

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the RFP provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these additional Technical Proposal instructions are tailored to the specific requirements of the RFP. The information requested in these instructions should be used, along with Section L. to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions requested here.

Offerors are advised to give careful consideration to the Statement of Work (SOW), Mandatory Qualification Criteria, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

Offerors should submit a proposal that addresses the Mandatory Qualification Criteria and all areas in the Statement of Work. If the proposed approach will involve subcontracting arrangements, then the offeror shall include a letter of commitment from each subcontractor, plus documentation of subcontractor's expertise, qualifications and prior performance, as well as a narrative describing how the contractor will manage the subcontractors.

A detailed work plan should be submitted indicating how each aspect of the Statement of Work is to be accomplished. Your technical proposal should be in as much detail as you consider necessary to explain fully your proposed methods and rationale for their selection and should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must also include information on how the project is to be organized, staffed, and managed. Information should be provided that will demonstrate your understanding of management of timeframes for planning and accomplishing the work to be performed.

Record and discuss specific factors not included elsewhere that support your proposal. Using specifically titled subparagraphs, items may include: Unique arrangements, equipment, etc., which none or very few organizations are likely to have that is advantageous for effective implementation of this project.

The Government encourages the offerors to be complete but succinct in the presentation and to limit the total number of pages to 150. See content below:

TOTAL PAGE COUNT DOES INCLUDE: Principal Investigator's (PI's) resume/*Curriculum Vitae* (CV), with highlights of any items that are directly related to the subject project, indicated by preceding them with a double asterisk (**).

TOTAL PAGE COUNT DOES NOT INCLUDE (some of which may be added as appendices): Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section; Resumes/CVs of other key personnel (same information and format as used for the PI); certificates and licensures, examples of protocols, Standard Operating Procedures (SOP), Health and Safety Manual, letters of commitment by proposed consultants and subcontractors.

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

FORMATTING AND LAYOUT:

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11").
- Offerors shall NOT use 8.5 x 14 legal size paper.
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers/reviewers to alternate sources of information.
- Additional appendices may be added as needed.
- The proposal with pagination, including appendices, shall be formatted by sections, cross referenced, and include a detailed Table of Contents with page references.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

General Instructions:

SECTION 1

- A. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
- B. PROJECT OBJECTIVES (NIH FORM 1688-1)
- C. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
- D. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
- E. TABLE OF CONTENTS

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

SECTION 2: MANDATORY QUALIFICATION CRITERIA

The offeror should include all information that documents and/or supports the mandatory qualification criterion in one clearly marked section of its technical proposal.

Mandatory Qualification Criteria can be found in Section M of the RFP.

This section related to the Mandatory Qualification Criteria must be listed in the Table of Contents with a page reference.

SECTION 3: TECHNICAL DISCUSSIONS

A. Personnel and Experience

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Clearly identify who is to be assigned as Key Personnel. Limit Curriculum Vitae (CVs) to 2-3 pages and provide selected references for publications relevant to the scope of the RFP, and include experience with projects of similar scope, size and complexity carried out by the Offerer and any proposed subcontractors over the past five (5) years.

1. **Principal Investigator**: Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract, including: managing an interdisciplinary team in the conduct of studies involving identification of agents *In Vitro* and *In Vivo* to qualify potential cancer preventative or other pharmacological, hormonal, or nutritional agents for further testing and clinical development. The Principal Investigator should have a Ph.D., D.V.M. or M.D. degree or equivalent experience. The qualification and experience of the Principal Investigator should be discussed in terms how they are appropriate to the management of any planned subcontracts. Discuss how the technical and scientific planning and implementation of Task Orders will be managed by the Principal Investigator.
2. **Other Scientific and Technical Personnel**: Describe the education, training, experience, expertise, qualifications, and percentage of effort for all proposed key scientific and technical personnel of the offeror and all proposed subcontractors. Document relevant qualifications for: pathology (specifically necropsy of animals and microscopic evaluation of blood and tissues), clinical pathology, statistics, veterinary medicine, laboratory animal care, analytical chemistry, pharmacokinetics and quality assurances.
3. **Additional Personnel**
 - Offerors staff should include an experienced DVM pathologist with certification as an American College of Veterinary Pathology (ACVP) diplomate to oversee necropsy and

conduct histopathological evaluations. If the offeror does not have a DVM pathologist with the above credentials, the offeror may propose a subcontractor.

B. TECHNICAL APPROACH

Offerors shall submit a proposal that addresses all areas in the Statement of Work. Only proposals from offerors who demonstrate the capability to perform all aspects of the Statement of Work, either at their institution or through their subcontractors, will be considered for award. If the proposed approach will involve a subcontracting arrangement, then the offeror shall include a letter(s) of commitment from the subcontractor(s), plus documentation of subcontractor's expertise, qualifications and prior performance, as well as a narrative describing how the contractor will manage the subcontractor(s).

1. Describe the procedures to be used for carrying out the types of preclinical *In vivo/In vitro* studies indicated in the Statement of Work, including criteria for moribund sacrifice, method and equipment to be used for euthanasia, collection, handling and storage of blood samples for clinical pathology and plasma drug analysis, necropsy and histopathology procedures, and analytical chemistry procedures.

