

November 10, 2004



Request for Proposals

An In Vitro Biological Assay Facility for Screening
Compounds in Cellular Models of Spinal Muscular Atrophy

RFP No: JL-31404-1

In support of:

**The National Institute of Neurological Disorders and Stroke (NINDS)
The SMA Project: A Collaborative Program to Accelerate Therapeutics
Development for Spinal Muscular Atrophy**



*An SAIC-managed program to support the NINDS, National Institutes of Health,
Department of Health and Human Services*

SAIC Prime Contract No.: N01-NS-3-2356



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1. Introduction

The [National Institute of Neurological Disorders and Stroke](http://www.ninds.nih.gov) (NINDS) launched The SMA Project: A Collaborative Program to Accelerate Therapeutics Development for Spinal Muscular Atrophy (SMA) in September 2003. The program aims to identify and rapidly develop a treatment for SMA, a paralyzing neurodegenerative disease of childhood. More information about the program can be found at <http://www.SMAProject.org>.

This purpose of this solicitation is to identify a facility to test small molecules in existing cell-based assays of SMA. In addition, the facility should be able to perform a variety of in vitro bioactivity assays on specimens received from other SMA Project facilities.

1.1 Spinal Muscular Atrophy and the SMA Project

SMA is an autosomal recessive neuromuscular disease with variable severity ranging from limited motor neuron loss and normal life expectancy (type III) to progressive infantile paralysis and death (type I). All forms of SMA are caused by loss of function of the survival motor neuron 1 gene (*SMN1*). Reduced levels of SMN protein result in the specific death of motor neurons but not of other cell types in which the gene is normally expressed. *SMN2*, a nearly identical gene, is present in variable copy numbers and produces low levels of full-length SMN protein. SMA disease severity inversely correlates with the number of copies of *SMN2*; patients with higher *SMN2* copy numbers have a less severe form of the disease than patients with a low copy number. This suggests that therapeutic strategies to increase the level of *SMN2* produced in motor neurons may compensate for loss of *SMN1* and result in an improved clinical outcome for SMA patients.

The *SMN2* gene differs from *SMN1* by a single nucleotide polymorphism. This sequence change causes alternative splicing so that *SMN2* produces two different transcripts. These transcripts differ by the presence or absence of exon 7 and only a fraction of the transcripts produced by the *SMN2* gene are full length. Thus, an increase in the level of full-length *SMN* may be achieved either by increasing *SMN2* promoter activity or by influencing alternative splicing to produce a higher fraction of full-length transcripts.

A number of small molecules have been identified that increase *SMN2* expression in cell culture, including phenylbutyrate, valproic acid, and aclarubicin. These appear to act by increasing *SMN2* promoter activity and/or altering the splicing of the *SMN2* message, which leads to increased levels of full-length *SMN2* RNA. To maximize the chances that members of these and other similarly active compound classes might improve the condition of SMA patients, the SMA Project will undertake to further develop and optimize such compounds for clinical testing.

The SMA Project is establishing a Lead Development Team that will identify candidate compounds for preclinical testing. These compounds may come from small molecule screens conducted by the SMA Project or may be submitted for consideration by the research community. Through service contracts,¹ the SMA Project seeks to establish the necessary services for the Lead Development Team to identify the most favorable compounds, direct their chemical optimization, and determine their potential for treatment of SMA (**Figure 1**). Three types of contract facilities will conduct (1) medicinal chemistry optimization through synthesis of small molecule analogs of active compounds, (2) testing of the bioactivity of compounds in a battery of in vitro assays relevant to SMA (this RFP), and (3) determination of the efficacy of compounds in in vivo mouse models of SMA. (Copies of SMA Project Solicitations for the medicinal chemistry facility and the mouse testing facility, as well as previous RFPs, are available on the SMA Project website, <http://www.SMAProject.org>).

¹ Awards will be made in the form of contracts. SMA Project contracts will be “subcontracts” to SAIC to support the NINDS. However, for simplicity, in this RFP, the term “Contractor” is used to refer to an organization that will serve as an SMA Project in vitro testing facility; the term “Subcontractor” refers to any organization that reports directly to the organization that is serving as the SMA Project in vitro testing facility.

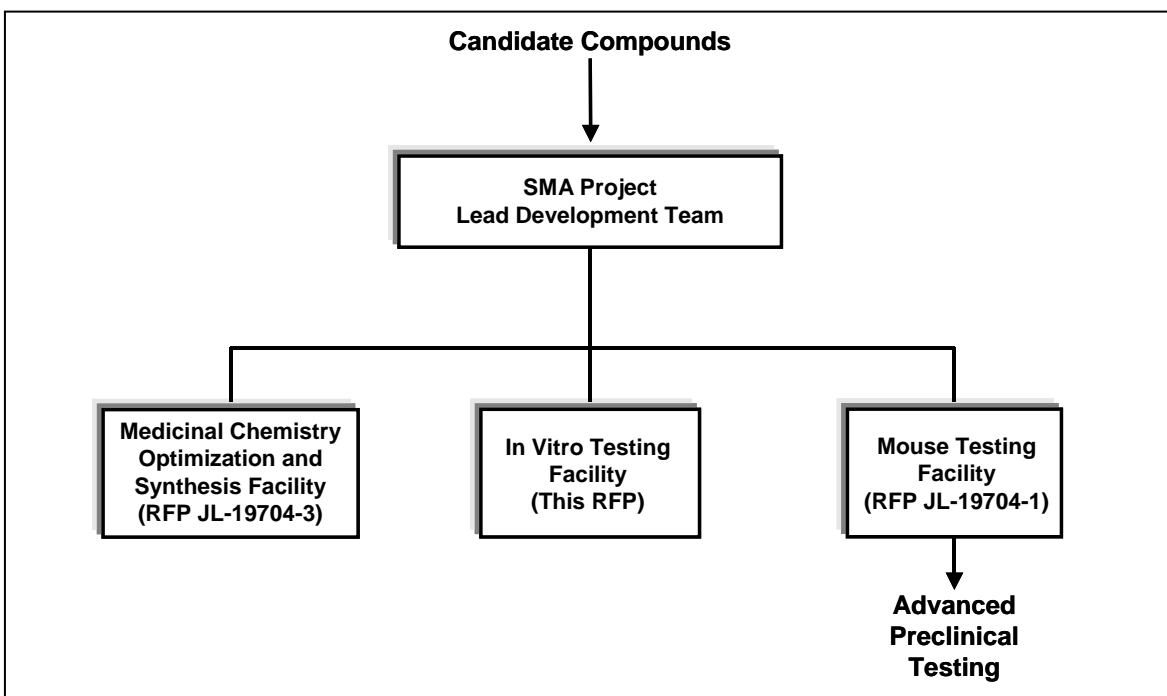


Figure 1 – Developmental Overview for SMA Project

This RFP is intended to identify a service facility for testing bioactivity of small molecules in in vitro models of SMA. This resource will be a critical component of the SMA Project effort to identify and develop candidate compounds for clinical testing.

