Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Amyotrophic Lateral Sclerosis Research Program

Therapeutic Development Award

Funding Opportunity Number: W81XWH-10-ALSRP-TDA

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I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

The Amyotrophic Lateral Sclerosis Research Program (ALSRP) was established in 2007 to provide support for research of exceptional scientific merit aimed at preclinical assessment of therapeutics for amyotrophic lateral sclerosis (ALS). Appropriations for the ALSRP from fiscal year 2007 (FY07) through FY09 totaled $10 million (M). The FY10 appropriation is $7.5M.

The goal of the ALSRP is to promote the introduction of improved therapies for ALS by encouraging ALS investigators to undertake preclinical studies of novel and existing agents.

B.   Award Description

The ALSRP Therapeutic Development Award mechanism was first offered in FY07. Since then, 61 Therapeutic Development Award applications have been received, and 6 have been recommended for funding.

The Therapeutic Development Award supports the preclinical assessment of therapeutics for ALS. The proposed studies are expected to be empirical in nature and product-driven, but may have a hypothesis-driven approach, provided the focus is on therapeutics. It is anticipated that the agents and/or data generated from these awards will lead to the advancement of therapeutics for ALS.

The Therapeutic Development Award mechanism is designed to support *preclinical* testing and development of therapeutics for ALS. Proposals must include *preliminary data* relevant to the phase(s) of the preclinical development process covered by the proposed research. The proposal should include a clear statistical plan of analysis, if appropriate. Applicants must clearly and explicitly articulate what impact the project may have on therapeutic development for ALS. **Clinical trials will not be supported with this Program Announcement/Funding Opportunity**.

In contrast, investigators interested in more basic research focused on ALS therapeutics should consider the FY10 ALSRP Therapeutic Idea Award, which does not require preliminary data. (*http://cdmrp.army.mil/alsrp*).

Therapeutic Development Award proposals are limited to the areas of programmatic interest listed below. Proposals must focus on one or more of these areas to be considered for funding. Proposals that do not focus on at least one of the following areas will be administratively withdrawn.

- Development and/or validation of high-throughput screens to define targets with therapeutic potential or to identify lead agents for ALS treatment and be an asset for the ALS research community;
- Development, modification, and/or validation of preclinical model systems in order to assess lead compounds and potential therapeutics by pharmacological and/or

pharmacokinetic testing. Such models would also serve as improved tools for the ALS research community;

- Development of pharmacologic agents through Adsorption, Distribution, Metabolism, Excretion, and Toxicity (ADMET) phase;

- Design and implementation of full-scale, pilot current Good Manufacturing Practice (cGMP) production of therapeutics and/or delivery systems for use in advanced preclinical and initial clinical trials;

- Development of pharmacologic agents to the Investigational New Drug (IND) stage in order to initiate Phase I clinical trials after the award's completion.

The preclinical drug development process may require resources beyond those available at a single organization. Therefore, *Therapeutic Development Awards are open to investigators participating in synergistic collaborations focused on identifying and/or testing lead agents for the treatment of ALS*. Collaborations should be dedicated to a single, synergistic preclinical development project or study rather than an additive set of subprojects (i.e., the combined efforts of the collaboration must provide greater benefit than the sum of individual research initiatives). *If a collaboration is proposed, letters confirming/supporting the collaboration are required*. If the collaboration is multi-organizational, participating organizations will ensure the success of the collaboration by resolving potential intellectual and material property issues, and by removing organizational barriers that might interfere with achieving high levels of cooperation. A proposed means to resolve these issues must be delineated in an Intellectual and Material Property Plan. Also, due to the nature of the work involved in the development process, biotechnology or pharmaceutical companies are invited to apply. Whether a biotechnology or pharmaceutical company applies for this mechanism as an individual applicant or as part of a collaboration, the company is expected to leverage its own resources to complement the funding provided by this award.

Use of human subjects and human biological substances: Because these awards are designed for preclinical studies, projects involving human subjects or specimens will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]). *Studies that do not qualify for exempt status during review at any level will be administratively withdrawn and will not be funded.*   Additional information regarding exempt status may be found on the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (https://mrmc.amedd.army.mil/rodorphrpo.asp) and the Application Instructions and General Information, Appendix 5, for this award mechanism.

C.   Eligibility

Independent investigators at all academic levels (or equivalent) are eligible to submit proposals. Refer to General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.

- The maximum allowable funding for the entire period of performance is **$1,500,000** in direct costs.

- More cost-effective studies that do not request the full available funding amount are encouraged. The maximum allowable direct cost funding may also be requested for a project that requires less than the maximum **3-**year period of performance.

- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

Within the guidelines provided in the General Application Instructions, funds can cover:

- Salary

- Research supplies

- Equipment

- Consultation with scientific and/or technical experts (e.g., statisticians, editors)

- Clinical research costs

- Travel between collaborating organizations

- Travel funds must be requested for the PI to attend one DOD military research-related meeting to be determined by the Office of the Congressionally Directed Medical Research Programs (CDMRP) during the award performance period.

