and drug registration.

To overcome these barriers to treatment improvements for schizophrenia, NIMH is taking steps to facilitate broad academic and industry consensus regarding the nature of cognitive impairments in schizophrenia relevant to function; the optimal tools for measuring cognition as a dependent variable in treatment trials; the capacity of industry and academic research institutions to develop compounds that address identified mechanisms of cognitive deficit; and the clinical trial designs sufficient to establish the efficacy of pharmacological agents for this clinical endpoint.

Because of the clinical and prognostic importance of cognitive deficits in schizophrenia and the scientific opportunity created by new insights into the neurobiology of attention, working memory, and other fundamental cognitive processes, NIMH plans to promote a broad academic and industry collaboration to:

- 1) define and specify critical aspects of cognition in schizophrenia as potential treatment targets;
- 2) achieve consensus regarding best current and potentially improved measures of cognition in schizophrenia as a dependent variable in treatment trials;
- 3) define optimal experimental designs to evaluate the efficacy of primary and augmentation strategies to enhance cognition in schizophrenia;
- 4) identify issues and opportunities for industry/academia/government collaboration in testing compounds of potential utility in alleviating cognitive deficits in schizophrenia;
- 5) broadly and equitably disseminate state-of-the art measurement tools and methodological strategies to evaluate the efficacy of treatments for cognitive deficits in schizophrenia.

It is envisioned that highly skilled and specialized professional services and expertise shall be provided to assist NIMH staff in facilitating regulatory acceptance of cognitive deficits as a valid clinical endpoint by:

- 1) designing, organizing, and executing a plan to develop consensus about the nature of cognitive deficits in schizophrenia and best current and future measures of cognitive function in schizophrenia;
- 2) identifying opportunities for government/industry collaboration to test new pharmacological treatments to remedy cognitive deficits in schizophrenia;
- 3) preparing for dissemination of key outcomes of the consensus processes; and
- 4) if necessary, developing and validating a new instrument to measure cognition in schizophrenia;
- 5) if necessary, conducting a proof-of-concept augmentation trial.

B). Services to be Performed:

General Requirements

- a. Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary labor, materials, supplies, equipment, and services to accomplish the work of this contract.
- b. This contract requires the contractor to provide services in accordance with a project work plan that describes the work to be accomplished to fulfill contract objectives.
- c. All work done under this contract shall be under the general guidance and technical monitoring of the NIMH Government Project Officer (GPO) whose position is defined in Section G of the contract. Contact between the GPO and the Contractor shall include frequent phone and e-mail contacts, faxing of information, and periodic meetings.

Specific Requirements

TASK 1:

Develop a work plan to accomplish all tasks and a plan to ensure appropriate involvement and oversight by the National Advisory Mental Health Council (NAMHC)/NIMH Workgroup on Treatment Development in all aspects of contract performance.

- a. Timetable for provision of all deliverables and completion of all tasks during the 24-month performance period.
- b. Written plan to ensure appropriate participation and oversight by NAMHC/NIMH Workgroup on Treatment Development

TASK 2:

Plan, coordinate, and or co-chair (with the GPO or designees) approximately 5-7 industry/government/academic consensus-oriented conferences regarding the fundamental components of human cognition; those components most associated with dysfunction in schizophrenia; components which represent the most promising clinical targets for new therapeutics; the relationship of these components to the neuropsychopharmacology of the neural circuits that implement cognitive function; state-of-the art measurement methods, experimental designs, conflict-of-interest and intellectual-property issues; and pharmacological agents potentially useful in remedying cognitive deficits in schizophrenia. Ensure broad participation of academic, industry, and regulatory opinion leaders in consensus development process. At a minimum, these conferences will generate one or more workshop reports, as outlined in item “d” below.

- a. Task: Organize and conduct proposed series of consensus-oriented conferences addressing key methodological, scientific, ethical and logistical aspects of promoting government/industry collaboration to identify, develop and test agents of potential utility in remedying cognitive deficits in schizophrenia.
- b. Develop agendas and participant lists for all conferences and workshops.
- c. Provide written plan to ensure participation of key academic, industry and regulatory opinion leaders in consensus building process including list of critical stakeholders required to achieve broad scientific consensus in content areas to be addressed by conferences.
- d. Provide a written report of each workshop to be published in a journal or other suitable forum, that includes and has been vetted by a broad list of opinion leaders from academia, industry, and regulatory officials. Reports are to be 5-7 pages in length, and provide an accurate integrative summary of the proceedings of each workshop.

Note: The contractor shall provide final participant lists and agendas to the GPO for approval. Another contract shall be used by NIMH to arrange the date, location, and travel of participants to each meeting. This contract shall not support costs for conference logistic activities, or costs related to the attendance of participants at each meeting. The contractor shall arrange for the Principal Investigator (PI), and other appropriate contractor staff (with the approval of the GPO) to attend each meeting. Costs related to the attendance of contractor personnel at each meeting will be borne under this contract.

If the consensus-oriented workshop process (2a-d) results in identifying an existing measurement tool sufficient and adequate to evaluate the efficacy of pharmacological agents in reducing cognitive impairment in schizophrenia, the published workshop report should explicitly identify that measurement tool.

If the consensus-oriented workshop process (2a-d) results in the determination that no existing measurement tools are sufficient and adequate to determine the efficacy of pharmacological

agents in reducing cognitive impairment in schizophrenia, the workshop report should indicate the specific deficiencies that render extant instruments inadequate for this determination. In addition, a *second and distinct* workshop report shall be delivered outlining the specific characteristics of an optimal assessment tool for cognition in schizophrenia and the specific steps required to develop and establish the reliability, validity and pharmacosensitivity of such a tool.

TASK 3:

Explore the feasibility of NIMH's entering into agreements with pharmaceutical and biotechnology companies to obtain access to compounds and/or compound libraries with the aim of identifying New Chemical Entities (NCE's) of potential utility to enhance cognition in schizophrenia. Candidate agents should be identified based upon their pharmacological profiles with respect to extant models of the modulation of human cognition, attention and/or working memory, bioavailability, pharmacokinetic and pharmacodynamic considerations, and pre-clinical and/or clinical toxicology data. The contractor is expected to identify and conduct face-to-face interviews with 50 to 100 key decision makers in large and small pharmaceutical and biotechnology companies with CNS drug development programs.