1.2 Schedule for This Solicitation

Key dates related to this RFP are as follows:

- | | |
|--|--------------------|
| • Offeror's ² Intent to Submit Form Due | December 14, 2004 |
| • Proposals Due | December 21, 2004 |
| • Review of Proposals and Supporting Documentation | ~January 14, 2005 |
| • Initiation of Negotiations | ~February 15, 2005 |
| • Anticipated Start Date | ~March 15, 2005 |
| • Notification of Unsuccessful Offerors | ~April 15, 2005 |
| • Anticipated End Date | ~September 1, 2007 |

1.3 Compliance Requirements for Offerors

Offerors with facilities outside the continental United States must include documentation to demonstrate that they are capable of consistently receiving within 48 hours both mouse and human biological samples that were shipped from a facility within the continental United States.

Only Offerors that meet criteria for federal funding eligibility (e.g., the continued ban on funding of human embryo research (45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g-1(b))) will be considered for award under this RFP.

2. Focus of This Solicitation

Proposals are requested for a service facility with capabilities for implementing and conducting a defined battery of bioactivity screening assays in cellular models of SMA to further preclinical

² "Offerors" are the institutional entities that respond to an RFP.

development of candidate small molecule compounds for the treatment of SMA. The following sections (2.1-2.2) describe the required capabilities of Offerors and components of the Statement of Work (SOW) required for successful performance of this Contract.

Offerors should note that the SMA Project may make more than one award for a facility for in vitro bioactivity screening of small molecule therapeutics. Ideally, the Offeror would possess all of the capabilities requested in this RFP, but offers are invited from organizations with a subset of the required capabilities if they are highly expert in particular areas.

Successful Offerors (i.e., Contractors) will work closely with experts selected and compensated by the SMA Project to rapidly implement a battery of existing cellular models and assays in the In Vitro Biological Assay Facility. Successful Offerors will not be required to develop assays de novo. In addition, Offerors will not be expected to negotiate for the existing assays; this will be done by the SMA Project. The specific models and assays to be implemented will be identified or developed by the SMA Project; it is anticipated that they will employ cell lines and endpoints similar to those described in Section 2.1. Offerors must demonstrate that they have a successful history of importing and utilizing established cell lines and assays.

Successful Offerors will be participants in the SMA Project's iterative process for developing small molecule therapeutics (**Figure 2**). Under the direction of the SMA Project Lead Development Team, the In Vitro Biological Assay Facility shall screen candidate small molecules identified by the SMA Project for bioactivity in the battery of cellular models and assays. This is **not** a solicitation for high-throughput screening. Successful Offerors can expect to test several hundred compounds per year at their facility. For efficiency, it is likely that the SMA Project will designate one assay as a primary screening assay and that only select compounds will be tested in the complete assay battery.

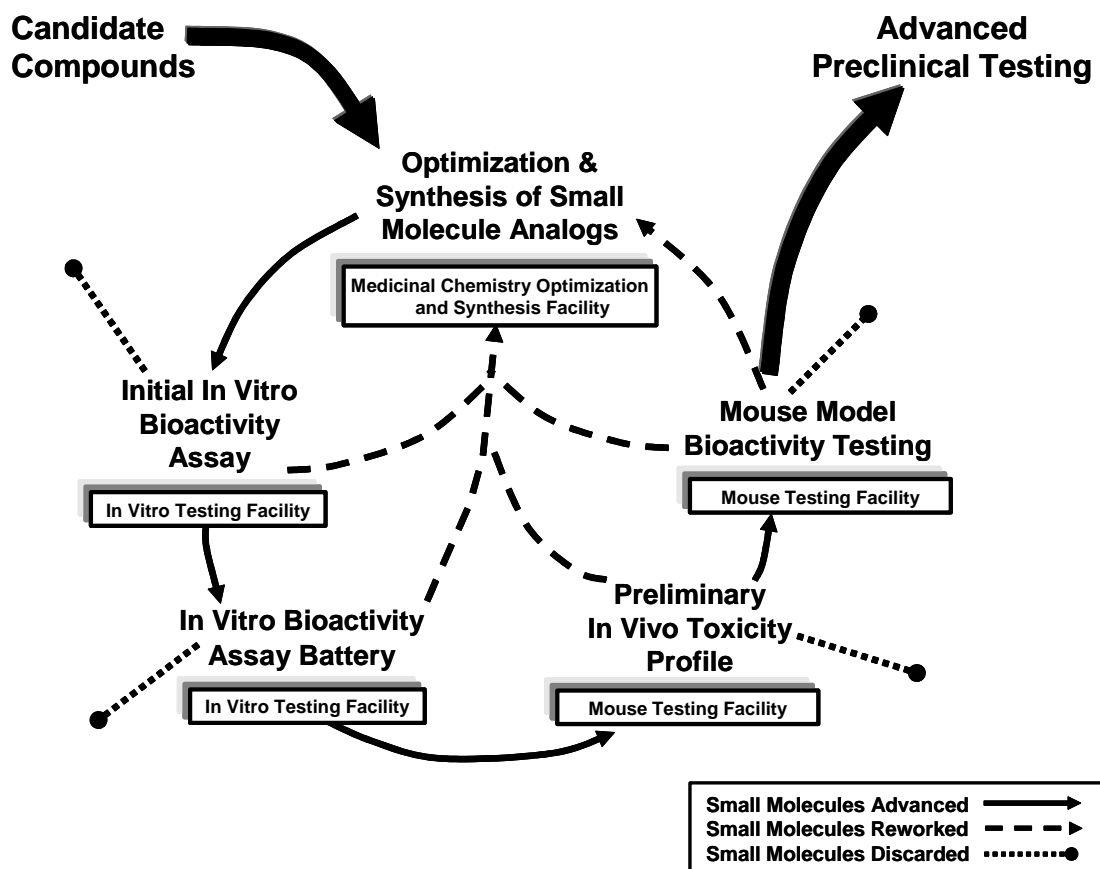


Figure 2 – Flow Plan for Development of SMA Project Small Molecule Therapeutics

The SMA Project anticipates that the battery of assays assembled under this program will be valuable to the entire SMA research community, and successful Offerors will have the option to provide screening services using these assays to investigators outside the SMA Project.

The screening process will require communication and collaboration between the different SMA Project contract facilities to avoid unnecessary delays in the overall process. Therefore, Offerors must demonstrate that they have a successful history of efficiently exchanging data and material with outside facilities.