Please provide a response to each of the below sample task orders for the following types of assays, as described in the Statement of Work:

- a) Sample Task Order – In Silico/cell free high throughput screens.
- b) Sample Task Order – mechanistic studies following screens of Chemopreventive agents *In vitro*.
- c) Sample Task Order – mechanistic studies following screens of Chemopreventive agents *In vivo*.
- d) Sample Task Order – Pharmacokinetics and pharmacodynamics in experimental animals.

See also the Additional Business Proposal Instructions regarding development of budgets for each sample Task Order response.

2. Describe the approach to the development of analytical procedures for the assay of a drug in plasma, urine, and tissues.
3. Describe the features and capabilities of data management, including software programs currently in use.
4. Describe proposed plans for oversight of data management functions, including protection of intellectual property and confidentiality of compound data.
5. Describe the operation of the Quality Assurance Unit within your organization concerning auditing of critical study events, raw data and study reports. Indicate when these audits take place in relation to the generation of data and reports.
6. Provide a copy of Standard Operating Procedures (SOPs) relating to the conduct of the type of work found in the Statement of Work, including laboratory SOPs.

C. FACILITIES AND EQUIPMENT

1. Facilities - The offeror shall have an operating laboratory that is suitable for cell culture and laboratory animal studies using hazardous and/or carcinogenic test materials. The laboratory shall be capable of handling hazardous chemicals safely and must be able to provide appropriate facilities for housing animals required in the study. The laboratory and animal care must be sanitary and properly maintained in accordance with the criteria set forth by the animal accreditation organizations (see Mandatory Qualifications Criteria).

Discuss operation, procedures, and administration of the In Silico/cell-free high through put systems, cell culture and animal facility and provide floor plan(s) drawn to scale (including scaling factor). The Offeror should also indicate the location (with distance) for any facilities which are not contiguous.

The offerors should describe the facilities and equipment that belong to subcontractors. Where facilities of the offeror (prime) are not contiguous and for any non-co-localized subcontractors, the offeror should describe logistical plans for the transfer of materials and/or data.

Discussion shall include, as appropriate, but not be limited to:

- available room capacities
- temperature controlled CO₂ incubators, sterile laminar flow hoods
- sterile tissue culture materials and techniques
- cryopreservation capability, microscopy capability
- climate controls and alarm systems
- caging and exercise areas
- diet and compound storage and preparation areas
- water systems
- cage washing areas
- data collection and computer systems
- animal treatment laboratories (cardiology, ophthalmology, phlebotomy, necropsy)
- clinical and anatomic pathology laboratories and established quality control practices
- electrical and environmental back up provisions for critical components e.g. animal rooms, chemical test article and biological samples, etc.
- data back-up systems

2. Equipment - The offeror shall have all the equipment necessary to accomplish the studies including, but not limited to, incubators, microscopes, centrifuges, animal racks and caging, hazardous chemical storage cabinets and refrigerators, pathology equipment such microtomes, laboratory and analytical chemistry equipment. The laboratory shall have or have access to appropriate terminal and computer facilities and equipment for data collection and storage.

D. ORGANIZATIONAL BACKGROUND AND EXPERIENCE

Discuss prior experience with similar tasks and provide documentation of completed studies. Provide documentation of abilities to interact with industrial collaborators and academic researchers.

1. Quality Assurance - The offeror shall discuss the organization, operation, and responsibilities of the Quality Assurance Unit in similar studies. Validation studies undertaken to assure the accuracy of transmitted data for the version(s) of software shall be described.

2. Statistics - Methods of statistical analysis (parametric versus nonparametric) shall be described by the offeror for data and underlying distributions being compared.
3. Subcontracts - In the event that the offeror does not have facilities, equipment, or personnel for performing any component of the described task, then the offeror shall be prepared to implement the work through a suitable subcontractor(s). Letters of commitment from and qualifications of all proposed subcontractors shall be included in the proposal. The offeror shall describe any previous working relationship with proposed subcontractors. Furthermore, the offeror shall address how they will handle privity of contract issues, i.e., the offeror should explain how information will flow between the NCI, the prime contractor (offeror), and any subcontractors since the prime contractor's presence is required for any discussions.
4. Agents - to be investigated by this project are potentially hazardous. Discuss laboratory practices that will be employed that shall keep any element of risk to personnel at an absolute minimum.
5. Safety and Health for Personnel - Provide a Safety and Health Plan. Offerors' Safety and Health Plan shall include recent and ongoing organizational background and experience in each task area in the Statement of Work (SOW). Offerors should also submit their Safety Manual on a CD.

Offerors should describe procedures and controls to be employed during tests included in the SOW to insure that the work is conducted in a safe and healthful manner. All pertinent chemical and or biological hazards shall be addressed in the Plan, from receipt of test agents to ultimate disposal of contaminated waste. Details of appropriate administrative and emergency controls, personnel, protective equipment and work practices should be addressed. All work shall comply with applicable local, State and Federal statutes relating to occupational safety and health, transportation and handling, and environmental protection. Discuss equipment and unusual operating procedures established to protect personnel from hazards associated with this project and other factors you feel are important and support your proposed approach.