- a. Task: Report of process used to identify potential industry collaborators (to be included in semi-annual report, 6 months after EDOC).
- b. Task: Comprehensive list of large and small biotechnology and pharmaceutical companies willing to participate by allowing access to compounds and/or libraries in a joint government/industry effort to identify agents of potential utility in remedying cognitive deficits in schizophrenia. (Also see task 5.c.) (to be included in annual report).
- c. Written report of proposed and accomplished feasibility activities three times per year delivered to the GPO for distribution to NAMHC/NIMH Treatment Development Workgroup.

TASK 4:

Develop and provide the GPO with a comprehensive list of lead compounds potentially accessible for government/industry collaborative development.

- a. Task: Based on activities specified above (3a-c) create and provide comprehensive index of identified candidate compounds that may be useful as augmentation agents in remedying cognitive deficits in schizophrenia. (Include in semi-annual report, 18 months after EDOC).
- b. Compound index provided in 4a. should be provided in data base form describing mechanism of action, stage of development, current availability of pharmacokinetic, pharmacodynamic, animal and human toxicology data, and existence and/or accessibility of data sufficient to obtain IND for use in human clinical trials. (Include in semi-annual report, 18 months after EDOC).
- c. Produce written plan to ensure full access to the investigative community of all information obtained concerning potential industry partners and potential NCE's identified under tasks 2 and 3 of this contract. (Include in semi-annual report, 18 months after EDOC).

TASK 5:

Based on face-to-face informal interviews with key industry decision makers, provide the GPO with a written report defining alternative approaches to management of intellectual property issues bearing on government/industry collaboration for pre-clinical and clinical drug development.

- a. Task: Detailed report outlining policy recommendations/approaches to management of intellectual property issues acceptable to widest array of potential industry partners in effort to develop compounds with potential utility in remedying cognitive deficits in schizophrenia. (Include in annual report).
- b. With prior GPO approval, obtain expert legal opinion on issues related to government/industry intellectual property negotiations. (Include in annual report).
- c. List (specified in 3b.) should also indicate any distinct or unique terms or consideration (beyond those specified in task deliverable 4 a&b) bearing on NIMH ability to negotiate access to the compound for collaborative development and/or human clinical trials. (Include in annual report).

TASK 6:

Based on broad input from academic, industry and regulatory experts, define options for establishing criteria to prioritize compounds potentially useful in improving cognition in schizophrenia. This information will be used for consideration by the NIMH/NAMHC Treatment Development Workgroup. (To be included in the 18 month semi-annual report).

- a. Define options for *a priori* evaluation criteria for potential lead compounds for testing, should NIMH establish a Cognition and Schizophrenia clinical trials network.
- b. Define options for process and criteria to ensure fairness and full and acceptable management of conflict-of-interest issues in relation to selection of compounds for development.
- c. Each option proposed pursuant to 6a&b should include a written plan to ensure agreement among academic, industry and regulatory leaders that the compound evaluation and selection process is free of bias and conflict of interest.

TASK 7:

With the GPO and/or other NIMH staff, prepare one or more issues or special sections of *Schizophrenia Bulletin* or similar journal to focus on some or all of the following substantive issues:

- 1) comprehensive assessment of extant and experimental measures of cognition in schizophrenia;
- 2) comprehensive assessment of methodological issues related to evaluating efficacy of augmentation strategies to remedy cognitive deficits in schizophrenia, including selection of optimal experimental populations, management of differential side-effect profiles of alternative agents,

- differentiating primary effect on cognition from secondary effects on other dimensions of schizophrenia psychopathology;
- 3) review of major neuropharmacological approaches to modulating cognition and working memory in schizophrenia, with emphasis on potential translation implications of pharmacological circuit-based models to human clinical trials;
 - 4) review of pharmacological agents potentially useful in remedying cognitive deficits in human subjects with schizophrenia;
 - 5) comprehensive assessment of legal, ethical and intellectual property issues affecting government/industry collaboration to develop augmentation strategies to remedy cognitive deficits in schizophrenia;
 - 6) comprehensive assessment of prospects for development of imaging-based biomarkers linked to efficacy in remedying cognitive deficits in schizophrenia;
 - 7) outline of research agenda to develop future measures of cognition in schizophrenia based on emerging advances in cognitive neuroscience.
- a. These special issues/sections may be based directly on one or more of the workshops (as described in Task 2), but may also be somewhat independent of the content and agenda of the workshops or workshop reports.
 - b. Task: Ready proof copy of peer-reviewed articles and/or Special Issues/Sections addressing specific areas to be defined by contractor and NIMH staff. Articles may vary in length, depending on the topic. A minimum of four and a maximum of seven such special issues or sections will be created. Schedule of delivery to be determined.

TASK 8 Reporting Requirements

In addition to the specific reports mentioned in the tasks 1-7, the Contractor shall provide the following general reports:

- a. The “semi-annual reports” should consist of a description describing the major activities of the prior 6 months of the contract work. This should include an overall summary of the status of the project, in addition to the detailed information as indicated in Tasks 3, 4, and 6.
- b. The “annual report” should consist of a summary of the first year's work. This document should: describe progress during the first year; indicate any problems that were encountered, and steps taken to overcome these problems; summarize the significance of the work to date; and describe the work to be conducted in the second year of the contract. In addition, detailed information should be included as indicated in Tasks 3 and 5.
- c. The “final report” should be similar in scope to the annual report delivered at the end of the first year. This includes a section describing activities for each Specific Requirement in the Statement of Work. This report should summarize all activities conducted during the contract, including a brief description of each workshop that was held, along with publication status of workshop reports and journal special issues. A paragraph should be specifically included regarding the status of FDA

approval of various aspects of cognition in schizophrenia as endpoints in clinical trials. The report should contain, as appendices, the various databases and lists that are described in the various Specific Requirements in the Statement of Work. The report should summarize the significance of the work that was conducted, and outline potential directions for future research endeavors in the area of schizophrenia and cognition. Semi – annual Technical Progress Reports are not due for periods in which an annual or final report is due, nor is an annual report due for a period when a final report is due. In the event the final report takes the place of a semi-annual or annual report, the final report should include the information specified in those reports (see above).