- Travel costs of up to $1,800 USD per year to attend scientific/technical meetings

- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $4.8M of the $7.5M FY10 ALSRP appropriation to fund approximately two Therapeutic Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), May 14, 2010**

- **Invitation to Submit an Application: June 2010**

- **Application Submission Deadline: 11:59 p.m. ET, August 4, 2010**

- **Scientific Peer Review: September 2010**

- **Programmatic Review: December 2010**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/). ***Applications will be invited based on pre-application screening.***

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

A.   Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by ***5:00 p.m. ET on the deadline***. Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs (Refer to the General Application Instructions for additional information on pre-application submission):

- **Proposal Information – Tab 1**

- **Proposal Contacts – Tab 2**

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

- **Required Files – Tab 4**

  Preproposal Narrative (three-page limit): The Preproposal Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The Preproposal Narrative should describe the following:

- o **Research Strategy and Objectives:** State the rationale on which the proposed work is based. Concisely state the project's objectives and specific aims.
- o **Impact:** How the project will make an important contribution to ALS research and/or therapeutic development.
- o **Personnel:** Briefly state the PI's qualifications to perform the described research project.

  Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- o References Cited (one-page limit): List relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.
- o Key Personnel Biographical Sketches (four-page limit per individual)

- • **Submit Pre-application – Tab 5**

  Pre-Application Screening: Pre-applications will be screened by the ALSRP Integration Panel (IP), composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- o **Research Strategy and Objectives:** How the scientific rationale supports the project objectives and feasibility.
- o **Impact:** How the project will make an important contribution to ALS research and/or therapeutic development.
- o **Personnel:** How the PI's qualifications are appropriate to perform the proposed research project.

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., strengths and weaknesses) on their pre-application.

B.   Step 2 – Application Components

Applications will not be accepted unless the PI has received a letter of invitation.

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (http://www.grants.gov/). Applications must be submitted **by *11:59 p.m. ET on the deadline.***

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.B., for detailed information.

2. **Attachments Form**

   - **Attachment 1: Project Narrative (20-page limit):** Upload as "ProjectNarrative.pdf."

     Describe the proposed project in detail using the outline below. The project narrative must include preliminary data relevant to the phase(s) of the preclinical development process covered by the proposed research.

     ○ **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this project.

     ○ **Objectives and Specific Aims:** Concisely explain the project's objectives and specific aims and their rationale.

     ○ **Research Strategy:** Describe the study design, methods and analyses, including statistical analyses where applicable, in sufficient detail for assessment of the proposal. Address potential problem areas and present alternative methods and approaches**.**

   - **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***Each component has no page limit unless otherwise noted.***

     ○ References Cited: List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.

     ○ List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).

     ○ Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.

     ○ Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.

     ○ Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters if applicable), signed by the Department Chair or appropriate

organization official, reflecting the laboratory space, equipment, and other resources available for the project.

- ○ Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

- ○ Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  Use the outline below.
  - ○ Background: Present the ideas and reasoning behind the proposed work.

  - ○ Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

  - ○ Specific Aims: State the specific aims of the study.

  - ○ Study Design: Briefly describe the study design including appropriate controls.

  - ○ Impact: Summarize briefly how the proposed project will impact development of therapeutics for ALS.

- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."

  Clearly describe, in a manner readily understood by laypersons, the rationale and objective for the proposal. Do not duplicate the technical abstract.

  Describe the ultimate applicability of the research.
  - o What types of patients will it help and how will it help them?

  - o What are the potential clinical applications, benefits, and risks?

  - o What is the projected time it may take to achieve a patient-related outcome?

  - ○ What are the likely contributions of this study in advancing development of therapeutics for ALS?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as "Budget.pdf." Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as "SubBudgets.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 8: Impact Statement (one page limit):** Upload as "Impact.pdf." Explain how the expected results of the study will make an important contribution to ALS therapeutic development. For projects involving hypothesis-driven research, describe the potential impact on the concepts or methods that drive therapeutic development. For projects involving product-driven research, describe the potential impact on patients' lives for the product.

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.B., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."

- PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."

- Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.B., for detailed information.

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a nondisclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal

awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B.   Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria. Research Strategy and Translational Potential are of equal importance.

- **Research Strategy (preliminary data are required)**
  - How the scientific rationale supports the feasibility and development of the proposed product as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning;
  - How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed (if the proposal is hypothesis-driven). Alternatively, whether the study has clearly identified endpoints (if the proposal is product-driven);
  - How well the applicant acknowledges potential problems and addresses alternative approaches;

  And, as appropriate:

  - The suitability of the screening assays and preclinical models to be developed, modified, and/or validated for identification and/or assessment of therapeutic agents;
  - Whether the applicant clearly demonstrates the intent to use the proposed tools or models for preclinical therapeutic testing, not for basic research;
  - How the outlined chemical synthetic pathways for modification of lead compounds or the formulation of potential delivery systems are based in rational design.

