

March 12, 2004

# Request for Proposals

  

## for

**Motor Neuron Cellular Models of Spinal Muscular Atrophy (SMA)**



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**

RFP No: JL-07204-1

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

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



## Table of Contents

|   | Page |
|---|------|
| 1. Introduction .....   | 1    |
| 1.1 Spinal Muscular Atrophy .....   | 1    |
| 1.2 Current Cellular Models for Evaluating SMA Therapeutics .....                         | 1    |
| 2. Solicitation Focus and Time Line .....   | 2    |
| 2.1 Focus of This Solicitation .....  | 2    |
| 2.2 Time Line for This Solicitation .....   | 2    |
| 3. Proposal Preparation Procedures .....  | 2    |
| 3.1 Overview .....  | 3    |
| 3.2 Pre-Proposals.....  | 3    |
| 3.2.1 Preparation of Pre-Proposals .....  | 3    |
| 3.2.2 Submission of Pre-Proposals .....   | 3    |
| 3.3 Full Proposals.....   | 3    |
| 3.3.1 Proposal Face Page .....  | 4    |
| 3.3.2 Proposal Executive Summary .....  | 4    |
| 3.3.3 Proposal Body .....   | 4    |
| 3.3.4 References .....  | 5    |
| 3.3.5 Project Time Line.....  | 5    |
| 3.3.6 Proposed Budget/Pricing Information .....   | 5    |
| 3.3.7 Biographical Sketches .....   | 5    |
| 3.3.8 Publication and/or Patent Information .....   | 5    |
| 3.3.9 Letters of Support .....  | 6    |
| 3.3.10 Submission of Proposals .....  | 6    |
| 3.4 Supporting Documentation .....  | 6    |
| 3.4.1 Preparation of Supporting Documentation .....                                       | 6    |
| 3.4.2 Submission of Supporting Documentation .....  | 6    |
| 4. Procedures for Evaluation of Pre-Proposals and Proposals and Selection of Awards ..... | 6    |
| 4.1 General Information.....  | 6    |
| 4.2 Pre-Proposal Screening .....  | 6    |
| 4.3 Full Proposal Review Process.....   | 7    |
| 4.4 Full Proposal Review Criteria .....   | 7    |
| 4.5 Funding Recommendations and Award Negotiations .....                                  | 8    |
| 5. Additional Information for Offerors .....  | 8    |
| 5.1 General Information.....  | 8    |
| 5.2 Contact Information .....   | 8    |
| 5.3 Progress Monitoring of Awards .....   | 8    |
| 5.4 Resource Sharing, Data Sharing, and Intellectual Property Management.....             | 9    |
| 6. Information Related to Subcontracts .....  | 9    |
| 6.1 General Information.....  | 9    |
| 6.2 Restrictions on the Use of Human Subjects and Human Tissues/Specimens .....           | 10   |
| 6.3 Proposal Validity.....  | 10   |
| 6.4 Qualifications of Prospective Offeror .....   | 10   |
| 6.5 Procurement of Certain Equipment .....  | 10   |
| 6.6 Late Offers.....  | 11   |
| 6.7 Offer Acceptance and Award .....  | 11   |
| 6.8 Right of Denial.....  | 11   |

## 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 funds milestone-driven research aimed at identifying and rapidly developing a treatment for SMA, a paralyzing neurodegenerative disease of childhood. (For more information about the program, visit the SMA Project website at <http://www.smaproject.org>.)

This solicitation is aimed at the development and characterization of human or animal motor neuron cell models that are deficient for SMN. Such cell lines or cultures are needed to test candidate therapeutics for activity in countering the neurodegenerative effects of SMA. Only proposed research that meets criteria for federal funding eligibility for stem cell research<sup>1</sup> will be considered for award under this solicitation.

### 1.1 Spinal Muscular Atrophy

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 (*SMN1*) gene, which results in the death of motor neurons, but not of other cell types in which the gene is normally expressed. A second gene, *SMN2*, is present in variable copy number and produces low levels of functional SMN protein. A single nucleotide polymorphism results in alternative splicing, and the majority of *SMN2* transcripts lack exon 7. SMA disease severity correlates with the number of copies of *SMN2*, suggesting that increasing the levels of SMN protein can result in an improved clinical outcome.

