

September 7, 2007



## Request for Proposals

### Preclinical Studies of Small Molecules with Therapeutic Potential for Spinal Muscular Atrophy

RFP No: LD-090707

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

This solicitation is in support of The SMA Project, a therapeutics development program sponsored by the [National Institute of Neurological Disorders and Stroke](http://www.NINDS.nih.gov) (NINDS), part of the National Institutes of Health (NIH). The program aims to develop a safe and effective treatment for Spinal Muscular Atrophy (SMA), a paralyzing neurodegenerative disease of childhood for which there are currently no approved treatments. More information about the program can be found at <http://www.SMAMProject.org>.

The SMA Project is developing and evaluating small molecule chemical compounds with therapeutic potential for SMA. The purpose of this solicitation is to identify facilities to conduct preclinical testing of chemical compounds with the ultimate goal of submitting an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA). Studies to be conducted under the resulting contract will include preclinical safety, toxicology, pharmacokinetic/dynamic, and biodistribution studies. While a broad range of Good Laboratory Practice (GLP) and non-GLP studies is anticipated, capability to conduct studies according to GLP is required. It is anticipated that awards from this solicitation will be Indefinite Delivery/Indefinite Quantity (ID/IQ) subcontracts with subordinate Time and Materials (T&M) and/or Fixed Price (FP) Task Orders. The SMA Project is funded by NIH through a prime contract to SAIC. Awards made through this solicitation will be subcontracts awarded and administered by SAIC.

The activities of the SMA Project are conducted at multiple subcontracted sites, including a medicinal chemistry facility, in vitro bioactivity testing facilities, and in vivo testing facilities. These activities are centrally coordinated by NINDS and SAIC, are highly integrated, and operate on an extremely tight schedule. Studies conducted as a result of this solicitation will be similarly integrated with and dependent on the results of work conducted at other SMA Project sites and will be conducted on the tightest possible schedule. Only Offerors with sufficient resources and willingness to respond quickly to the ever-changing requirements of a drug development program should respond to this solicitation.

This Request for Proposals (RFP) is intended to identify and fund facilities capable of providing the necessary research and development support for an IND submission in a format acceptable to the FDA. Facilities will be evaluated on their past experience in preclinical, IND-directed small molecule development, as well as the proposed schedule and cost of studies required.

### 1.1 Schedule for This Solicitation

Key dates related to this RFP are anticipated as follows:

- Offeror's Intent to Submit Form Due September 21, 2007
- Proposals Due 3 p.m., Eastern Time, October 5, 2007
- Supporting Documentation Due October 12, 2007
- Review of Proposals and Supporting Documentation ~ October 23, 2007
- Initiation of Negotiations ~ October 26, 2007
- Anticipated Start Date ~ January 4, 2008
- Notification of Unsuccessful Offerors ~ January 11, 2008

### 1.2 Requirements for Offerors

Offerors must be based and comply with all laws and regulations within the United States.

Only Offerors that meet criteria for federal funding eligibility—for example, 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

The overall goal of the SMA Project is to accelerate the movement of small molecules from discovery into early phase clinical trials. To meet the program's stated aim of accelerated drug development, Offerors

should be able to simultaneously conduct multiple stages of preclinical small molecule IND-enabling studies and to advance individual compounds according to an aggressive schedule. In addition, Offerors should be able to conduct preliminary in vitro and in vivo ADME studies to aid in clinical candidate selection and formulation of compounds for in vivo testing. Multiple awards may be made from this solicitation to facilitate scheduling of compound studies and comparative pricing.

Proposals are requested from facilities that have successfully performed preclinical studies of small molecules that supported successful IND submissions.

The successful Offeror will deliver a broad range of preclinical studies including:

1. All necessary preclinical development services, to include assay development;
2. Preliminary pharmacokinetics (PK) studies and formulations to support evaluation and selection of clinical candidate compounds;
3. Preclinical GLP and non-GLP Safety, Toxicology, and Pharmacodynamics/Pharmacokinetics (PD/PK) services to support IND submissions;
4. Participation in annual meetings with SAIC, NINDS, and other SMA Project participants;
5. As requested, an overall Product Development Plan for advanced preclinical development of specific compounds; and
6. Deliverables as required and scheduled in each Task Order.