Efficient time lines are critical to the success of the SMA Project's accelerated program for therapeutics development. In preparing time lines for proposals, Offerors should note at what stage(s) their proposed services/products would be required in the SMA Project's Flow Plan (Figure 2). Of note, the end date for all facility contracts will be ~September 1, 2007.

2.1 Cellular Models and Assays

The Offeror will be required to implement existing cellular models of SMA for in vitro screening of candidate compounds. The cellular models have not been finally selected but may include those that have already been established by other investigators to study SMA and may also include the following:

- Modifications of the established models,
- New models that become available during the course of the contract period, and
- Models already established in the Offeror's facility that are proposed for consideration by the Offeror.

Cell Types

The following cell types are examples of those that might be employed in models selected for implementation in the In Vitro Biological Assay Facility:

- The immortalized **NSC34 motor neuron/neuroblastoma fusion cell line** described in Cashman et al., 1992 [1]. This cell line, which retains the characteristics of motor neurons, has been used to demonstrate that valproic acid [2] is able to increase the activity of the *SMN2* promoter. It has also been used to show that aclarubicin increases retention of exon 7 in an *SMN2* minigene transcript [3].
- **Established human fibroblast cell lines** that have been derived from SMA patients, SMA carriers, and healthy subjects. Existing fibroblast lines have been used to demonstrate that aclarubicin [3], phenylbutyrate [4], valproic acid [2,5], and other compounds are effective at increasing levels of the *SMN2* RNA and protein and increasing exon 7 incorporation into full-length *SMN2* mRNA.
- **Differentiated mouse and human embryonic stem (ES) cell cultures** that are currently being developed by the SMA Project under RFP JL-07204-1: [Motor Neuron Cellular Models of Spinal Muscular Atrophy \(SMA\)](#). Protocols for directing differentiation of ES cells into spinal progenitor cells and motor neurons are described in Wichterle et al., 2002 [6].

In addition to performing assays using cell lines similar to those described above, measurement of SMN RNA or protein levels in biological specimens provided by the SMA Project Mouse Testing Facility and other SMA Project investigators may also be required. Anticipated specimens include blood samples and other tissues derived from mouse models of SMA. If such testing is required under the contract, the biological specimens will be provided by the SMA Project.

SMA Project experts work closely with Offerors to assist in implementation of the specific cellular models selected by the SMA Project. Offerors should demonstrate that they have the necessary capability to successfully implement the types of cellular models they propose to

conduct at the In Vitro Biological Assay Facility. As noted in the beginning of this section, the SMA Project will accept offers from organizations with a subset of these capabilities if they are highly expert in particular areas.

Assay Endpoints

For in vitro screening of candidate compounds, the Offeror will be required to measure a number of assay endpoints. For example, assays will be designed to determine whether candidate compounds are effective at increasing levels of SMN RNA and protein and possibly motor neuron cell survival in the in vitro setting.

The following relevant endpoints have previously been used in SMA assays for compound screening. The specific assays selected by the SMA Project for implementation in the In Vitro Biological Assay Facility may address each of these endpoints. As noted in the beginning of this section, the SMA Project will accept offers from organizations with a subset of these capabilities if they are highly expert in particular areas.

- **Human *SMN2* gene promoter activity.** Effects of compounds on *SMN2* promoter activity have been assessed in cells carrying a β -lactamase reporter driven by the *SMN2* promoter [3]. An *SMN2* promoter assay has been used by Aurora (Vertex Pharmaceuticals) and FSMA to screen over 550,000 small molecules [7].
- **SMN protein level.** Levels of SMN protein have been assessed in cells and tissues by immunofluorescence staining [4], Western blot analysis [3,4,5], and immunoblot analysis [2]. Standardized ELISA methodologies are currently being developed by the SMA Project under the RFP JL-07604-1: A Protein Detection Kit for Quantifying Survival Motor Neuron (SMN) Protein.
- **Human *SMN2* mRNA levels.** Levels of full-length and truncated *SMN2* mRNA have been assessed in cells by semiquantitative PCR [3], quantitative PCR [5], and real-time quantitative PCR [4].
- **Survival of SMN-deficient cells.** A cell survival assay has been developed in a cell line in which the homologous *SMN* gene is disrupted and SMN protein levels are under the control of an inducible *SMN* cDNA construct [8].
- **SMN-positive gem counts.** Gems are SMN protein-containing subcellular particles. Gems have been detected by immunofluorescence microscopy in a variety of cell types [2,3,4,9].

SMA Project experts will work closely with the Offeror to assist in implementation and validation of the specific bioactivity assays selected by the SMA Project. Sufficient quantities of compounds for screening will be provided by the Chemical Optimization and Synthesis Facility, along with instructions regarding compound storage and handling for optimum safety and stability. Offerors should demonstrate that they have the necessary capability and experience to collaborate in assay implementation and validation, in receiving and handling chemical compounds, and in testing compounds in in vitro cellular assays.

2.2 Additional Assay and Support Services

As a participant in the SMA Project's iterative process for developing small molecule therapeutics (Figure 2), the In Vitro Biological Assay Facility will be required to perform assays on specimens received from other facilities and collaborate with other investigators. The Contractor may be required to issue subcontracts for highly specialized assays, as necessary.

The Offeror should propose methods to determine the level of SMN protein and RNA in biological specimens from animals, including blood and central nervous system (CNS) tissues. These

specimens will be provided by outside sources that include the SMA Project Mouse Testing Facility.

Offerors will demonstrate that they have experience in collaborating with other institutions. Specifically, Offerors will demonstrate the ability to conduct and accurately document frequent exchanges of data (preferably in electronic format) and materials (compounds, biological samples, and special supplies). Offerors should also demonstrate that they have successfully managed subcontracted work.