### 1.2 Current Cellular Models for Evaluating SMA Therapeutics

Drugs and other molecules have been recently identified that can upregulate *SMN2* expression in cultured cells. In cultures of human fibroblasts from SMA patients, levels of full-length *SMN2* transcript and/or functional SMN protein were found to be increased following treatment with phenylbutyrate, valproic acid, and aclarubicin, or a tailed antisense oligonucleotide containing binding motifs for splicing activators.

Unlike humans, mice do not contain a second *SMN* gene. A mouse cellular model has been constructed by inserting an *SMN2* minigene reporter construct into the NSC34 mouse cell line (a hybrid of neuroblastoma and ventral spinal cord cells). In this line, aclarubicin increased the level of *SMN2* minigene transcripts that include exon 7. Nonneuronal cellular models have also been developed in which SMN levels can be reduced through double-stranded RNA interference (RNAi) or through a tetracycline-repressible promoter.

These models have proven useful in the identification of compounds that can increase SMN levels or compensate for reduced SMN in a variety of cellular contexts. However, since the SMA disease phenotype is specific for motor neurons, it is desirable to evaluate the promise of candidate therapies for SMA in a cell type that most closely resembles motor neurons.

---

<sup>1</sup> Offers must comply with 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 USC 289g(b)).

## 2. Solicitation Focus and Time Line

### 2.1 Focus of This Solicitation

Pre-proposals are requested for the development and characterization of motor neuron cellular models of SMA that are appropriate for measuring the activity of drugs on the human *SMN2* promoter and on the splicing and stabilization of *SMN2* RNA. Ideally, the cellular models would be deficient for SMN to allow the evaluation of the phenotypic consequences of a drug's action. Such cell models are needed to rapidly assess the promise of candidate therapeutics for SMA.

Strategies appropriate for the development of a cell model of SMA might include but are not limited to:

- ES cell-derived motor neuron cultures
- Primary motor neuron cultures from animals
- Organotypic spinal cord slice cultures from animals
- Immortalized motor neuron cell lines

Characterization of cellular models should include:

- Demonstration of stable, reproducible, and quantifiable expression of a human *SMN2* reporter construct
- For SMN-deficient models, demonstration of a specific and reproducible phenotype in response to reduced SMN function
- For SNM-deficient models, tests of whether increasing SMN levels results in reversal of the relevant phenotypes
- Tests of whether compounds known to increase SMN levels in other model systems have the desired effects on SMN reporters or phenotypes, as appropriate

Cellular models produced under this program will be made freely available to the scientific community and will be used in further research supported by the program to identify a treatment for SMA.

### 2.2 Time Line for This Solicitation

Key dates related to this Request for Proposal (RFP) are as follows:

- |   |                             |
|---|-----------------------------|
| • 2-Page Pre-Proposals Due                      | April 9, 2004               |
| • Invitation to Submit Full Proposal            | ~ April 23, 2004            |
| • Full 10-Page Proposals Due                    | ~ May 21, 2004 <sup>2</sup> |
| • Supporting Documentation for Subcontracts Due | May 28, 2004 <sup>3</sup>   |
| • Peer Review of Full Proposals                 | ~ June 4, 2004              |
| • Notification of Award Status                  | ~ June 15, 2004             |
| • Anticipated Start Date                        | ~ July 9, 2004              |

## 3. Proposal Preparation Procedures

**NOTE:** Before preparing a pre-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 subcontracts and task orders. Offerors should also review the Subcontract Agreement

<sup>2</sup> Exact date to be provided in invitation letter.

<sup>3</sup> Proposals will NOT be considered further if supporting documentation has not been received by this date.

and the Representations and Certifications document, which are posted on the [Supporting Documentation](#) page of the SMA Project website.

### 3.1 Overview

The proposal preparation procedure has been designed to accelerate the time from solicitation to award. There are three submission deadlines for offerors that correspond to the submission of pre-proposals, full proposals, and supporting documentation for subcontracts.

- Pre-Proposals: Approximately 4 weeks after the release of an RFP, offerors are requested to submit 2-page pre-proposals that respond to the aims of the solicitation (see sections 2.1 and 3.2). Pre-proposals will be screened to determine which submissions best meet the intent of the solicitation.
- Full Proposals: Offerors whose pre-proposals are deemed most responsive to the solicitation will be invited to submit full 10-page proposals (see section 3.3); offerors will have approximately 4 weeks to prepare this technical proposal.
- Supporting Documentation: Additional supporting documentation for subcontracts will be due 1 week after full proposals are due (see section 3.4). However, the offeror may elect to submit the supporting documentation at the deadline for the full proposal.