The Offeror shall provide services for preclinical development of compounds identified by SAIC. The specific services required shall depend on the status of the individual candidate(s) as part of an overall Product Development Plan and/or regulatory submission plan to the FDA. The Offeror shall use state-of-the-art techniques and technologies, which are accepted by the FDA, in evaluating promising therapeutics and, as appropriate, shall incorporate new and improved FDA-accepted techniques and technologies into the contract testing/evaluation activities.

## **2.1 Statement of Work**

As elaborated in the following, the Contractor shall:

1. Provide an infrastructure for the overall technical and administrative management of the projects;
2. Provide the personnel, equipment, technical expertise, and infrastructure to complete all parts of the technical requirements specified herein and to provide all deliverables according to agreed schedules;
3. Deliver timely reports for each required study in a format suitable for inclusion in FDA submissions;
4. Retain all records, samples, histopathological slides, etc., and make them available as directed by the SAIC Principal Investigator and as indicated by GLP guidelines;
5. Maintain awareness of evolving regulatory requirements for preclinical evaluations of therapeutic agents;
6. Arrange for site visits and independent audits, as needed or as requested by the SAIC Principal Investigator. Audits may be requested to ensure Contractor facilities and all planned procedures meet the FDA-required GLP and cGMP standards. The Contractor shall ensure that all Contractor records and staff are available in response to site visits or study-specific audits by NINDS or its designee and provide interim and final audit reports to the SAIC Principal Investigator;
7. Immediately inform the SAIC Principal Investigator in the event that the FDA identifies deficiencies in the facilities of the Contractor or any of its subcontractors;
8. Participate as necessary in discussion with the FDA during pre-IND, IND, and pre-new drug application (NDA);
9. Prepare and deliver a Product Development Plan for specific compounds as requested, including a description of the technical approach, key objectives, start date, project milestones, time lines for the completion of milestones and deliverables, and a detailed budget for each activity; and

10. Provide an orderly transition to a successor Contractor or to the U.S. Government at the end of the contract.

The Statement of Work (SOW) for this contract will contain the following items. The Offeror's proposal must demonstrate their ability to support these tasks.

**A. *Preclinical Development Services***

Provide a broad range of preclinical development services, including, but not limited to, those listed in the following paragraphs.

As directed by SAIC, the Contractor shall conduct work according to non-GLP, GLP, or cGMP in accordance with FDA requirements, regulations, and standards in effect during the course of the project period and provide predetermined complete Quality Assurance and Quality Control information for all services provided. The Contractor shall provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and management of all projects performed under this contract and effective communications with the SAIC Principal Investigator and SAIC Subcontracts Administrator. In addition, the Contractor shall evaluate the data resulting from the preclinical services and draw relevant conclusions specific to the objective of the service, to be included in any required reports.

The Contractor shall perform preclinical safety, toxicity, and PD/PK studies of chemical compounds in vitro and in vivo, including both rodents and non-rodents. This includes all such tests that are required to support clinical use in humans. Testing must be sufficient to meet requirements for IND/NDA filing and, when directed by SAIC, must be performed under GLP requirements (21 CFR 58). The Contractor is responsible for acquisition, housing, and care of animals. All animal work must be conducted in accordance with the Animal Welfare Act and Public Health Service Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/phspol.htm>), including the implementation of an animal care and use program, and animal use protocol approval process.

Preclinical safety, toxicology, and PD/PK services to be provided by the Contractor include, but are not limited to:

- i. Determination of maximum tolerated dose and no observed effect levels (NOEL);
- ii. Determination of acute and subchronic toxicity;
- iii. Single and repeated dose toxicity studies;
- iv. Determination of relevant pharmacokinetic/toxicokinetic parameters;
- v. Bioavailability studies;
- vi. Absorption, distribution, metabolism, and excretion studies;
- vii. Genotoxicity testing;
- viii. Carcinogenicity testing, if relevant for therapeutic candidate;
- ix. Reproductive toxicity studies;
- x. Biotransformation assays conducted in vitro;
- xi. Cytotoxicity of compounds for actively dividing mammalian cells (e.g., IC<sub>50</sub>);
- xii. Immunotoxicity studies to determine the toxicity of candidate compounds to the immune system, or other specialized target organ systems;
- xiii. Behavioral pharmacology (e.g., functional observational battery, locomotor activity, convulsant activity, gastrointestinal motility, and sleep-time potentiation);
- xiv. Cell permeability; and
- xv. All other safety and pharmacology assays and studies that may be required for a particular therapeutic candidate.