- d. An “ad hoc report” is to consist of a 2-3 page report regarding any specific activity or incident that is requested by the GPO, which does not fall within the scope of one of the other reports required, and/or for which more timely or detailed information is necessary. This might include, e.g., reports of meetings with the FDA regarding approval of clinical endpoints; events of particular significance regarding intellectual property issues in evaluating compounds; or new and unusually significant research findings which could affect the nature of the scope of work, e.g., the development of a new measure of cognition in schizophrenia or a new class of relevant compounds.

C). Option Items

If the NIMH exercises either one or both of the following options, the contractor should be prepared to carry out all required work, or if NIMH chooses, to cooperate with another NIH contractor or grantee to carry out this work.

OPTION ITEM ONE:

Period of performance – One (1) option period consisting of twelve (12) months

If the consensus-oriented workshop process (2a-d) results in the determination that no extant measurement tools are sufficient and adequate for determining the efficacy of pharmacological agents in reducing cognitive impairment in schizophrenia, at the discretion of NIMH, the contractor may be asked to create a new instrument that conforms to the specific characteristics of an optimal assessment tool for cognition identified in 2a-d. by performing the specific steps required to develop and establish the reliability, validity and pharmacosensitivity of such a new instrument outlined in the workshop report specified in 2d. It is anticipated that this new instrument development would entail:

- a. the selection and aggregation of key sub-tests from extant instruments;
- b. the creation of a users’ manual, paper and pencil materials, and/or computerized software to allow uniform instrument administration across diverse clinical trial sites;
- c. sufficient pilot testing of the new aggregate instrument to allow confidence in its reliability and validity as an endpoint in trials of pharmacological augmentation strategies to remedy or improve cognitive deficits in schizophrenia

OPTION ITEM TWO:

Period of performance – One (1) option period consisting of twelve (12) months

There may be a need for the contractor to, with CO and GPO approval, to design and conduct a small (N=20-40) proof-of-concept augmentation trial of a lead compound identified in 4b. The contractor will participate with the GPO in appointing a trial steering committee to design and oversee all aspects of the trial with the ultimate aim of determining if preliminary evidence of safety and efficacy of the lead compound is sufficient to warrant proceeding with larger scale phase II safety and efficacy studies. The proof of concept trial will be designed in conformity with methodological principles articulated as a product of the consensus-oriented workshop process outlined in 2a-c, and reported in 2d, and shall:

- (1) require IRB approval;
- (2) be accomplished in accordance with and meet the standards of other NIH sponsored clinical trials:
 - a. development of protocol and consent;
 - b. recruitment, screening (using the measurement tool to be developed under Option 1, or another measurement tool with the approval of the GPO), and enrollment of subjects; and
 - c. collection, analysis, and reporting of data; and
- (3) be structured in a manner to facilitate the accomplishment of contract objectives.

D). Exercise of Options**1. OPTION TO EXTEND THE TERM OF THE CONTRACT**

- (a) The Government may extend the term of this contract by written notice to the contractor provided that the Government shall give the contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises this option, the extended contract shall be considered to include this option provision.
- (c) The total duration of this contract, including the exercise of any options under this clause, shall not extend beyond 60 months from the effective date of this contract.

2. Your attention is drawn to the following clause appearing in full text and located at the end of Section L of this Request for Proposal package - FAR 52.217-5
EVALUATION OF OPTIONS (JUL 1990)

E). Acronyms

CNS	Central Nervous System
CO	Contracting Officer
FDA	Food and Drug Administration
GPO	Government Project Officer
IND	Investigational New Drug
IRB	Institutional Review Board
NAMHC	National Advisory Mental Health Council
NCE	New Chemical Entities
NIMH	National Institute of Mental Health
PI	Principal Investigator

ATTACHMENT 2

REPORTING REQUIREMENTS AND DELIVERABLES RFP NO. NIMH-02-DM-0006

1. Period of Performance

Performance of this contract shall begin on the effective date of the contract (EDOC) and shall not exceed beyond the estimated completion date of the contract unless the period is extended by modification to the contract. The period of performance of this contract is twenty-four (24) months, with two (2) twelve (12) month option periods commencing from the effective date of this contract. Each twelve (12) month option is tied to the “option items” specified in the Statement of Work, reference item C.

2. Delivery and Reports Schedule

After the contract award date, the Contractor shall deliver the following items to the Government Project Officer (GPO) and Contract Officer (CO) in accordance with the delivery schedule set forth below:

<u>Deliverable/Due</u>	<u>No. of Copies</u>	<u>Addressee*</u>
Workplan (See SOW, B.1) (Due 1 month after EDOC)	3	Two copies to GPO One copy to CO
Agenda and Participant List (See SOW B.2.b.) (Due 3 months in advance of each conference)	2	Two copies to GPO
Written Plan (See SOW B.2.c.) (Due 2 months after EDOC)	2	Same as above
Workshop Reports for publication (See SOW B.2.d.) (Due 6 weeks after each workshop)	3	Two copies to GPO One copy to CO
Report (See SOW B.3.c.) (Due 1 month before each meeting of NAMHC)	2	Two copies to GPO
Semi-annual (B.8) (6 months after EDOC)	3	Two copies to GPO One copy to CO
Annual (B.8) (12 months after EDOC)	3	Two copies to GPO One copy to CO
Final (B.8) (Within 30 days of contract expiration)	3	Two copies to GPO One copy to CO

Other materials or Ad hoc reports (B.8)	As required by the GPO	
Monthly progress reports (Submitted with monthly voucher)	2	One copy to GPO One copy to CO
OPTION ITEM 1 Workshop Report (Due date TBA) Further option item deliverables will be determined at time of award	TBA	Submitted to GPO/CO
OPTION ITEM 2 IRB Approval Protocol and Consent (Submitted immediately following approval) Annual report for gender/minority tracking (Submitted 15 days after each annual anniversary date) Further option item deliverables will be determined at time of award	TBA	Submitted to GPO Submitted to GPO

NOTE: Semi – annual Technical Progress Reports are not due for periods in which an annual or final report is due, nor is an annual report due for a period when a final report is due.

*Actual addresses to be announced in resulting contract.