2.3 References

1. Cashman NR, Durham HD, Blusztajn JK, Oda K, Tabira T, Shaw IT, Dahrouge S, Antel JP. Neuroblastoma x spinal cord (NSC) hybrid cell lines resemble developing motor neurons. *Dev Dyn*. 1992 Jul;194(3):209-21.
2. Sumner CJ, Huynh TN, Markowitz JA, Perhac JS, Hill B, Coovert DD, Schussler K, Chen X, Jarecki J, Burghes AH, Taylor JP, Fischbeck KH. Valproic acid increases SMN levels in spinal muscular atrophy patient cells. *Ann Neurol*. 2003 Nov;54(5):647-54.
3. Andreassi C, Jarecki J, Zhou J, Coovert DD, Monani UR, Chen X, Whitney M, Pollok B, Zhang M, Androphy E, Burghes AH. Aclarubicin treatment restores SMN levels to cells derived from type I spinal muscular atrophy patients. *Hum Mol Genet*. 2001 Nov 15;10(24):2841-9.
4. Andreassi C, Angelozzi C, Tiziano FD, Vitali T, De Vincenzi E, Boninsegna A, Villanova M, Bertini E, Pini A, Neri G, Brahe C. Phenylbutyrate increases SMN expression in vitro: Relevance for treatment of spinal muscular atrophy. *Eur J Hum Genet*. 2004 Jan;12(1):59-65.
5. Brichta L, Hofmann Y, Hahnen E, Siebzehnrubl FA, Raschke H, Blumcke I, Eyupoglu IY, Wirth B. Valproic acid increases the SMN2 protein level: A well-known drug as a potential therapy for spinal muscular atrophy. *Hum Mol Genet*. 2003 Oct 1;12(19):2481-9.
6. Wichterle H, Lieberam I, Porter JA, Jessell TM. Directed differentiation of embryonic stem cells into motor neurons. *Cell*. 2002 Aug 9;110(3):385-97.
7. FSMA and Aurora Biosciences - A partnership to develop a drug to cure SMA (<http://www.fsma.org/aurora03.shtml>).
8. Wang J, Dreyfuss G. A cell system with targeted disruption of the SMN gene: functional conservation of the SMN protein and dependence of Gemin2 on SMN. *J Biol Chem*. 2001 Mar 30;276(13):9599-605.
9. Andreassi C, Patrizi AL, Monani UR, Burghes AH, Brahe C, Eboli ML. Expression of the survival of motor neuron (SMN) gene in primary neurons and increase in SMN levels by activation of the N-methyl-D-aspartate glutamate receptor. *Neurogenetics*. 2002 Mar;4(1):29-36.

3. Offerors Provide Information on Intent to Submit

Potential Offerors are strongly encouraged to complete the Intent to Submit form on the [Open Solicitations](#) page of the SMA Project website or to send an e-mail to smaproject-fd@saic.com.

4. Proposal Preparation Procedures

Before preparing a proposal, Offerors should read over this entire document and visit the SMA Project website (<http://www.SMAProject.org>) to learn more about the program and the nature of SMA Project contracts and task orders. Offerors should also review the Subcontract Agreement and the Representations and Certifications document, which are posted on the [Open Solicitations](#) and [Supporting Documentation](#) pages of the SMA Project website.

NOTE: Unlike previous SMA Project RFPs, there will only be one deadline for Proposals and all Supporting Documentation; pre-proposals will not be accepted or evaluated.

Proposals should only be submitted if the Offeror meets the Compliance Requirements for Offerors (Section 1.3).

To assist Offerors in assembling all the required documents, a Proposal Preparation Checklist has been included in Attachment A. *Note:* Items covered in Sections 4.1–4.5, 4.7, and 4.9–4.10 should be submitted on a CD in addition to paper copies.

4.1 Proposal Face Page

The face page of the proposal must contain the following items:

- Proposal Title
- Name of Offeror Institution
- Principal Investigator's First Name, Middle Initial, Last Name, and Degree(s)
- Principal Investigator's Signature
- Contracting Officer's First Name, Middle Initial, Last Name, and Degree(s)
- Contracting Officer's Signature
- Principal Investigator's Contact Information: mailing address, telephone number, fax number, e-mail address, and, if available, alternate telephone number and e-mail address.
- Contracting Officer's Contact Information: mailing address, telephone number, fax number, e-mail address, and, if available, alternate telephone number and e-mail address.
- The following statement "Response to An In Vitro Biological Assay Facility for Screening Compounds in Cellular Models of Spinal Muscular Atrophy, JL-31404-1."
- The following statement "This proposal complies with the Salary Rate Limitation pursuant to P.L. 108-199, and the Offeror certifies that no costs for independent research and development, to include any indirect costs have been claimed under this submission." (Please note the certification regarding IR&D applies only to commercial institutions. If IR&D costs are a part of your institution's indirect cost application that portion must be excluded for this proposal.)

4.2 Proposal Executive Summary

One-page limit. The proposal must contain an Executive Summary that demonstrates an understanding of the objectives/goals to be met, summarizes the Offeror's capabilities, and includes a summary of the Offeror's approach for providing in vitro biological assay screening for SMA. The Executive Summary will be forwarded to the SMA Project Steering Committee after review as part of the material that will be used to make a funding recommendation (see also Section 7.5).

4.3 Proposal Body

30-page limit inclusive of any figures, tables, and graphs. Please note that additional technical information can be included in an appendix to the proposal (see Section 4.5, Proposal Appendix: Standard Operating Procedures). The body of the proposal should contain, at a minimum, the following elements:

A Background Information/Demonstrated Capabilities section. This section should demonstrate that the Offeror has a comprehensive understanding of the goals/objectives to be met as described in Section 2 and include a description of the Offeror's capabilities for meeting them.

The description of capabilities should address experience, facilities, equipment, special resources, personnel, management structure, and any subcontractor organizations that are being proposed. If any subcontractor organizations are being proposed, it is necessary to include a description of the Prime Contractor's subcontract management capabilities and a description of each subcontractor's capabilities for performing any work to which it will be assigned.

This section should also include an overall project Management Plan and address the Offeror's capability to coordinate multiple concurrent analyses. The Management Plan should include a proposed monthly reporting plan to concisely summarize overall project efforts.

A Technical Approach section. As detailed in Section 2.1, the Offeror should propose to rapidly implement a battery of existing cellular models and assays that can be used for the in vitro screening of small molecule compounds for SMA. The cellular models and assays will be selected by the SMA Project. Offerors should address the cellular models and endpoints listed in Section 2.1 and should include information on the additional assay and support services identified in Section 2.2.

If not indicated in the Background Information/Demonstrated Capabilities section, information for each assay in the battery of assays should include where the work will be performed, the personnel who will be performing the work, and unique equipment. The technical approach should include a demonstration of the understanding of the requirements (Section 2) and, at a minimum, detail the following:

- The amount of test compound required for performance of the work (test compounds will be provided by the SMA Project Chemical Optimization and Synthesis Facility);
- If applicable, the number of cells or amount of tissue required for performance of the assay;
- Source suppliers for unusual reagents;
- The problems that are most likely to occur and how they will be corrected;
- Capacity for performance of the work (i.e., maximum number of compounds and replicates that can be examined in parallel);
- Any procedures or calibration methods that will be used for ensuring standardization;
- A Time Line* for establishing cellular models and assays; and
- A summary of contract deliverables, including a format for presentation of assay results and instructions for preparing biological specimens prior to shipping to the Offeror's facility.

* Time Lines: Time Lines should be as efficient/short as possible and should include performance milestones. Milestones should be brief descriptions of expected and required outcomes, not just completion of tasks. For a sample Time Line, see the [Open Solicitations](#) page of the SMA Project website.