### ***B. Comprehensive Product Development Plans for Compound Development, as Requested***

For certain compounds provided to the Contractor, SAIC may request a comprehensive Product Development Plan for services to be provided by the Contractor. The Product Development Plan is to be submitted to SAIC within 30 calendar days of notification for services. The Product Development Plan shall include: (i) specification of the resources and services to be provided; (ii) a description of the key development objectives; (iii) delineation of start date, project milestones, and time lines for the accomplishment of milestones; (iv) a description of the technical approach to carrying out the project and the physical facilities and other necessary resources to be made available; (v) a description of the project deliverables and a time line for their completion; (vi) a plan for Quality Assurance and Quality Control of the project; and (vii) a proposed budget that includes pricing for all components of the Product Development Plan, including management (i.e., the technical and administrative infrastructure for the Plan).

Project initiation shall proceed upon approval from SAIC. A reporting schedule for the Contractor shall be established upon approval of the Product Development Plan. A final report for the work proposed in each Product Development Plan is required. This report shall describe objectives, methodologies, results, and accomplishments relative to each milestone and deliverable. The format of the delivered final report will be one that is considered acceptable for inclusion in submissions to the FDA.

### ***C. Confidential Treatment of Sensitive Information***

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by SAIC during the performance of the contract. The Government has determined that the information/data that the Contractor will be providing during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the SAIC Subcontracts Administrator. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the SAIC Subcontracts Administrator.

### ***D. Technical Reporting Requirements***

#### ***i. General Reporting Requirements***

To meet the SMA Project's stated aim of accelerated drug development, Contractors should be able to promptly provide detailed status reports in a format acceptable to the FDA. See Section 7.3 for additional reporting requirements.

#### ***ii. Product Development Plan***

For some compounds provided to the Contractor, SAIC may request a comprehensive Product Development Plan for services to be provided by the Contractor leading to an IND application. The Product Development Plan, if requested, shall be submitted for review to the SAIC Principal Investigator within 30 days of notification for services. A reporting schedule for the Contractor to the SAIC shall be established upon approval of the Plan.

Contractors shall submit a final report for work proposed in each Product Development Plan. This report shall describe objectives, methodologies, results, and accomplishments relative to each milestone and deliverable. The due date for this report will be specified within each Product Development Plan. The format for this report shall be one that is acceptable for inclusion in FDA submissions.

#### ***iii. Offerors who receive funding may be asked to participate in an annual SMA Project meeting. The Contractor's Principal Investigator, SAIC staff, consultants, and NINDS staff attend these meetings. These meetings involve oral and electronic presentations including: (1) updates to include results of studies completed since the prior meeting, (2) interim reports on active protocols, (3) a description of any problem that may have arisen, and (4) a discussion of potential future protocols influenced by the evolving regulatory environment or other action items.***

### 3. INTENT TO SUBMIT FORM

Potential Offerors are requested to complete the Intent to Submit form (**Attachment A**). This form is neither binding nor required but will assist SAIC in planning for the expedited review of proposals. Offerors who do not submit an Intent to Submit form may still submit a proposal if all other deadlines and requirements are met.

### 4. PROPOSAL PREPARATION PROCEDURES

Before preparing a proposal, Offerors are advised to read this entire document and visit the SMA Project website (<http://www.SMAProject.org>) to learn more about the program, the nature of SMA Project contracts, and the SMA Project Testing Funnel. Offerors should also review the Subcontract Agreement, which is posted on the [Solicitations](#) page of the SMA Project website.

Proposals should only be submitted from Offerors based in the United States. In addition, only Offerors that meet criteria for federal funding eligibility, for example, the continued ban on funding of human embryo research, will be considered for award under this RFP.