Copies of deliverables for the Contracting Officer:

One copy of each annual, semi-annual and final report shall also be delivered to the Contracting Officer by the specified delivery date. In addition, a monthly progress report detailing expenditures and activities carried out during the month, (including problems encountered and solutions made), shall be submitted to the Contracting Officer and accompany the monthly voucher/invoice. The progress report is intended to provide document support for the justification of costs and payment of the monthly voucher.

3. Clauses Incorporated by Reference (FAR 52.252-2 - JUN 1988)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. A full text of this clause may be accessed electronically at the following address: <http://www.arnet.gov>.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER I) CLAUSES

52.242-15	Stop Work Order (AUG 1989) Alternate I (APR 1984)
52.246-8	Inspection of Research and Development – Cost Reimbursement (April 1984)

ATTACHMENT 3 EVALUATION CRITERIA FOR AWARD

I. GENERAL-BASIS FOR AWARD

Selection of an offeror for contract award will be based on an evaluation of proposals against four (4) factors. The factors, in order of importance are Technical, Past Performance, Small disadvantaged business participation (SDBP), and Cost/Price. Although technical factors are of paramount consideration in the award of the contract, past performance, SDBP and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

Offers from qualified HUBZone firms and small disadvantaged business concerns may have special evaluation terms as explained in this attachment below.

The small disadvantaged business participation (SDBP) factor is explained in this attachment below.

Proposals are intended to be evaluated and award made after discussions with offerors, but an award may be made without discussions with offerors.

II. EVALUATION FACTORS FOR CONTRACT AWARD- TECHNICAL EVALUATION CRITERIA AND ASSIGNED WEIGHTS

1. GENERAL

The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the RFP. The merit of each proposal will be evaluated carefully, based on responsiveness to the RFP and thoroughness and feasibility of the technical approach taken. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration. Proposals which merely offer to conduct a project in accordance with the requirements of the Government's scope of work will be considered non-responsive to this request and will not be considered further. Offerors must submit an explanation of the technical approach and a detailed description of the tasks to be performed to achieve the project objectives.

2. RELATIVE IMPORTANCE OF TECHNICAL AND COST FACTORS

Award will be made based on technical, past performance, SDBP and cost factors. Paramount consideration shall be given to the evaluation of the technical proposals, past performance and SDBP, but not to the exclusion of cost considerations. While high competency is sought, capabilities that exceed those needed for successful performance of the contract work/statement are not requested. In the event that the technical evaluation reveals that multiple Offerors are

approximately equal in technical ability, then the estimated cost of performance will become paramount. Proposals are intended to be evaluated and award made after discussions with Offerors, but an award may be made without discussions with Offerors.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. Proposals submitted in response to this RFP will be evaluated based on the following factors, which are listed and weighted in order of their relative importance.

<u>CRITERIA</u>	<u>WEIGHT</u>
A. TECHNICAL APPROACH	55
The proposal shall evidence:	
1. Soundness and practicality of the technical approach for responding to the objectives as stated in the Statement of Work, with adequate justification and substantiation for the recommended methods; also, demonstration of Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties which may arise in the performance of this work. The evaluation will assess:	
a. Technical approach for convening conferences and workshops as described in Task 2 of the Statement of Work (SOW); including, but not limited to, a description of the anticipated content and ordering of the workshops, relationships in content among the workshops, disciplines to be represented, etc. (8 points)	
b. Technical approach for work as described in the SOW, Task 2, item d, and, SOW, Task 7, for creating one or more workshop reports, and preparing one or more issues or special sections of a major journal such as <u>Schizophrenia Bulletin</u> related to the proceedings of the workshops; including anticipated plans for assignment of writing responsibilities, reviewing completed papers, editing the manuscripts, etc. (8 points)	
c. Technical approach as described the SOW, Task 3, for procedures to explore the feasibility of agreements between NIMH and pharmaceutical/biotechnology companies, for the purpose of obtaining access to compound libraries for identification of New Chemical Entities (NCEs) useful for remediating cognitive deficits in schizophrenia, and creating a list of potential lead compounds to the GPO. (8 points)	
d. Technical approach as described in Task 5, for interacting with industry officials and NIMH staff to create a written report addressing intellectual property issues regarding government/industry collaborations in pre-clinical and clinical drug development. (8 points)	

- e. Technical approach as described in Task 6, for preparation of options to be used by the NIMH/NAMHC Treatment Development Workgroup in prioritizing potentially useful compounds for cognition in schizophrenia. (8 points)
- f. Experience and ability: 1) to develop an instrument that conforms to the specific characteristics of an optimal assessment tool for fundamental aspects of cognition, as described in Option Item One; and 2) to conduct a psychiatric proof of concept clinical trial as described in Option Item Two (2). (15 points)

B. PERSONNEL & MANAGEMENT PLAN

40

The proposal shall evidence:

1. The Offeror can provide staff who have the appropriate training, expertise, experience, availability, and levels of utilization of contractor/subcontractor staff required to plan and implement this project as described in the Statement of Work. The evaluation will assess:
 - a. Roles, responsibilities, and lines of authority of staff in these activities. (*See Sample Staff Loading Chart in Attachment 3 below)
 - b. Documentation to endorse and explain previous efforts that reflect length and variety or experience in similar tasks and clearly demonstrate specific accomplishments.
2. Experience of Principal Investigator in managing teams of scientific investigators, and in overall administrative ability to direct the project.
3. Composite expertise of professional personnel in the areas of cognitive processes, and developing batteries to assess cognitive dysfunction in psychopathology as treatment-related variables.
4. Composite understanding of professional personnel, as evidenced by peer-reviewed publications and/or federally funded grants, of the nature and implications of cognitive deficits in schizophrenia.
5. Composite expertise of professional personnel in convening and organizing meetings with experts and opinion leaders and creating associated publications in complex areas related to clinical neuroscience.
6. Composite experience of professional personnel in managing large, multi-center clinical trials providing data in support of FDA-accepted New Drug Applications.
7. Composite experience of professional personnel in conducting double-blind augmentation trials to enhance cognition or reduce negative symptoms in schizophrenia.

C. FACILITIES AND RESOURCES

5

Adequacy and availability of the facilities and resources necessary for conducting the work to be proposed, including office space, computers, phone lines, and other equipment, in order to successfully implement the requirements of the proposed work.