- **Translational Potential**
  - How the project addresses one or more of the programmatic interests stated in the program announcement;
  - How the study will make an impact on the development of therapeutics for ALS;
  - For projects involving hypothesis-driven research, the potential impact on the concepts or methods that drive therapeutic development;
  - For projects involving product-driven research, the potential impact on patients' lives.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Personnel**
  - How the research team's background and expertise are appropriate to develop

the proposed product or, for hypothesis-driven proposals, to conduct the proposed research;

- o Appropriateness of the levels of effort for successful development of the proposed product;

- o If multiple investigators are participating in the project, whether the letters of collaboration adequately describe all aspects of the collaborative effort.

- **Environment**
  - o The appropriateness of the scientific environment for the proposed research;
  - o How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements);
  - o The quality and extent of organizational support;
  - o If multi-organizational, the quality and completeness of the Intellectual and Material Property Plan.

- **Budget**
  - ○ Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**
  - ○ How the writing and components of the application influenced the review.

2. Programmatic Review: The following equally weighted criteria are used by programmatic reviewers to make funding recommendations.

- Ratings and evaluations of the peer reviewers
- Programmatic relevance
- Relative impact
- Program portfolio composition
- Adherence to the intent of the award mechanism

V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application for which a letter of invitation was not sent.
- Submission of an application for which a pre-application was not submitted.

B. Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY10 ALSRP Integration Panel (IP) member(s) is found to be involved in the preapplication or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY10 ALSRP IP members may be found at http://cdmrp.army.mil/alsrp/panel10
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- The Proposal does not focus on at least one of the listed areas of programmatic interest.

D.   Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be requested to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

VI.   CONTACT INFORMATION

A.   CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Email: cdmrp.pa@amedd.army.mil

B.   CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Email: help@cdmrp.org

C.   Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1	
	Upload Supporting Documentation (Support.pdf) as Attachment 2	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4	
	Upload Statement of Work (SOW.pdf) as Attachment 5	
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
	Upload Impact Statement (Impact.pdf) as Attachment 8	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field	
Project/Performance Site Location(s) Form	Complete form as instructed	

Detailed Budget and Justification

Name of Principal Investigator: _____ _____ _____ _____
                                                    Last Name   *First Name*   *Middle Name*   *Suffix*
CDMRP log number: _____
Period of Performance: **From:** _____   **Through:** _____

SENIOR/KEY PERSON & OTHER PERSONNEL		TYPE APPT. (MONTHS)	ANNUAL BASE SALARY	EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED (OMIT CENTS)		
DETAILED BUDGET FOR YEAR ONE							
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
	Principal Investigator						

A. SUBTOTAL PERSONNEL COSTS				

Detailed Budget and Justification

DETAILED BUDGET FOR YEAR ONE (CONTINUED)	
OTHER DIRECT COSTS	
MAJOR EQUIPMENT (ITEMIZE)	
TRAVEL COSTS	
MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)	
CONSULTANT COSTS	
SUBAWARD/CONSORTIUM/CONTRACTUAL COSTS (ITEMIZE, INCLUDE TOTAL COSTS INCLUDING DIRECT AND INDIRECT COSTS)	
RESEARCH-RELATED SUBJECT COSTS	
OTHER EXPENSES (ITEMIZE BY CATEGORY)	
B. SUBTOTAL OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD	
C. TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (A+B)	
D. TOTAL INDIRECT COSTS FOR INITIAL BUDGET PERIOD	
TOTAL COSTS FOR INITIAL BUDGET PERIOD (C+D)	

Detailed Budget and Justification

BUDGET CATEGORY TOTALS*	BUDGET YEAR ONE	ADDITIONAL YEARS OF SUPPORT REQUESTED				TOTAL
		2nd	**3rd**	**4th**	**5th**	
BUDGET FOR ENTIRE PROPOSED PERIOD OF PERFORMANCE						
A. **PERSONNEL COSTS**						
SALARY REQUESTED						
FRINGE COSTS						
B. **OTHER COSTS**						
MAJOR EQUIPMENT						
TRAVEL COSTS						
MATERIALS, SUPPLIES, AND CONSUMABLES						
CONSULTANT COSTS						
SUBAWARD/CONSORTIUM/CONTRACTUAL COSTS						
RESEARCH-RELATED SUBJECT COSTS						
OTHER EXPENSES						
C. TOTAL DIRECT COSTS						
D. TOTAL INDIRECT COSTS						

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT	
TOTAL INDIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT	
TOTAL COSTS FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT THIS AMOUNT MUST MATCH WITH THAT ENTERED **ON THE SF 424, BLOCK 16A**	

 * Itemize all budget categories for additional years on the Justification page that follows.

Detailed Budget and Justification

JUSTIFICATION

FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

Detailed Budget and Justification

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JUSTIFICATION

FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel on page 1 of the Detailed Budget and Justification form for the initial budget period.

NAME	POSITION TITLE

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*			
INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

Biographical Sketch Format Page