**Do NOT submit a full proposal or supporting documentation unless you receive a letter of invitation.**

### 3.2 Pre-Proposals

#### 3.2.1 Preparation of Pre-Proposals

The pre-proposal consists of a Pre-Proposal Submission Form (available on the [Open Solicitations](#) page of the SMA Project website) and an electronic file containing (1) the 2-page body of the pre-proposal, (2) up to 1 page of references, and (3) up to 3 biographical sketches. Please follow the instructions provided on the Pre-Proposal Submission Form.

#### 3.2.2 Submission of Pre-Proposals

To submit a pre-proposal, the Contracting Officer (the individual at the offering institution who is authorized to conduct subcontract negotiations and contractually bind the offer) must send an e-mail to Jonathan Logan at [jonathan.h.logan@saic.com](mailto:jonathan.h.logan@saic.com) by 3:00 P.M. Eastern Time (ET) on **April 9, 2004** with the following electronic files attached:

- A copy of the Pre-Proposal Submission Form.
- A file containing (1) the 2-page body of the pre-proposal, (2) up to 1 page of references, and (3) up to 3 biographical sketches (see Pre-Proposal Submission Form for details).

In addition, offerors must print the completed Pre-Proposal Submission Form, have the Principal Investigator (PI) and Contracting Officer sign it in the appropriate places, and **fax the signed form to Jonathan Logan at 301-698-6188** by the deadline stated above. Offerors experiencing difficulty with the electronic submission procedure should contact Adam Book at 301-228-3114 or send an e-mail to [smaproject-fd@saic.com](mailto:smaproject-fd@saic.com).

### 3.3 Full Proposals

Full proposals should only be submitted if the offeror receives an invitation. Offerors must complete sections 3.3.1 – 3.3.10 and section 3.4.

### 3.3.1 Proposal Face Page

The Face Page must include items 1-9 (including signatures) from the Pre-Proposal Submission Form. In addition, please notate the following in a header on the Face Page:

- Response to JL-07204-1.
- Unique identifier for your pre-proposal (this number can be found in your e-mail invitation to submit a full proposal).

### 3.3.2 Proposal Executive Summary

The proposal must contain a 1-page Executive Summary consisting of a proposal abstract, a list of objectives/goals of the project, and a description of the approach for the project. The Executive Summary will be forwarded to the Steering Committee after peer review as part of the material they will use to make funding recommendations (see also section 4.5). The format specifications outlined in section 3.3.3 are also applicable to this summary.

### 3.3.3 Proposal Body

There is a **10-page limit** inclusive of any figures, tables, and graphs. Note that the description of facilities/resources is to be included within the 10-page limit.

#### Proposal Body

The body of the proposal should contain the following elements:

- Background information.
- Objectives/goals of the project.
- Relevance: Describe how the proposed work relates to the aims of this solicitation (as detailed in section 2.1).
- Research strategy: Provide details about the experimental study design and methodology (include information on reagents, cell lines, and animals to be used in the study). For studies employing human embryonic stem cells, this section should include a clearly worded statement regarding how the proposed research meets current eligibility criteria for federal funding of research on human embryonic stem cells (see information posted at <http://stemcells.nih.gov/registry/eligibilityCriteria.asp>).
- Milestones: Identify performance milestones to guide development and evaluate progress. Please describe how these milestones will be achieved. Milestones should be descriptions of outcomes not just completion of tasks (e.g., generating a construct is not a milestone, but demonstrating expression from the construct is a milestone). **The feasibility and appropriateness of the milestones will be subject to peer review as the timely meeting of milestones will be the basis for continued funding during the period of performance of the subcontract.** For more information on performance milestones, see the [Milestone-Driven Research](#) page on the SMA Project website.
- Facilities/resources: Specify the facilities (laboratory, clinical, etc.) to be used for the conduct of the proposed research. If there are multiple performance sites, then resources available at each site should be described.

#### General Format Specifications

The following format instructions must be followed when preparing the Executive Summary and Body of the proposal **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.
- Page numbers: Pages for sections 3.3.2 – 3.3.5 should include numbers and the PI's name in the header or footer.

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.

### **3.3.4 References**

One-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).