TOTAL POINTS-----100

* SAMPLE STAFF LOADING CHART (referenced in B.1.a. above)

The offeror should provide a detailed staff loading chart for each component, identifying all staff who will participate in the coordinating center(s) (including individuals not paid from this Contract). This should be provided in a tabular format, and must include the name of the individual, the task to be performed, the percent of the individual's total effort to be spent on that task for the Contract, how much of that percent effort will be paid for by the Contract (i.e., if an individual will spend 20% of total effort on a task, and the Contract will pay for half of this, the Contract Support Percentage would be 10%), and estimated total hours per year for that individual and that task. For example (assuming a 40 hr work week and 50 weeks worked per year):

Name	Task	% Effort	Contract %	Total hrs/yr
Mary Roe	Monitor sites	50%	50%	1000
John Doe	Secretary	20%	10%	200

III. PAST PERFORMANCE

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offerors, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offerors' likelihood of success in performing the acquisition requirement as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's businlike-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

IV. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions(s) and period(s). In accordance with FAR Clause 52.217-5, Evaluation of Options (July, 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise any option.

V. HUBZONE SMALL BUSINESS CONCERNS

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, incorporated by reference into this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

VI. OFFERS FROM SMALL DISADVANTAGED BUSINESS FIRMS:

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Attachment 5, RFP References, offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23, which can be found on-line at <http://www.arnet.gov/far/>

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment. **AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.**

VII. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

This factor entitled "Extent of Small Disadvantaged Business Participation" shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:

<http://www.sba.gov/size>

The Department of Commerce website for the annual determination is:

<http://www.arnet.gov/References/sdbadjustments.htm>.

Offerors shall include with their offers, SDB targets, expressed as percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Technical Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the “Small Business Subcontracting Plan,” if it is required by this solicitation.

SDB participation will not be numerically scored, but the Government’s conclusions about overall commitment and realism of the offeror’s SDB Participation targets will be used in determining the relative merits of the offeror’s proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror’s Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror’s plan provided with the business proposal (see format for plan provided below). The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

NOTE: The “SDB Participation Plan” is not to be confused with the “Small Business Subcontracting Plan” referenced in attachment 4, under “Just in Time.”

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Realism of the proposal
- (e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation.
- (f) Extent of participation of SDB concerns in terms of the value of the total acquisition

Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

OFFERORS - PLEASE COMPLETE THE PLAN BELOW AND INCLUDE IT IN THE TECHNICAL PROPOSAL

Small Disadvantaged Business Participation Plan

1. The extent of an Offeror’s commitment to use SDB concerns.

Directions: Commitment should be as specific as possible, i.e., SDB concerns are specifically identified, subcontract arrangements are already in place, letters of commitment are attached to the SDB plan, etc. Specific SDB concerns must be identified with points of contact and phone numbers. Enforceable commitments will be weighted more heavily than non-enforceable ones. Targets expressed as percentage of total contract value for each SDB participating will be incorporated into and become part of any resulting contract. The extent of participation of all SDB concerns in terms of the value of the total acquisition must be identified. NOTE: Additional weight will not be given simply for higher percentages of work going to SDBs if that work is deemed unnecessary to the requirements of the SOW or, unnecessarily elaborate or frivolous and, included merely to boost the appearance of SDB participation.

RESPOND HERE

2. The complexity and variety of the work SDB concerns are to perform.

Directions: Greater weight will be given for arrangements where the SDB shall be performing a greater variety of work, and work of greater complexity.

RESPOND HERE:

3. Fairness, reasonableness, and realism of costs proposed by SDBs for the work they will perform.

Directions: Provide information regarding how the Offeror determined that the SDB costs are fair and reasonable. NOTE: DO NOT provide actual costs, but rather the process that you followed to ensure reasonable costs, i.e. competition, negotiation, discussions, etc.

RESPOND HERE:

4. Past performance of the Offeror in complying with subcontracting plans for SDB concerns.

Directions: An Offeror with an exceptional record of participation with SDB concerns will receive a more favorable evaluation than another whose record is acceptable. Please explain your track record in compliance with subcontracting plans for SDB concerns.

RESPOND HERE:

VIII. HUMAN SUBJECTS EVALUATION - If Option Item Two (2) is exercised

1. This research project involves human subjects. NIH policy requires:

a. Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIMH that a designated exemption is appropriate.

If concerns are identified you will be afforded the opportunity to further discuss and/or clarify your position during discussions and in your Final Proposal Revision (FPR). If, after discussions, concerns still exist, your proposal may not be considered further for award.

b. Data and Safety Monitoring

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work for the solicitations specific requirements for data and safety monitoring.

The NIMH will evaluate the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis.

If the information provided about Data and Safety Monitoring is determined to be inadequate, you will be afforded the opportunity to further discuss and/or clarify your plan during discussions and in your Final Proposal Revision (FPR). If after discussions, the plan is considered inadequate, your proposal may not be considered further for award.

2. Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for Phase III clinical trials, it is required that all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic

groups, including subgroups if applicable, unless the Government has specified in the Statement of Work that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups.

Where the offeror determines that inclusion of women and minority populations is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIMH will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify, or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

3. Children

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are scientific and ethical reasons not to include them.

The offeror's proposal must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. If the offeror determines that exclusion of a specific age range of child is appropriate, the proposal must also address the rationale for such exclusion.

If the information about the inclusion of children is absent or considered inadequate, you will be afforded the opportunity to further discuss, clarify or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

Attachment 4
INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

A. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (reference attachment 5), 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 541720.
- (2) The small business size standard is 5 million.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

B. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 30, 2002.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement, completion type contract with a period of performance of one (1) base year consisting of twenty-four (24) months, and, two (2) option years consisting of twelve (12) months each and that incremental funding will be used [see Attachment 4, Business Proposal Instructions].

C. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

D. 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:

Contracting Officer
Contract Management Branch
NIMH, NIH
6001 EXECUTIVE BLVD, Room 6107
BETHESDA MD 20892-9603

- (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)

E. HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

- (a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).
- (b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.
- (c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.
- (d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.
- (e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor. (End of clause)

2. GENERAL INSTRUCTIONS TO OFFERORS

A. INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions. In addition, the Offeror should mark each page of data it wishes to restrict from public disclosure with the following statement, "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal."