4.4 References

No page limit. List relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of article, publication, volume, chapter, page numbers, and publisher, as appropriate).

4.5 Proposal Appendix: Standard Operating Procedures (SOPs)

No page limit. List and briefly state the purpose (in a paragraph or less) of the SOPs currently used by your organization that are relevant to the work being proposed in the Technical Approach section. In addition, SOPs for methodologies that might be required for an assay that is transferred into the facility should be listed. The following methodologies could be included:

- Cell survival and growth assays,
- Histological analysis of preserved neuronal tissue,

- Immunohistochemical analysis,
- Well- or flow-based immunofluorescence,
- Enzyme-linked immunosorbent assay (ELISA),
- Western blot analysis (including quantitative Western blot),
- Polymerase Chain Reaction (PCR),
- Quantitative Reverse Transcription-PCR (RT-PCR),
- Northern blot analysis, and
- In situ hybridization.

If desired, a sample SOP may be included in this appendix.

4.6 General Format Specifications

The following format instructions must be followed when preparing the Executive Summary, Proposal Body, References, and the Proposal Appendix **or the application may be returned without review**. Prepare the documents single-sided. The proposal should not be stapled or otherwise bound. The documents must be clear, readily legible, and conform to the following requirements:

- Type font: Must be 10 point or larger (suggested font = 11-point Arial).
- Type density: Must not be more than 15 characters per inch (cpi) including spaces. For proportional spacing, the average for any representative section of text must not be more than 15 cpi or 114 characters per line.
- Spacing: Single-spaced; must not be more than 6 lines of type within a vertical inch.
- Margins: Must be a minimum of ½ inch in all directions.
- Paper size: 8½ × 11 inch.
- Header or Footer: The Principal Investigator's (PI's) name and consecutive page numbers should be included on the Proposal Executive Summary, Body, References, and Proposal Appendices.

Charts, tables, figures, figure legends, and footnotes may be smaller in size but must be readily legible. Do not use photo reduction. Prepare all graphs, tables, diagrams, and charts in black ink. The application must contain only material that reproduces well when photocopied or printed in black and white since some reviewers may only receive a printed version. Do not use Internet website addresses to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that directly accessing an Internet site could compromise their anonymity.

4.7 Biographical Sketches

Four-page limit for each biosketch; unlimited number of biosketches allowed. Include a biosketch for key personnel, including the PI. The National Institutes of Health's (NIH's) biosketch form (<http://grants1.nih.gov/grants/funding/phs398/biosketch.pdf>) can be used. Required elements of a biographical sketch are as follows:

- Education/Training: List all degrees received, universities attended, and other pertinent information.
- Positions and Honors: List previous positions in chronological order, concluding with present position. Include present membership on any advisory committee. List any honors.
- Publications: List selected peer-reviewed publications, manuscripts in press, and manuscripts submitted (in chronological order). Do not include manuscripts in preparation.

- Research Support: List both selected ongoing research projects and projects completed within the last 3 years (federal or non-federal support). Beginning with the most relevant projects, compare this Offer to ongoing project(s) and include information on the degree of scientific uniqueness and overlaps. Briefly indicate the overall goals of the ongoing projects and responsibilities of the Offeror. *Note:* Do not include percent of effort or direct costs.

4.8 Letters of Intent

No page limit. Provide letters of intent from all proposed subcontractors and consultants.

4.9 Publication and/or Patent Information

Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent application abstract should provide a nonproprietary description of the patent application.

4.10 Proposed Budget/Pricing Information

No page limit. An Indefinite Delivery/Indefinite Quantity (ID/IQ) subcontract will be issued for one or more offers received in response to this RFP. A time and material or cost-reimbursement contract is anticipated. The Offer shall provide separate budgets for the following:

- Project Management: The budget should cover overall Project Management, inclusive of preparing monthly reports, time to consult with the Lead Development Team and SMA project investigators, and participation in two, 2-day SMA Project meetings per year.
- Cellular Models and Assays: The budget should support the technical plan proposed in the Body of the proposal.

The Summary of Costs form, which is available on the [Open Solicitations](#) page of the SMA Project website, may be used to submit pricing information. The Summary of Costs should be accompanied by a budget justification.

Estimates for Compound Screening: The Offeror should propose an estimate for performing assays in the proposed battery on as a fixed price, on a per-compound-to-be-evaluated basis. If cost savings can be achieved by simultaneous evaluation of multiple compounds, volume-adjusted rates should also be provided. (See also Section 9 for additional information on post-award management.)

4.11 Past Performance and Customer Surveys of Performance

To demonstrate successful performance on work that is similar to that required, the Offeror should submit a Summary of Pertinent Contracts and Grants and Customer Surveys of Performance.

- Summary of Pertinent Contracts and Grants: This document should summarize either ongoing or completed projects that are comparable or related to the work required by this RFP. Pertinent Contracts and Grants should be limited to those in which work is ongoing or completed in the last 3 years. This document should include (1) who performed the work, i.e., the Offeror or a subcontractor; (2) the contract/grant number; (3) the client; (4) the dollar value; (5) the period of performance; (6) a description of the work performed; and (7) an explanation of relevance of the work to this RFP.
- Customer Surveys of Performance: The Customer Survey of Performance form in Attachment B of this RFP should be completed by **three clients** for which the Offeror has already completed or is presently conducting work. For each proposed subcontractor organization, Customer Survey of Performance forms should be completed by one to **two clients** for which the subcontractor has already completed or is presently conducting similar work.

Offerors shall mail or e-mail the Customer Survey of Performance (Attachment B) to previous clients, collect the surveys from previous clients, and submit the surveys with their proposal. Offerors may provide information on problems encountered on the identified contracts and the Offeror's corrective actions.

An MS Word version of the Customer Survey of Performance is also available on the [Open Solicitations](#) page of the SMA Project website.

5. Supporting Documentation

Note: Only **two paper copies** of the following documents need to be provided with your proposal. This information does not need to be provided electronically on the CD.

Offerors shall send in the following Supporting Documentation **at the same time** as their proposals:

- **Subcontract Agreement:** Available on the [Open Solicitations](#) and [Supporting Documentation](#) pages of the SMA Project website. When completing this document, pay particular attention to the Contract Clauses in Schedule B, Part II. This section contains numerous items pertinent to laboratory research (e.g., Animal Welfare Assurance, Continued Ban on Funding of Human Embryo Research, Recombinant DNA and Human Gene Transfer Research, and Research Misconduct). **This section also contains intellectual property management provisions.**
- **Representations and Certifications:** Available on the [Open Solicitations](#) and [Supporting Documentation](#) pages of the SMA Project website.
- **Non-U.S. Facility Shipping Requirement** (No information needs to be submitted if facility is within the United States): Offerors' testing facilities that are outside the continental United States must include documentation to demonstrate that they are capable of consistently receiving, within 48 hours, mouse and human biological samples that were shipped from a facility within the continental U.S. borders.