To assist Offerors in assembling all the required documents, a Checklist for Submitting a Proposal and Supporting Documentation has been included as **Attachment B**.

#### 4.1 Proposal Face Page

The face page of the proposal must contain the following: The Proposal Title; Name of Offeror Institution; Principal Investigator's name, contact information, and signature; and the Business Representative's name, contact information, and signature.

The following statement should also be included: "This proposal complies with the Salary Rate Limitation pursuant to P.L. 108-149, and the Offeror certifies that no costs for independent research and development [IR&D], 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 Body

There is a **10-page limit** on the body of the proposal, including figures, tables, and graphs.

The body of the proposal should:

- Demonstrate a comprehensive understanding of the goals of this RFP and the capability to efficiently accomplish the SOW tasks and milestones (see Section 2).
- Demonstrate successful experience performing similar IND enabling studies and familiarity with FDA guidelines for small molecule preclinical research and development.
- Demonstrate current availability and schedule of the facility to perform the work in a timely manner.
- Develop an outline of required, suggested, and optional preclinical studies including cost, differential cost depending on animal model, and time line for each study.
- Describe approaches for quality control and assurances. Include a description of the problems that are likely to occur and how they will be corrected.
- Identify which studies will be performed in house and which will be subcontracted to other provider(s).
- Describe the roles, level of effort, and experience of personnel proposed to accomplish the work and the management structure for the project, as appropriate.
- Demonstrate the availability of necessary facilities and equipment.

### 4.3 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).

### 4.4 General Format Specifications

Proposals will be submitted electronically as an Acrobat PDF file or in Microsoft Word; proposals will be submitted via e-mail or on compact disk. The following format instructions must be followed when preparing the Proposal Body and References **or the application may be returned without review.** Prepare the documents so they will have the following appearance when printed single-sided on 8½ × 11 inch paper:

- The documents must be clear, readily legible, i.e., 10-point type font or larger, not more than 15 characters per inch (cpi) including spaces, single-spaced (6 lines of type within a vertical inch), and ½ inch margins in all directions.
- The Principal Investigator's (PI's) name and consecutive page numbers should be included on the Body, References, and Proposal Appendices.

Charts, tables, figures, figure legends, and footnotes may be smaller in size but must be readily legible. It is recommended that all graphs, tables, diagrams, and charts be prepared for printing with black ink. The application should contain only material that reproduces well when photocopied or printed in black and white since some reviewers may only receive a printed version. We discourage use of Internet website addresses to provide information necessary for the review since reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that directly accessing an Internet site could compromise their anonymity.

### 4.5 Biographical Sketches

**No page limit.** An unlimited number of biosketches are allowed. In general, each biosketch should be no longer than 4 pages in length; a full curriculum vitae should not be submitted. A biosketch for the PI must be included. Biosketches for additional key personnel should accompany the proposal. 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, Positions and Honors, Publications, and Research Support.

### 4.6 Past Performance

**Five-document limit, no page limit.** To demonstrate successful performance on work that is similar to that required, the Offeror should submit documentation to support past experience and success in advanced preclinical development of promising candidate compounds. Specific areas of performance include conducting applicable safety, toxicology, PD/PK, and biodistribution studies for small molecule compounds. This documentation can be in the format of the Offeror's choice, e.g., letters of recommendation, performance surveys, publications, and/or patent information. A two-page summary of past performance can be used as a cover/summary for this section.

### 4.7 Letters of Intent

**No page limit.** Provide evidence of intent (e.g., letters or e-mail) from all proposed sub-Offerors, collaborators, and consultants.

### 4.8 Proposed Pricing Information

**No page limit.** Use the Summary of Costs form, which is available on the [Solicitations](#) page of the SMA Project website, to submit pricing information. Note: It is anticipated that the award from this solicitation will be an ID/IQ Subcontract with subordinate T&M and FP Task Orders as specified in the following.

