Enter a name for the application in the Application Filing Name field.
- This application can be completed in its entirety offline; however, you will need to login to the Grants.gov website during the submission process.
- You can save your application at any time by clicking the “Save” button at the top of your screen.
- The “Submit” button will not be functional until the application is complete and saved.

Open and complete all of the documents listed in the “Mandatory Documents” box. Complete the SF-424 form first.
- It is recommended that the SF-424 form be the first form completed for the application package. Data entered on the SF-424 will populate data fields in other mandatory and optional forms and the user cannot enter data in these fields.
- The forms listed in the “Mandatory Documents” box and “Optional Documents” may be predefined forms, such as SF-424, forms where a document needs to be attached, such as the Project Narrative or a combination of both. “Mandatory Documents” are required for this application. “Optional Documents” can be used to provide additional support for this application or may be required for specific types of grant activity. Reference the application package instructions for more information regarding “Optional Documents”.
- To open an item, simply click on it to select it, then click on the “Open Form” button. When you have completed a form or document, click the form/document name to select it, and then click the “Close” button. When you have completed all the forms/documents to the “Complete Documents” box.

Click the “Submit” button to submit your application to Grants.gov.
- Once you have properly completed all required documents and saved the application, the “Submit” button will become active.
- You will be taken to a confirmation page where you will be asked to verify that this is the funding opportunity and Agency to which you want to submit an application.
Do you wish to sign and submit this Application?

Please review the summary provided to ensure that the information listed is correct and that you are submitting an application to the opportunity for which you want to apply.

If you want to submit the application package for the listed funding opportunity, click on the "Sign and Submit Application" button below to complete the process. You will then see a screen prompting you to enter your user ID and password.

If you do not want to submit the application at this time, click the "Exit Application" button. You will then be returned to the previous page where you can make changes to the required forms and documents or exit the process.

If this is not the application for the funding opportunity for which you wish to apply, you must exit this application package and then download and complete the correct application package.
**APPLICATION FOR FEDERAL ASSISTANCE**

**SF 424 (R&R)**

1. **TYPE OF SUBMISSION**
   - [ ] Pre-application
   - [ √ ] Application
   - [ ] Changed/Corrected Application

2. **DATE SUBMITTED**
   - 

3. **DATE RECEIVED BY STATE**
   - 

4. **Federal Identifier**
   - 

5. **APPLICANT INFORMATION**
   - * Organizational DUNS: 016000860
   - * Legal Name: University of Kansas Medical Center Research Institute, Inc.
   - Department: 
   - Division: 
   - * Street1: MSN 1039, 3901 Rainbow Boulevard
   - Street2: 
   - * City: Kansas City
   - County: Wyandotte
   - * State: KS: Kansas
   - Province: 
   - * Country: UNITED ST
   - * ZIP / Postal Code: 66160

   Person to be contacted on matters involving this application:
   - Prefix: Mei-Shya
   - First Name: Mei-Shya
   - Middle Name: 
   - Last Name: Chen
   - Suffix: 
   - Phone Number: 913-586-1251
   - Fax Number: 913-586-3225
   - Email: spa@kumc.edu

6. **EMPLOYER IDENTIFICATION (EIN) or (TIN):**
   - 148110830A3

7. **TYPE OF APPLICANT:**
   - X: Other (specify)
   - Other (Specify): University Affiliated Nonprofit Organization
   - Small Business Organization Type
   - Women Owned
   - Socially and Economically Disadvantaged

8. **TYPE OF APPLICATION:**
   - [ √ ] New
   - [ ] Resubmission
   - [ ] Renewal
   - [ ] Continuation
   - [ ] Revision

   If Revision, mark appropriate box(es):
   - [ ] A. Increase Award
   - [ ] B. Decrease Award
   - [ ] C. Increase Duration
   - [ ] D. Decrease Duration
   - [ ] E. Other (specify):

   * Is this application being submitted to other agencies? Yes [ ] No [ √ ]
   - What other Agencies?