6. Submission of Proposals and Supporting Documentation

A complete submission consists of a proposal (as described in Section 4) and supporting documentation (as described in Section 5). Details on the required format (i.e., paper vs. electronic) for submission, number of copies needed, and address to which your documents must be sent are provided below.

Please submit:

- **Eight** identical paper copies of the proposal,
- **One** electronic copy of the proposal on a CD (exclusive of signatures, Letters of Intent, and Past Performance and Customer Surveys of Performance), and
- **Two** paper copies of the Supporting Documentation,

all complying with the requirements described in this RFP, via **mail** or **overnight carrier** so that they are received by **5:00 P.M. ET on December 21, 2004** at

Science Applications International Corporation (SAIC)
Attn: Jonathan Logan
5340 Spectrum Drive, Suite N
Frederick, MD 21703-7357
Phone: 301-228-3149

A Checklist for Submitting a Proposal and Supporting Documentation is included as Attachment A to assist Offerors in the preparation of the required documents for submission.

7. Procedures for Evaluation of Proposals and Selection of Award

7.1 General Information

Final funding decisions will be based on (1) review of proposals that will be performed in accordance with the evaluation review criteria outlined in Section 7.4, (2) recommendations of the Steering Committee, (3) priorities of NINDS, and (4) availability of funds.

7.2 Compliance Check

Prior to forwarding proposals for review, all documentation will be compliance checked to ensure the following:

- Offerors' testing facilities that are outside the continental United States must include documentation to demonstrate that they are capable of consistently receiving, within 48 hours, mouse and human biological samples that were shipped from a facility within the continental U.S. borders.
- The proposal contains a cover page with signatures, an Executive Summary, a technical approach with required time lines, a biographical sketch for the PI, letters of intent from all proposed subcontractors and consultants, a budget, and customer surveys.
- The Supporting Documentation contains required signatures.

Proposals that do not meet the aforementioned requirements will be returned to the Offeror without review.

7.3 Proposal Review Process

A review panel composed of scientists with appropriate expertise will evaluate the proposals based on the criteria listed below.

Offerors should be prepared to be available by telephone during the review meeting to answer questions pertaining to their proposal; details of this procedure will be provided to Offerors approximately 1 week prior to the scheduled review meeting.

7.4 Proposal Review Criteria

Reviewers will evaluate proposals against the review criteria listed below. The relative importance of these criteria is indicated by the assigned point weights. The maximum total score possible is **100 points**. *The sample questions provided for each criterion are examples of points to be considered in review.*

Customer Survey of Performance forms will weigh heavily in the evaluation of proposals; survey responses should clearly demonstrate that the contract described involved testing compounds in cell-based screens.

- **Past Experience (40 points)** – Do the Background Information/Demonstrated Capabilities and Technical Approach sections demonstrate a history of collaboration and experience in adopting, validating, and successfully performing bioactivity screening assays that are similar to those being proposed for evaluation of SMA therapeutics? Does the Offeror provide Customer Surveys for compound testing in cell-based assays? Does the Offeror have experience at acquiring and utilizing cellular models that were developed by other investigators? Does the Offeror have experience with cultured neuronal cells? Is there experience in critical assay methodologies? Does the Offeror have experience with receiving, storing, and testing chemical compounds for bioactivity in cellular assays? Does the Offeror demonstrate a history of timely and accurate data exchange with other facilities?
- **Technical Approach and Time Lines (25 points)** – Does the Technical Approach section propose feasible strategies and methods for implementing and utilizing existing cellular models

of SMA? Does the Offeror propose feasible strategies and methods for implementing, validating, and conducting assays for bioactivity screening in cellular models of SMA? Is the proposed schedule for establishing cellular models and assays realistic? Have all conceivable efficiencies been considered? Are there sound methods proposed for receiving, handling, and administration of chemical compounds? Is the proposal method for data exchange with other contracted facilities as efficient and accurate as possible? Have quality control and assurance issues been addressed?

- **Personnel and Project Management (20 points)** – Is there a proposed Project Manager with education and experience commensurate with the level of responsibility to be assumed? Is the Management Plan well thought out? Do the Background Information/Demonstrated Capabilities and the Management Plan demonstrate a thorough understanding of the requirements and the broader goals and objectives of the SMA Project? Are personnel adequately trained and experienced in use of the equipment, reagents, and procedures needed for establishing, validating, and utilizing the proposed assays?
- **Facilities/Equipment (15 points)** – Do the Background Information/Demonstrated Capabilities and Technical Approach sections and Supporting Documentation demonstrate that the Offeror has an appropriately equipped and licensed facility for conducting the proposed screening assays? Is the equipment in good repair and being maintained according to manufacturer specifications? Are adequate measures in place to ensure the safety of all personnel and the proper disposal of all hazardous waste?

In addition to the review criteria listed previously, reviewers will consider the appropriateness of the **pricing information** supplied by the Offeror.

7.5 Funding Recommendations and Award Negotiations

Upon completion of peer review, Steering Committee members will be provided a copy of each proposal's Executive Summary and a summary of reviewers' evaluations. The Steering Committee will use this information to make funding recommendations to SAIC and NINDS for approval by NINDS.

Site visits may be conducted for some offers within 6 weeks of review. With prior notification from SAIC, each Offeror should make the facility available during normal business hours.

SAIC will formally notify your organization of the technical merit review results. Notification of award status will be made in accordance with Federal Acquisition Regulations 15.503.

8. Additional Information for Offerors

8.1 General Information

The Offeror is to furnish all information required by this RFP to SAIC. Any erasures or changes to a proposal must be initialed by an individual authorized to submit the offer, on behalf of the Offeror. The individual submitting the offer must have the authority to contractually bind the offer.

This RFP does not commit SAIC to pay any costs associated with the Offeror's preparation and submission of a proposal. The SAIC Subcontracts Representative is the only individual legally authorized to contractually bind SAIC for this solicitation. This is not an authorization to proceed with the work referenced herein.

8.2 Contact Information

For technical questions regarding this RFP, please contact Adam Book at 301-228-3114. For contractual questions related to this RFP, please contact Jonathan Logan at 301-228-3149. Alternatively, technical or contractual questions can be e-mailed to smaproject-fd@saic.com.

8.3 Progress Monitoring of Awards

Progress on each contract and task order will be monitored. Offerors who receive funding will be asked to submit brief monthly reports/updates on overall progress and separate reports with detailed test results. Offerors will propose a monthly reporting plan to concisely summarize overall project efforts, separate reports with detailed assay results, and if applicable, additional means to share data. A format and schedule for delivery of data and reports will be negotiated.