- The Offeror shall provide a fully loaded FP or T&M budget for the following drug development tasks to support a determination of cost reasonableness:

- Single dose acute toxicity (one species only [rat]; M/F; n = 20/group; GLP)<sup>1</sup>
- Single dose acute toxicity (one species only [rat]; M/F; n = 20/group; non-GLP)<sup>1</sup>
- In vivo micronucleus (mouse; GLP)<sup>2</sup>
- In vivo micronucleus (mouse; non-GLP)<sup>2</sup>
- 14-day toxicology study (one species only [rat])<sup>3</sup>
- Safety pharmacology, CV (in vivo)<sup>4</sup>
- Safety pharmacology, CNS (functional observational battery)<sup>4</sup>
- In vivo chromosome aberration (rat)<sup>2</sup>
- Oral bioavailability (dog)<sup>5</sup>
- 28-day repeated administration (rodent, beagle dog)<sup>6</sup>
- The Offeror may choose to provide budgets for additional drug development tasks.
- The Offeror shall provide a T&M budget for a comprehensive Product Development Plan for compound development, which may be requested by the SMA Project.
- Offerors should submit their most competitive offer initially since best and final offers will not be requested.

## 5. SUBMISSION OF PROPOSALS AND SUPPORTING DOCUMENTATION

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

### 5.1 Submission of Proposals

The Business Representative (the individual at the offering institution who is authorized to conduct subcontract negotiations and contractually bind the offer) must submit an electronic version of the proposal (PDF or Microsoft Word) so that it is received by **3:00 P.M. Eastern Time (ET) on October 5, 2007**.

Proposals may be submitted via e-mail to Lynne Darby at SMAProject-fd@saic.com or on CD (postmarked on or before the aforementioned required submission deadline) to:

Science Applications International Corporation (SAIC)  
Attn: Lynne Darby  
5340 Spectrum Drive, Suite N  
Frederick, MD 21703-7357

The electronic file should contain all items covered in Section 4, Proposal Preparation Procedures.

Signatures on the cover page can be submitted electronically or via fax to Lynne Darby at 301-698-7437 by the deadline stated previously. Questions related to proposal submission can be directed to Adam Book at 301-228-3114.

### 5.2 Submission of Supporting Documentation

The Subcontract Agreement, which is available on the [Solicitations](#) page of the SMA Project website, must be provided by **October 12, 2007**.

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<sup>1</sup> Guidance for Industry: Single Dose Acute Toxicity Testing for Pharmaceuticals, Center for Drug Evaluation and Research, 1996

<sup>2</sup> International Conference on Harmonisation (ICH) Guidance for Industry, S2A, Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals, 1996; and S2B, Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals, 1997

<sup>3</sup> ICH Guidance for Industry, S4A, Duration of Chronic Toxicity Testing in Animals, 1999

<sup>4</sup> ICH Guidance for Industry, S7A, Safety Pharmacology Studies for Human Pharmaceuticals, 2001

<sup>5</sup> ICH Guidance for Industry, S3B, Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution, 1995

<sup>6</sup> Following generally recognized experimental approach.

When completing the Subcontract Agreement, pay particular attention to the Schedule A Terms and Conditions, and Contract Clauses in Schedule B, Part II. The Subcontract Agreement must be signed on the final page of Schedule A as evidence of your concurrence with SAIC's terms and conditions. This section also contains intellectual property management provisions.

The Offeror's Business Representative must submit an electronic version of the Subcontract Agreement via e-mail to Lynne Darby at [SMAProject-fd@saic.com](mailto:SMAProject-fd@saic.com) or on CD to SAIC at the address listed in Section 5.1. Signatures can be submitted electronically or via fax to Lynne Darby at 301-698-7437 by the deadline stated previously.

**Note:** Proposals will not be considered further if this document is not received by **October 12, 2007**.

## **6. PROCEDURES FOR EVALUATION OF PROPOSALS AND SELECTION OF AWARD**

### **6.1 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 6.4, (2) recommendations of the SMA Project Steering Committee, (3) priorities of NINDS, and (4) availability of funds.

### **6.2 Compliance Check**

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

- Offerors are based within the United States.
- Only Offerors that meet criteria for federal funding eligibility—for example, 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.
- The proposal contains a cover page with signatures of the PI and Business Representative, a technical approach with the required time lines, a biographical sketch for the PI, and a budget.
- The Supporting Documentation contains required signatures.