(1) Contract Type and General Clauses

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the cover letter to this Request for Proposal package. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in Attachment 5.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in Attachment 5.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Attachment 5, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

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 must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment 5, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS). However, the technical proposal should **NOT** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. 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.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Attachment 3 this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) [see information at the following website: <http://oma.od.nih.gov/ms/privacy/>], 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.

(10) Selection of Offerors

- a) The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or

written discussions will be conducted with all offerors in the competitive range.

While it is NIMH's policy to conduct discussions with all offerors in the competitive range, NIMH reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

(11) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures

must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
 - 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
 - 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
 - 4) the Institution will otherwise comply with the regulations.

(12) Institutional Management of Conflicting Interests

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions

should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
- (ii) monitoring of research by independent reviewers;
- (iii) modification of the research plan;
- (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
- (v) divestiture of significant financial interests; or
- (vi) severance of relationships that create actual or potential conflicts of interests.

- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(13) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(14) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate

information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- (1) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- (2) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- (3) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- (4) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- (5) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).
- (6) Instructions To Offerors--Competitive Acquisition [Far Clause 52.215-1 (May 2001)] Alternate I (October 1997).

3. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

A). **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal

indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

B). Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(Reference Attachment 5 - Form of other support)

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

C). **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

D). **Past Performance Information**

Offerors shall submit the following information as part of their technical proposal.

a) A list of the contracts completed during the past three years and all contracts currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.
- c) List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

E). Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.

F). Technical Evaluation

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Attachment 3).

G). Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

H). Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.

- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

I). Information Technology Systems Security

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site:

<http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html>

J). GOVERNMENT NOTICE FOR HANDLING PROPOSALS

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE OF HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 352.215-1.

- (a) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:
 - (1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;
 - (2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;
 - (3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

- (4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and
- (5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.
- (b) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

K). Human Subjects

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

- a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.
- b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.
- c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.
- d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination

of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, (telephone: 301-496-7014*), is recommended.

- e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR* an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.
- f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at <http://ohrp.osophs.dhhs.gov/>*

L). **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the

design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at <http://ohsr.od.nih.gov/cbt/>. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

M). Inclusion of Women and Minorities in Research Involving Human Subjects

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of clinical research adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human

disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research"

(<http://www.nih.gov/news/crp/97report/execsum.htm>).

The revisions relating to NIH defined Phase III clinical trials and require: a) all proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences. The proposal must also include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include an analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

In addition, the proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants

The form entitled, "Targeted/Planned Enrollment Table," should be used when preparing your response to the solicitation requirements for inclusion of women and minorities. (Reference Attachment 5).

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See attachment 3 of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other

Attachments of the RFP) entitled, "Inclusion Enrollment Report," shall be in reporting in the resultant contract. (Reference Attachment 5).

N). Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

Offerors may also obtain copies from the contact person listed in the RFP.

O). Data and Safety Monitoring in Clinical Trials

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

P). **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of

new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>.

Q). NIMH Data and Safety Monitoring in Clinical Trials

In June 1998, the National Institutes of Health (NIH) issued a policy on data and safety monitoring (<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>) that requires oversight and monitoring of all intervention studies to ensure the safety of participants and the validity and integrity of the data. The policy further elaborates that monitoring should be commensurate with risks and with the size and complexity of the trials. The NIH already requires data and safety monitoring, generally in the form of Data and Safety Monitoring Boards (DSMBs), for phase III clinical trials. For earlier trials (phase I and II), a DSMB may be appropriate if the studies have multiple clinical sites, are blinded (masked), and/or employ particularly high-risk interventions or vulnerable populations.

The following provides further guidance for monitoring of phase I and II trials. This guidance does not take the place of the Institutional Review Board (IRB) guidelines, Food and Drug Administration (FDA) requirements, or special NIH guidelines (e.g. NIH Guidelines for Research Involving Recombinant DNA Molecules).

R). Monitoring Plan

For phase I and II clinical trials, investigators must submit a general description of the monitoring plan as part of the research application. This plan will be reviewed by the scientific review group and any comments or concerns will be included as an administrative note in the summary statement. In addition, before the trial begins, a

detailed monitoring plan must also be included as part of the protocol, and submitted to NIMH and the local IRB. Oversight by NIMH staff must ensure that monitoring plans are in place for all phase I and II trials. At a minimum, all monitoring plans must include a description of the reporting mechanisms for serious and unexpected adverse events, as well as any other unanticipated problems involving risks to subjects or others, to the local IRB, the FDA (as appropriate), and those monitoring data and safety. Investigators must ensure that the NIMH Project Officer is informed of any actions taken by the IRB as a result of such adverse events. The decision for any NIMH action lies with the Institute Director.

The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the trial. For multi-site phase III clinical trials, NIH requires the establishment of an independent DSMB. The DSMB should be composed of experts in scientific disciplines needed to interpret the data and ensure participant safety, or have these experts available if warranted. Other requirements are detailed in the NIH policy notice cited above. If the DSMB notes serious and unexpected adverse events, or any other unanticipated problems involving risks to subjects or others, related to the study, IRBs at all sites should be notified in a timely fashion. This can be done via a letter from the DSMB Chair/Administrator to the PI (or Coordinating Center) for distribution to local IRBs. This letter from the DSMB should also note whether serious adverse events (SAEs) were discussed, whether they appeared to be related to the trial, and whether the trial was approved to continue.

In phase I and II trials, a number of factors influence risk. A phase I trial or a new intervention (e.g., novel psychosocial treatment, drug or other somatic treatment) may involve increasing risk to a small number of participants as the intervention is escalated in intensity or dosage. For phase II trials, there is sometimes information about risks determined from pilot studies or work with normals, but risk may be increased as more participants are involved and the untoward effects may be confounded by the disease process. In clinical trials involving potentially high risks, special populations, blinded and/or multisite designs, investigators must consider additional monitoring and safeguards. Occasionally, phase I or II trials have established formal Data and Safety Monitoring Boards.