Through open communication between SMA Project investigators and SAIC's professional staff of doctoral-level scientists, regulatory affairs specialists, and project control specialists, any issues or concerns will be efficiently addressed. As needed, SMA Project Steering Committee members and technical experts who are formally associated with SAIC will also review reports/updates.

Offerors should note that continued funding for issued Task Orders during the period of performance of the SMA Project contract will be dependent on successful completion of assays according to the time lines specified in the proposal. SAIC will work with an SMA Project contractor to adjust time lines if necessary to best meet the needs of the SMA Project.

Through open communication between SMA Project investigators and SAIC's professional staff of doctoral-level scientists, regulatory affairs specialists, and project control specialists, any issues or concerns will be efficiently addressed. As needed, SMA Project Steering Committee members and technical experts who are formally associated with SAIC will also review reports/updates.

8.4 Resource Sharing, Data Sharing, and Intellectual Property Management

As the full name of the program (The SMA Project: A Collaborative Program to Accelerate Therapeutics Development) suggests, the SMA Project is intended as a **collaborative program**. Collaboration is deemed essential for being able to identify and rapidly complete preclinical development of the SMA therapeutics that are most likely to be safe, effective, and approved for clinical use by the FDA. In vitro bioactivity screening of candidate compounds is important for the success of this program; screening results must be made freely available for use in any component of this program. In making award recommendations to NINDS, the Steering Committee and SAIC will consider whether the Offeror's plans for resource sharing, data sharing, and intellectual property management are consistent with the goals of this program and NIH policies.

In awarding funds to successful Offerors, SAIC will act as a contractor to NINDS. As such, these funds are subject to the provisions of the *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999) and the *NIH Grants Policy Statement* concerning the availability of research results: publications, intellectual property rights, and sharing biomedical research resources. An intellectual property plan will be negotiated as part of the [Subcontract Agreement](#).

To ensure that intellectual property claims are adequately protected and/or appropriately pursued, program participants who are not employees of the federal government will be required to read and sign the program's Data Sharing Plan (see the [Subcontract Agreement](#)). Enforcement of the Plan will be carried out by NINDS with assistance from SAIC. To facilitate data and resource sharing and the generation of new ideas, funded investigators will be required to participate in quarterly investigator teleconferences and meetings. (For more information, see [About the Program](#) on the SMA Project website.)

<p>The following section is intended primarily for the Offeror's Business Office. Offerors should familiarize themselves with the information contained in this section and forward the material to their Business Office as soon as possible.</p>

9. Information Related to Subcontracts

9.1 General Information

ID/IQ subcontracts will be issued for one or more offers received in response to this RFP. Awards will be made for the base subcontract to support managing the in vitro facility and establishing cellular models and assays. After assays have been validated by the test facility, the SMA Project will send requests for performing individual assays to the subcontractor. The subcontractor will have 2 to 14 days to submit a cost and protocol for performing the assay. (*Note:* The time to respond will depend upon the complexity of the task and how often it has been performed previously.) Individual assay costs and protocols will be approved prior to performing compound screening.

Any subcontract resulting from this solicitation shall resemble the Subcontract Agreement posted on the SMA Project website, with the exception of appropriate modifications made at the time of award, including all applicable provisions required for flowdown by the prime contract to SAIC and any provisions required by law on the date of execution of the subcontract. The terms and conditions set forth or referenced herein shall apply, and SAIC objects to and shall not be bound by any additional alternate terms and conditions proposed by the Offeror. The Offeror agrees, if an offer is accepted, to furnish any or all services for which the offer is submitted at the price(s) proposed and upon the terms and conditions contained in this RFP, and the proposal shall be inclusive of all costs associated with performing the work, including profit/fee.

9.2 Restrictions on the Use of Human Subjects and Human Tissues/Specimens

Research involving human subjects shall not be conducted under SMA Project subcontracts. Research involving tissues or other biological specimens derived from living or deceased humans and cell lines derived from human tissues may only be conducted if Offerors have demonstrated their compliance with all appropriate guidelines pertaining to the use of human specimens and approval of the Contracting Officer. Please see the NIH brochure [Research on Human Specimens: Are You Conducting Research Using Human Subjects?](#), which is based on *Regulations for Protection of Human Subjects* (45 CFR Part 46), for more information.

9.3 Proposal Validity

To be considered valid, your proposal must be addressed to Jonathan Logan and remain firm for 180 calendar days.

9.4 Qualifications of Prospective Offeror

The Offeror must have adequate resources to perform any resulting subcontract, in accordance with the terms and conditions of this RFP, and upon request furnish proof of the same. The SAIC Subcontracts Representative may request verification of the Offeror's financial status, cost data related to the proposal, verification of insurance, anticipated technical approach, preliminary project scheduling, and/or any other pertinent data needed to establish the responsibility of the Offeror. Offers will not be accepted from any SAIC employee or business unit.

9.5 Procurement of Certain Equipment

Offerors will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the government contracting officer:

- 67 - Photographic Equipment
- 69 - Training Aids and Devices

- 70 - General Purpose ADP Equipment, Software, Supplies, and Support (Excluding 7045-ADP Supplies and Support Equipment)
- 71 - Furniture
- 72 - Household and Commercial Furnishings and Appliances
- 74 - Office Machines and Visible Record Equipment
- 77 - Musical Instruments, Phonographs, and Hometype Radios
- 78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Offeror and determined essential by the contracting officer, the government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

Additional unallowable items include accountable government property (defined as both real and personal property with an acquisition cost of \$1,000 or more and a life expectancy of more than 2 years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property, <http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>, 1990), regardless of acquisition value.

9.6 Late Offers

Formal offers, amendments, or requests for withdrawal of offers received after the date specified for submittal may not be considered.

9.7 Offer Acceptance and Award

SAIC reserves the right under all circumstances to select and award to the Offeror, in whole or in part, any portion of this project that is in the best interest of SAIC and its client.

Of note:

- SAIC may accept any offer regardless of whether there are negotiations conducted subsequent to its receipt. Any such negotiations shall not constitute a rejection or counteroffer on the part of SAIC.
- SAIC reserves the right to reject the offer, to waive minor informalities in offers, and/or to conduct further negotiations with the Offeror.
- SAIC assumes no responsibility for any promise or representation, either oral or written, that a subcontract award will be made, unless done so by the SAIC Subcontracts Representative and only when an SAIC Pro-Forma Subcontract of the type referenced in this RFP is executed with the Offeror.
- SAIC reserves the right to make multiple awards.

9.8 Right of Denial

SAIC reserves the right to deny the services of an Offeror due to inadequate qualifications and/or failure to complete a contract or demonstrated poor performance on contracts similar in nature, or the Offeror who, under investigation, shows is not in a position to perform the contract.