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

### **6.3 Proposal Review Process**

A review panel composed of scientists with appropriate expertise will evaluate the proposals based on the criteria listed in Section 6.4, Proposal Review Criteria.

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.

### **6.4 Proposal Review Criteria**

Reviewers will evaluate proposals against the review criteria listed in the following paragraphs. The relative importance of each criterion 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 items to be considered in review.

- **Past Experience (30 points)** – Does the Offeror have past experience and success in developing a preclinical data set for small molecules resulting in a successful IND submission that was accepted, reviewed, and approved by the FDA for a clinical trial? Has the Offeror consistently remained in good standing with the FDA? Does the Offeror have successful experience in a comprehensive range of studies that may be required for preclinical compound evaluation?
- **Time Lines (30 points)** – Does the Offeror have the ability to deliver data on a schedule commensurate with the aggressive time lines of the SMA Project? Are the time lines technically feasible? Have all conceivable efficiencies been considered?

- **Technical Approach (20 points)** – Does the proposal address feasible strategies and methods to meet the proposed tasks and overall project goals? Do the assays and methods offered provide comprehensive coverage of requirements for preclinical compound evaluation? Have quality control and assurance issues commensurate with GLP and cGMP requirements been addressed?
- **Personnel/Facilities/Equipment (20 points)** – Are the available personnel adequately trained and experienced in use of the equipment, reagents, and procedures needed for establishing, validating, and utilizing the proposed assays? Are the appropriate facilities and equipment available to perform all of the preclinical research and development activities that are required for preclinical compound evaluation and to support preparation of an IND application? Is the capacity of the available personnel, facilities, and equipment sufficient to efficiently meet the changing needs of a small molecule development project? How much of the Offeror’s proposed work must be subcontracted?

**Price/Cost** – All the above mentioned evaluation criteria, other than cost or price, when combined, are significantly more important than cost or price.

## **6.5 Funding Recommendations and Award Negotiations**

Upon completion of the technical review and cost evaluation by SAIC, the Steering Committee will make funding recommendations to SAIC and NINDS for approval by NINDS.

NINDS and SAIC may want to conduct site visits within 6 weeks of proposal submission. With prior notification from SAIC, the Offeror is requested to make the facility available during normal business hours.

Notification of award status will be made in accordance with Federal Acquisition Regulations 15.503.

Awards will be made in the form of SMA Project contracts. These contracts will be funded by the Federal Government as subcontracts to the SAIC prime contract with NINDS/NIH.

## **7. ADDITIONAL INFORMATION FOR OFFERORS**

### **7.1 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.

### **7.2 Contact Information**

Technical or contractual questions can be e-mailed to [SMAProject-fd@saic.com](mailto:SMAProject-fd@saic.com) for resolution or clarification. The deadline for submission of questions will be 2 weeks after issuance of RFP; after this time period, no other questions will be addressed.

### **7.3 Progress Monitoring of Awards**

SAIC will monitor progress on each contract and task order. Offerors who receive funding will be asked to submit reports/updates on overall progress and separate reports with detailed results. Offerors will propose a 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 participants and NINDS’ 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.

#### **7.4 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 identifying and rapidly completing preclinical development of the SMA therapeutics that are most likely to be safe, effective, and approved for clinical use by the FDA. 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 an agent of the 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.

**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.**

### **8. BUSINESS INFORMATION RELATED TO SUBCONTRACTS**

#### **8.1 General Information**

ID/IQ subcontracts with Time and Materials (T&M) and/or Fixed Price (FP) Task Orders will be issued for one or more offers received in response to this RFP. Subcontract awards and subsequent Task Orders will be made to support the tasks outlined in the SOW (Section 2.1).

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 flow-down 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.

#### **8.2 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 Subcontracts Administrator. 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.

#### **8.3 Proposal Validity**

To be considered valid, your proposal must be received by the stated deadlines, be complete, and remain firm for 180 calendar days.

#### **8.4 Qualifications of Prospective Offeror**

The Offeror must have adequate technical and business management 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.