### **3.3.5 Project Time Line**

One-page limit. Present a detailed time line for the length of the subcontract with specific performance milestones. Time lines should be as efficient/short as possible yet feasible for the proposed project. For a sample time line, see the [Open Solicitations](#) page of the SMA Project website.

### **3.3.6 Proposed Budget/Pricing Information**

No page limit. Offerors should provide pricing information using the forms provided on the SMA Project website. The Summary of Costs form must be submitted with the full proposal. This form is available on the [Open Solicitations](#) page of the SMA Project website.

Offerors may be requested to provide additional information as necessary to make a proper determination of price in accordance with Federal Acquisition Regulation (FAR) Part 15.404 (<http://www.arnet.gov>). Failure to provide the additional information upon request may deem an offeror to be nonresponsive.

### **3.3.7 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 biosketch form (<http://grants1.nih.gov/grants/funding/phs398/biosketch.pdf>) can be used. Required elements of a biographical sketch are presented in Item 14 on the Pre-Proposal Submission Form.

### **3.3.8 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.

### 3.3.9 Letters of Support

No page limit. Provide letters of support from any collaborating individuals. Include letters of support documenting availability and quality control for all critical reagents. Less senior principal investigators should ensure that institutional support and the role of more senior co-investigators are made clear in the proposal.

### 3.3.10 Submission of Proposals

Eight identical copies of the full proposal, complying with the requirements described in this RFP, must be submitted via **mail** or **overnight carrier** and received by **5:00 P.M. ET** on or about **May 21, 2004** (exact date to be provided in offeror's invitation letter):

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

## 3.4 Supporting Documentation

### 3.4.1 Preparation of Supporting Documentation

Offerors invited to submit full proposals must also send in the following supporting documentation:

- **Subcontract Agreement** – available on the [Supporting Documentation](#) page 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 [Supporting Documentation](#) page of the SMA Project website.

### 3.4.2 Submission of Supporting Documentation

Two identical copies of the supporting documentation outlined above are due 1 week after the full proposal submission deadline. This documentation is to be sent via **mail** or **overnight carrier** to SAIC at the address listed in section 3.3.10. **Note:** Proposals **will not** be considered further if these documents are not received by 1 week after the full proposal submission deadline.

## 4. Procedures for Evaluation of Pre-Proposals and Proposals and Selection of Awards

### 4.1 General Information

Final funding decisions will be based on (1) peer review of full proposals that will be performed in accordance with the evaluation review criteria outlined in section 4.4, (2) recommendations of the Steering Committee, (3) priorities of the NINDS, and (4) availability of funds.

### 4.2 Pre-Proposal Screening

The Steering Committee will screen pre-proposals for appropriateness to this solicitation's aims (as described in section 2.1). Pre-proposals will also be assessed to ensure the offeror's plan to meet current eligibility criteria for federal funding for using human embryonic stem cells (for more

information see <http://stemcells.nih.gov/registry/eligibilityCriteria.asp>). Invitations for full proposals will be e-mailed to offerors after screening.

#### 4.3 Full Proposal Review Process

Proposals will be evaluated in a **2-step process**. The first step is a pass/fail for meeting federal funding eligibility; only proposals that pass the first step will be fully evaluated against the criteria for the second step.

The second step, a full evaluation of the proposal, will be performed by an independent peer review panel composed of scientists with appropriate expertise. Peer reviewers will evaluate proposals based on the criteria listed in section 4.4. Offerors should be prepared to be available by telephone during the peer review meeting to answer questions pertaining to their proposal; details of this procedure will be provided to offerors upon request or with invitations to submit full proposals.

#### 4.4 Full Proposal Review Criteria

##### Step 1: Federal Funding Eligibility (pass/fail)

For studies employing human embryonic stem cells, does the approach meet current eligibility criteria for federal funding (see <http://stemcells.nih.gov/registry/eligibilityCriteria.asp>)?

##### Step 2: Proposal Scoring (maximum of 100 points)

Peer reviewers will evaluate proposals against the review criteria listed below. The relative importance of these criteria is indicated by the assigned point weights.