To form a complete offer, the Offeror is required to provide a detailed cost proposal in accordance with this solicitation, a technical proposal that demonstrates the Offeror's understanding of the requirements, and other pertinent documents as outlined in Section 5 of this RFP.

Checklist for Submitting a Proposal and Supporting Documentation

Proposal

Submit 8 identical paper copies and a CD with one electronic copy of the following (items marked with an * are not needed in electronic form):

- Proposal Face Page (with signatures on original paper copy)
- Proposal Executive Summary (1-page limit)
- Proposal Body (30-page limit)
- References (no page limit)
- Proposal Appendix: Standard Operating Procedures (no page limit)
- Biographical Sketches (4-page limit for each biosketch; unlimited number of biosketches)
- Letters of Intent* (no page limit)
- Publication and/or Patent Information (5-document limit)
- Proposed Budget/Pricing Information and Budget Justification (no page limit)
- Past Performance and Customer Surveys of Performance*
 - Forms from 3 current or past clients
 - For proposed subcontractors, forms from 1-2 current or past clients of the subcontractor

Supporting Documentation

Submit 2 identical paper copies of the following:

- Subcontract Agreement
 - The entire document must be read and completed as necessary. Of note, signatures are needed in the following places:*
 - Schedule A, page 13
 - Attachment II (Memorandum – Requirements Related to Human Subjects, Specimens, and Recombinant DNA Research), page 31
 - Also note that as part of the Subcontract Agreement you must provide:*
 - An approved Animal Welfare Assurance from the Office of Laboratory Animal Welfare, page 22
 - An intellectual property management plan that satisfies the requirements outlined in the Subcontract Agreement, page 25
 - In addition, prior to the start of research involving animals you must provide:*
 - Verification of approval (including the date of most recent approval) by the IACUC with appropriate documentation, page 22
- Representations and Certifications document
 - This document must be read and completed as necessary, including a signature of the person authorized to bind Offeror on page 12.*
- Non-U.S. Facility Shipping Requirement
 - Note: No information needs to be submitted if your facility is within the United States.*



www.SMAMProject.org

The SMA Project: Customer Survey of Performance

Please complete Parts 1, 3, and 4 of the questionnaire and return via regular mail or fax to the attention of:

(Name) By _____
(Date)

(Address)

(Fax Number)

Our organization is planning to submit a proposal to the SMA Project. The Request for Proposals (RFP) to which we intend to respond requires comments from customers for whom we have tested small molecules in existing cell-based assays.

PART 1: GENERAL INFORMATION

Name of Contracting Organization: _____

Department/Component: _____

Contract Number: _____

Contract Type: _____

Contract Value (including options): \$_____

Period of Performance (including option periods): _____

Approximate percentage of work being performed (or completed) by subcontractor(s): _____%

Contracting Officer's Name and Telephone Number: _____

Program Manager's Name and Phone Number: _____

Did this contract include providing services for cell-based assays? (check one box below)

- Yes – central to contract Yes – but peripheral to contract No – not part of contract

Please elaborate on how this contract relates to the focus of the SMA Project RFP (i.e., providing support services for testing small molecules in existing cell-based assays of SMA). In addition, provide a general description of products/services required under this contract (continue on an additional page if needed):

PART 2: RATINGS

Use the table below as a guide to complete Part 3.

	Quality of Product or Service	Cost Control	Timeliness of Performance	Business Relations
0 – Unsatisfactory	Contractor is not in compliance and is jeopardizing achievement of contract objectives	Contractor is unable to manage costs effectively	Contractor delays are jeopardizing performance of contract objectives	Response to inquiries and technical/service/administrative issues is not effective
1 – Poor	Major problems have been encountered	Contractor is having major difficulty in managing costs effectively	Contractor is having major difficulty meeting milestones and delivery schedule	Response to inquiries and technical/service/administrative issues is marginally effective
2 – Fair	Some problems have been encountered	Contractor is having some problems in managing costs effectively	Contractor is having some problems meeting milestones and delivery schedule	Response to inquiries and technical/service/administrative issues is somewhat effective
3 – Good	Minor inefficiencies/errors have been identified	Contractor is usually effective in managing costs	Contractor is usually effective in meeting milestones and delivery schedule	Response to inquiries and technical/service/administrative issues is usually effective
4 – Excellent	Contractor is in compliance with contract requirements and/or delivers quality products/services	Contractor is effective in managing costs and submits current, accurate, and complete billings	Contractor is effective in meeting milestones and delivery schedule	Response to inquiries and technical/service/administrative issues is effective
5-Outstanding: The contractor has demonstrated an outstanding performance level in any of the above four categories that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent."				

Assign each area a rating of 0 (Unsatisfactory) , 1 (Poor) , 2 (Fair) , 3 (Good) , 4 (Excellent), or 5 (Outstanding) .

PART 3: SMA PROJECT CUSTOMER SURVEY OF CONTRACTOR PERFORMANCE

Circle the appropriate rating using the table in Part 2. If you do not have enough personal knowledge or feedback from internal customers who directly received products and services from the Contractor to make a determination on any of the performance criteria below, please circle "N/A" (not applicable/no opinion).

QUALITY OF PRODUCT OR SERVICE

- | | | | | | | | |
|--|---|---|---|---|---|---|-----|
| 1. Compliance with contract requirements | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 2. Accuracy of reports | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 3. Effectiveness of personnel | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 4. Technical Excellence | 0 | 1 | 2 | 3 | 4 | 5 | N/A |

COST CONTROL

- | | | | | | | | |
|---|---|---|---|---|---|---|-----|
| 1. Record of forecasting and controlling target costs | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 2. Current, accurate, and complete billings | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 3. Relationship of negotiated costs to actuals | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 4. Cost efficiencies | 0 | 1 | 2 | 3 | 4 | 5 | N/A |

TIMELINESS OF PERFORMANCE

- | | | | | | | | |
|--|---|---|---|---|---|---|-----|
| 1. Met interim milestones | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 2. Reliability | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 3. Responsive to technical directions | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 4. Completed on time including wrap-up and contract administration | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 5. Met delivery schedules | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 6. Liquidated damages assessed: Yes No (circle one) | | | | | | | |

BUSINESS RELATIONS

- | | | | | | | | |
|---|---|---|---|---|---|---|-----|
| 1. Effective management, including management of subcontracts | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 2. Reasonable/cooperative behavior | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 3. Responsive to contract requirements | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 4. Notification of problems | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 5. Flexibility | 0 | 1 | 2 | 3 | 4 | 5 | N/A |
| 6. Pro-active vs. reactive | 0 | 1 | 2 | 3 | 4 | 5 | N/A |