#### **8.5 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 *Offeror's Guide for Control of Government Property*, <http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/Offerorsguide.htm>, 1990), regardless of acquisition value.

#### **8.6 Late Offers**

Formal offers, amendments, or requests for withdrawal of offers received after the date specified for submittal may be considered at SAIC's discretion.

#### **8.7 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 Administrator 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.

### **8.8 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, does not appear to be in a position to perform the subcontract.

**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.**

**Attachment A**

**Intent to Submit:** A Proposal for RFP LD-090707, “Preclinical Studies of Small Molecules with Therapeutic Potential for Spinal Muscular Atrophy.”

Submission of this Intent to Submit form will assist in planning for the expedited review of proposals. Offerors who do not submit an Intent to Submit form may still submit a proposal if all other deadlines and requirements are met. Additionally, submission of this form does not bind the Offeror to submit a proposal.

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**Potential Offerors are requested to provide the following information.**

**Submitting Organization**

Principal Investigator’s Name \_\_\_\_\_

Institution/Organization \_\_\_\_\_

Principal Investigator’s E-mail \_\_\_\_\_

**Probable Consultant/Collaborators**

1. Consultant/Collaborator Name \_\_\_\_\_

Institution/Organization \_\_\_\_\_

2. Consultant/Collaborator Name \_\_\_\_\_

Institution/Organization \_\_\_\_\_

3. Consultant/Collaborator Name \_\_\_\_\_

Institution/Organization \_\_\_\_\_

4. Consultant/Collaborator Name \_\_\_\_\_

Institution/Organization \_\_\_\_\_

**This form can be submitted by September 21, 2007.**

1. Via fax to Lynne Darby/SAIC at 301-698-7437

OR

2. You may provide the information noted above in an e-mail to [SMAProject-fd@saic.com](mailto:SMAProject-fd@saic.com).

**Attachment B**  
**Checklist for Submitting a Proposal and Supporting Documentation**

**Proposal** (Deadline: 3:00 P.M. Eastern Time, October 5, 2007)

One electronic copy of the following:

- \_\_\_ Proposal Face Page with signatures of the PI and Business Representative
- \_\_\_ Proposal Body (10-page limit)
- \_\_\_ References (no page limit)
- \_\_\_ Biographical Sketches (PI biosketch must be included; 4-page limit per biosketch)
- \_\_\_ Past Performance (5-document limit; 2-page limit for cover/summary)
- \_\_\_ Letters of Intent (no page limit)
- \_\_\_ Proposed Pricing Information (no page limit)
- \_\_\_ Subcontractor proposed reporting format

**Supporting Documentation** (Deadline: October 12, 2007)

One electronic copy of the following:

- \_\_\_ Subcontract Agreement (Attachments 2–5)  
*The entire document must be read and completed as necessary. Of note, a signature is needed in the following place:*
- \_\_\_ Schedule A, page 10 – Offeror must identify any exceptions or changes at the time of submission.

*Also note that as part of the Subcontract Agreement you must provide the following:*

- \_\_\_ An approved Animal Welfare Assurance from the Office of Laboratory Animal Welfare if you propose using animals (Schedule B, Part II, Section 6a).
- \_\_\_ An intellectual property management plan that satisfies the requirements outlined in the Subcontract Agreement (Schedule B, Part II, Section 16).

*In addition, prior to the start of research involving animals you must provide the following:*

- \_\_\_ Verification of approval (including the date of most recent approval) by the Institutional Animal Care and Use Committee with appropriate documentation (Schedule B, Part II, Section 6b).
- \_\_\_ Memorandum – Requirements Related to Human Subjects, Specimens, and Recombinant DNA Research (Attachment 6)  
*Note that a signature is needed on page 2 of this document.*
- \_\_\_ U.S. Government Property Questionnaire (Attachment 7)  
*Note that a signature is needed on page 2 of this document.*

**Note:** A Subcontracting plan approved by SAIC and completed Online Representations and Certification Application or Representations and Certifications documents will be required prior to subcontract award if the successful offeror is a large business.

This form is provided to assist the Offeror in submitting all the required information. This form does not need to be submitted with the Offeror's proposal or Supporting Documentation.