For many phase I and phase II trials, however, independent DSMBs may not be necessary or appropriate when the intervention is low risk. In most low risk, small-scale NIMH-supported studies, the Principal Investigator would be expected to perform the monitoring function as part of the general oversight and scientific leadership of the study. Such PIs must comply with prompt reporting of study-related toxicity and any unanticipated problems involving risks to subjects or others. In some instances, the study investigator or the IRB may determine that an independent individual may be needed for monitoring. In studies of small numbers of subjects, untoward effects may more readily become apparent through close monitoring of individual patients, while in larger studies risk may be assessed through statistical comparisons of treatment groups.

All institutions now carrying out an NIMH-funded multi-site phase I or II clinical trial must establish a data monitoring system (Central Reporting Entity – CRE). In

accordance with 45 CFR part 46, serious and unexpected adverse events, as well as any other unanticipated problems involving risks to subjects or others, must be reported to the local IRB associated with the trial. If considered related to the trial, such events must also be reported to appropriate institutional officials and the Office for Human Research Protection (OHRP). In multi-site trials, one site may take on this latter responsibility, and report back to other PIs. Local investigators are to report SAEs to their IRB, and any Coordinating Center and/or CRE. If SAEs are considered related to the trial, then they must also be reported to IRBs at other participating sites.

The CRE for a particular trial will submit summary reports of the discussions of serious and unexpected adverse events (as well as any unanticipated problems involving risks to subjects or others) that are found to be related to the trial to the local IRBs associated with the trial, the NIMH Project Officer, the FDA (as appropriate) and OHRP. Each summary report should contain the following information:

A statement that review of data and outcomes (as appropriate) across all centers took place on a given date.

A summary of the review of the cumulative serious and unexpected adverse events (as well as any other unanticipated problems involving risks to subjects or others) that are related to the trial. This should include such events reported from all participating sites without specific disclosure by treatment arm, unless safety considerations require such disclosure.

The CRE recommendations for modification to the protocol

The frequency of summary reports to NIMH may depend on the nature of the trial. Additional NIH guidance regarding Data and Safety Monitoring and Reporting Adverse Events are found in the NIH Guide for Grants and Contracts Announcements at the following web sites: <http://grants.nih.gov/grants/guide/notice-files/not99-107.html> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>.

- S). **Research Patient Care Costs – Applicability of this clause to be determined prior to exercise of option item.**
- (a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.
 - (b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

- (c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payers (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.
- (d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.
- (e) Only those charges not recoverable from third party payers or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

4. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic 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.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal (Reference Form 2043 Attachment 5):

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

- a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the

information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

(4) **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. Materials and services.

Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

- (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).
- (2) *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or

purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. Direct Labor.

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

**C. Costs
Indirect Costs.**

Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

Other Costs. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

D. Royalties.

If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:

- (1) Name and address of licensor.
- (2) Date of license agreement.
- (3) Patent numbers.

- (4) Patent application serial numbers, or other basis on which the royalty is payable.
- (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
- (6) Percentage or dollar rate of royalty per unit.
- (7) Unit price of contract item.
- (8) Number of units.
- (9) Total dollar amount of royalties.
- (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

E. Facilities Capital Cost of Money.

When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)
(This is applicable if you are a commercial organization.)

- (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.

F. Formats for Submission of Line Item Summaries

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Attachment 5). For each

separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at:

<http://rcb.nci.nih.gov/forms/cpi.htm>

- G. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
- H. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

****** (Please note that data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.) ******

I. Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

J. Salary Rate Limitation in Fiscal Year 2002*

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) 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, patent 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. 107-116 applies only to Fiscal Year 2002 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. 107-116 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."

***Information regarding the FY-2002 rate can be found at:**

<http://www.opm.gov/oca/02tables/ex.pdf>

(5). Other Administrative Data

a) **Property**

- (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:
 - (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
 - (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **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.

c) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

- (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.
(End of provision)

(d). **Subcontractors**

If subcontractors are proposed, please include a complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

(e). **Travel Costs**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

5. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

A. Travel Policy.

The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

B. Annual Report.

The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a copy of their most recent annual report as a part of their final proposal revision.

C. Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. All offerors included in the competitive range will be required to submit a copy of Section K with their final proposal revision.

D. Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

INSTRUCTIONS

- a) 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. All offerors [included in the competitive range will be required to/as a part of their business proposal] will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) 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).

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

EVALUATION

- 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.

FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY
REFERENCE

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

E. Small Business Subcontracting Plan.

The offeror's "Small Business Subcontracting Plan" shall **not** be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit **an acceptable** subcontracting plan which will be incorporated as part of the contract upon award. The "Small Business Subcontracting Plan" is not to be confused with the "SDB Participation Plan" in attachment 3, item VII, which *is* submitted with the business proposal and evaluated before the CO sets the competitive range.

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable 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, Attachment to this RFP is an example of such a plan.

- 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 Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses 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 Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned 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, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

- (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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses 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.

F. Cost/Pricing Information

The offeror's business proposal shall include the basic cost/pricing information specified in Section L.2.c. of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism and financial responsibility. [The information may also include submission and certification of cost or pricing data.]

1. General Instructions

A. You must provide the following information on the first page of your pricing proposal:

- (1) Solicitation, contract, and/or modification number;
- (2) Name and address of offeror;

- (3) Name and telephone number of point of contact;
 - (4) Name of contract administration office (if available);
 - (5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
 - (6) Proposed cost; profit or fee; and total;
 - (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
 - (8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
 - (9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
 - (10) Date of submission; and
 - (11) Name, title and signature of authorized representative.
- B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
- C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

- (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
 - (2) The nature and amount of any contingencies included in the proposed price.
 - D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
 - E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
 - F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
 - G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
 - H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.
- G. 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 paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries 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.

I. 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.

ATTACHMENT 5 TO STREAMLINED RFP No. NIMH-02-DM-0006**APPLICABLE RFP REFERENCES**

- A. The following general clauses and provisions are applicable to this specific RFP depending on your organizational status: Negotiated Cost-Reimbursement Contract with an Educational Institution, Negotiated Cost-Reimbursement Contract with a Non-Profit or, Negotiated Cost-Reimbursement Research and Development Contract. The clauses are located in the file "General Clauses" at URL: <http://amb.nci.nih.gov/clauses/clauses.html> .
- B. The following items are applicable to this specific RFP and are located in the file entitled (except as noted) FORMS, FORMATS AND ATTACHMENTS at: <http://ocm.od.nih.gov/contracts/rfps/Forms1.htm> .