- **Understanding the Requirements of This Solicitation (35 points)** – Does the proposed research demonstrate a thorough understanding of the requirements of this solicitation? Overall, how relevant is the proposed research to the aims of this solicitation (as detailed in section 2.1)? Is proposed research likely to yield a useful motor neuron cell model that satisfies the following conditions:
  - Will the model be generated on an accelerated schedule?
  - Is the model likely to have properties that optimally resemble motor neurons?
  - Can it be used to test candidate therapies for SMA?
  - Can the model be transferred/exchanged to another laboratory so that testing of candidate therapies can be reliably replicated?
- **Research Strategy (25 points)** – How feasible is the proposed technology/approach for efficiently developing a useful motor neuron cell line? Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Is the research well conceived and scientifically sound?
- **Time Line/Milestones (15 points)** – Does the project time line meet the accelerated nature of this program, i.e., is the time line as efficient/short as possible yet feasible for the proposed work? Are the performance milestones well described? Are the milestones descriptions of outcomes and not just descriptions of tasks? Do the milestones provide a defined measure of both positive and negative outcomes?
- **Qualifications of PI and Key Personnel (15 points)** – Do the investigators (including the PI) have a record of achievement in the development and/or characterization of cell lines? Are appropriate personnel available to successfully complete the proposed research within the subcontract period? Have the PI and other key personnel committed a sufficient level of effort to ensure the success of this project? Are conflicts-of-interest and commercial interests adequately identified and justified (if applicable)?

- **Environment and Facilities (10 points)** – Is the scientific environment in which the work will be performed appropriate for the proposed research and does it contribute to the probability of success? Does the offeror have the necessary facilities/equipment for the conduct of the proposed research?

In addition to the review criteria listed above, peer reviewers will consider the appropriateness of the **budget/pricing information** supplied by the offeror. The estimated cost of a proposal must be reasonable for the work to be performed.

#### **4.5 Funding Recommendations and Award Negotiations**

Upon completion of peer review, Steering Committee members will be provided a copy of the Proposal Executive Summary (section 3.3.2), Project Time Line (section 3.3.5), and a summary of peer review evaluations for each proposal. The Steering Committee will use this information to make funding recommendations to SAIC and NINDS for approval by NINDS. SAIC will formally notify your organization of your impending award or non-selection. Notification of award status will be made in accordance with FAR 15.503.

SAIC will negotiate the subcontract awards. Funding of subcontracts will be based on the approved annual appropriation of funds. Multiple-year contracts shall be incrementally funded based on the prime contractor's annual increment received under the contract.

### **5. Additional Information for Offerors**

#### **5.1 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 its 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.

#### **5.2 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](mailto:smaproject-fd@saic.com).

#### **5.3 Progress Monitoring of Awards**

Progress on each subcontract and task order will be monitored. Offerors who receive funding will be asked to submit brief monthly reports/updates on progress for subcontract milestones. SAIC's professional staff of doctoral-level scientists, regulatory affairs specialists, and project control specialists will openly communicate with subcontract investigators to efficiently address any issues or concerns. As needed, SMA Project Steering Committee members will also review reports/updates.

Offerors should note that the meeting of milestones will be the basis for continued funding during the period of performance of the subcontract. SAIC will work with subcontractors to adjust time lines if necessary to best meet the mutual needs of researchers and the SMA Project. In the unlikely event that funding is discontinued, this will not adversely affect future funding through the NIH. For more information on reporting requirements, progress monitoring,

and the differences between grants and subcontracts, please see [About the Program](#) on the SMA Project website and review the reporting requirements outlined in the [Subcontract Agreement](#).

#### **5.4 Resource Sharing, Data Sharing, and Intellectual Property Management**

As the title 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 U.S. Food and Drug Administration. Development of cell lines and other research resources is important for the success of this program, and these models and research resources must be made freely available for use in any component of this program. Further, the use of these cell lines and research resources must not unduly encumber future therapeutic research and discovery. In making award recommendations to the 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 National Institutes of Health (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).

**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.**

### **6. Information Related to Subcontracts**

#### **6.1 General Information**

Cost Plus Fixed Fee/Time and Materials, Indefinite Delivery/Indefinite Quantity (ID/IQ) subcontracts will be issued for offers received in response to this RFP. 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.

## **6.2 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) and the conditions outlined in HHS Acquisition Regulation 352.270-8.

## **6.3 Proposal Validity**

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

## **6.4 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.

## **6.5 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/contractorsguide.htm>), 1990), regardless of acquisition value.

## **6.6 Late Offers**

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

## **6.7 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.

## **6.8 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 3.4 of this RFP.**