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

1. Technical Proposal Cover Sheet
2. Summary of Current and Proposed Activities
3. Technical Proposal Cost Information
4. Government Notice for Handling Proposals (as applicable)

SUBMIT WITH BUSINESS PROPOSAL:

1. Proposal Summary and Data record, NIH-2043, with every copy of business proposal.
2. Business Proposal Cost Information (Use form entitled "Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours" which is located at <http://ocm.od.nih.gov/contracts/rfps/FORMS1.HTM>)
3. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original
4. Representations and Certifications - Negotiated Contract, only one completed and signed copy

OTHER - TO BE SUBMITTED LATER, "JUST IN TIME":

1. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, as required by the CO
2. DHHS Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Subcontracting Plan, to be submitted as directed by the CO

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

1. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
2. NIH 2706, Financial Report of Individual Project/Contract, the form with instructions
3. Procurement of Certain Equipment, NIH(RC)-7
4. NIH Women and Minority Policy
5. Protection of Human Subjects Assurance/Identification/Certification/Declaration, OF310
6. NIH Policy for the Inclusion of Children as Participants In Research Involving Human Subjects

7. Research patient Care Costs, NIH(RC)-11
8. Annual Technical Progress Report Format for Each Study
9. NIH Policy for the Inclusion of Children as Participants in Research Involving Human Subjects.
10. Small Business Subcontracting, Form 294
11. NIMH Publication By-Lines

C. The Sample Contract Format for R&D Cost Reimbursement contracts is located in the file entitled, RFP FORMS, FORMATS AND ATTACHMENTS at <http://ocm.od.nih.gov/contracts/rfps/Forms1.htm> .

D. Supplemental information pertaining to Sections G, H and I of the Sample Contract Format include the following:

1. Section G, “Contract Administration Data” paragraph entitled “Invoice Submission” is amended to read as follows:

Invoice Submissions/Contract Financing Request

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a “proper” payment request pursuant to FAR 32.9. Invoice/financing requests shall be submitted as follows:

a. An original and two copies to the following designated billing office:

If hand-delivered or delivery Service

Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health
6001 Executive Boulevard
Room 6107, MSC 9603
Rockville, Maryland 20852

If using U.S. Postal Service

Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health
6001 Executive Boulevard
Room 6107, MSC 9603
Bethesda, Maryland 20892-9603

Inquiries regarding payment of invoices should be directed to the designated billing office (301) 443-2696.

b. At a minimum, the Contractor agrees to include the following information on each invoice:

1. Contractor’s name and invoice date,
2. NIMH's Contract number, or other authorization for delivery of property and/or services
3. Description, cost or price, and quantity of property and/or services actually delivered or rendered,
4. Shipping and payment terms,

5. Other substantiating documentation or information as required by the contract (see paragraph G.3.c, "NIMH Supplemental Billing Instructions" below,
6. Name where practicable, title, phone number, and complete mailing address of responsible official to whom payment is to be sent.

c. NIMH Supplemental Billing Instructions

1. The contractor agrees to provide, as applicable, a detailed breakdown on each invoice of the following cost categories:

- (a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
- (b) Fringe Benefits - Cite rate and amount
- (c) Overhead - Cite rate and amount
- (d) Materials & Supplies - Include detailed breakdown.
- (e) Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate.
- (f) Consultant Fees - Identify individuals and amounts.
- (g) Subcontracts - Attach subcontractor invoice(s). (Should be in same format and detail as required of the Prime Contractor.) Include COA Letter Number if applicable.
- (h) Equipment - Cite authorization and amount.
- (i) G&A - Cite rate and amount.
- (j) Total Cost
- (k) Fee (if applicable)
- (l) Total Cost & Fee

Monthly invoices must include the cumulative total expended to date, adjusted (as applicable) to show any amounts suspended or disallowed by the Government.

2) The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

2. Section G, "Contract Administration Data" the paragraph entitled "Post Award Evaluation of Contractor Performance" is amended to add:

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web Site for review and comment by completing the registration form that can be obtained at the following address:

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

3. Section H “Human Subject” is amended to read as follows:

Human Subjects

Research involving human subjects shall not be conducted under this contract until the final protocol has been approved by, both your local Internal Review Board (IRB) and the NIMH, written notice of such approval has been provided by the NIMH Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the Optional Form 310.

4. Section H “Options”

Unless the Government exercises its option pursuant to the Option Clause set forth below, the contract will consist only of years 1 through 5. Pursuant to clause 52.217-9 set forth below, the Government may, by unilateral contract modification, require the Contractor to perform additional Years of the Statement of Work. If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in Article B.

Option to Extend the Term of the Contract (Mar 2000)

The Government may extend the term of this contract by written notice to the Contractor within 10 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days. The preliminary notice does not commit the Government to an extension.

If the Government exercises this option, the extended contract shall be considered to include this option clause.

The total duration of this contract, including the exercise of any options under this clause shall not exceed 10 years.

5. Section H “Required Education In The Protection Of Human Research Participants”

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) Announcement dated June 5, 2000 at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

6. Section H “Data And Safety Monitoring In Clinical Trials”

The contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

The contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring PLAN shall be established and approved prior to beginning the conduct of the clinical trial.

7. Section I Rights in Data, Patents, etc.

Section I of the resulting contract will contain the applicable “Patents, Data, and Copyrights, provisions and clauses for FAR Part 27 (FAR 52.227).

Attachment 6
PROPOSAL INTENT RESPONSE SHEET

RFP NIMH-02-DM-0006

PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE **March 12, 2002**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

DO INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING:

DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

TYPED NAME AND TITLE: _____

INSTITUTION: _____

SIGNATURE: _____

TELEPHONE NO.: _____

EMAIL ADDRESS: _____

FAX NO. _____

DATE: _____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)

RETURN TO: National Institute of Mental Health, NIH
Contracts Management Branch
Attn: Suzanne Stinson
Neuroscience Center Bldg., Rm. 6107
6001 Executive Blvd. (MSC 9603)
Bethesda, MD 20892-9603
FAX (301) 443-0501
ss704b@nih.gov