9. **NAME OF FEDERAL AGENCY:**
   - National Institutes of Health

10. **CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:**
    - TITLE: 

11. **DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:**
    - The Study of Everything

12. **AREAS AFFECTED BY PROJECT** (cities, counties, states, etc.)
    - N/A

13. **PROPOSED PROJECT:**
    - * Start Date: 12/01/2008
    - * Ending Date: 11/30/2013

14. **CONGRESSIONAL DISTRICTS OF:**
    - a. * Applicant: KS-003
    - b. * Project: KS-003

15. **PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION**
    - Prefix: 
    - * First Name: John
    - Middle Name: 
    - Last Name: Doe
    - Suffix: PhD
    - Position/Title: Professor
    - Department: Neurology
    - Division: School of Medicine
    - * Street1: MSN 2012, 3901 Rainbow Boulevard
    - Street2: 
    - * City: Kansas City
    - County: Wyandotte
    - * State: KS: Kansas
    - Province: 
    - * Country: UNITED ST
    - * ZIP / Postal Code: 66160
    - * Phone Number: 913-588-0000
    - Fax Number: 913-588-0000
    - Email: jdoe@kumc.edu

OMB Number: 4040-0001
Expiration Date: 04/30/2008
16. ESTIMATED PROJECT FUNDING
   a. * Total Estimated Project Funding 1,837,500.00
   b. * Total Federal & Non-Federal Funds 1,837,500.00
   c. * Estimated Program Income 0.00

17. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?
   a. YES □ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
      DATE:
   b. NO ☑ PROGRAM IS NOT COVERED BY E.O. 12372; OR
      ☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

18. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 16, Section 1001)

   ☑ * I agree

   * The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

19. Authorized Representative
   Prefix:               * First Name: Paul
   Middle Name: F.
   * Last Name: Terranova
   Suffix: PhD

   * Position/Title: Vice Chancellor for Research
   * Organization: University of Kansas Medical Center Research Institute, Inc.
   Department: 
   Division: 
   * Street1: MSN 1038, 3901 Rainbow Boulevard
   Street2: 
   * City: Kansas City
   County: Wyandotte
   * State: KS: Kansas
   Province: 
   * Country: US
   * ZIP / Postal Code: 66160

   * Phone Number: 913-588-1251
   Fax Number: 913-588-3225
   * Email: spa@kumc.edu

   * Signature of Authorized Representative
   Completed on submission to Grants.gov

   * Date Signed
   Completed on submission to Grants.gov

20. Pre-application

21. Attach an additional list of Project Congressional Districts if needed.

OMB Number: 4040-0001
Expiration Date: 04/30/2008
# RESEARCH & RELATED Senior/Key Person Profile (Expanded)

## PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Prefix</th>
<th>* First Name</th>
<th>Middle Name</th>
<th>* Last Name</th>
<th>Suffix</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>John</td>
<td></td>
<td>Doe</td>
<td>PhD</td>
</tr>
</tbody>
</table>

**Position/Title:** Professor  
**Department:** Neurology  
**Organization Name:** University of Kansas Medical Center  
**Division:** School of Medicine  
**Street1:** MSN 202, 3901 Rainbow Boulevard  
**City:** Kansas City  
**County:** Wyandotte  
**State:** KS  
**Province:**  
**Country:** UNITED ST/  
**Zip / Postal Code:** 66160  
**Phone Number:** 913-588-0000  
**Fax Number:** 913-588-0000  
**E-Mail:** jdoe@kumc.edu

**Credential, e.g., agency login:** JDOE  
**Project Role:** PD/PI  
**Other Project Role Category:**  

*Attach Biographical Sketch*  
**Biographical Sketch.pdf**  
**Add Attachment**  
**Delete Attachment**  
**View Attachment**  

**Attach Current & Pending Support**

## PROFILE - Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>* First Name</th>
<th>Middle Name</th>
<th>* Last Name</th>
<th>Suffix</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Paul</td>
<td></td>
<td>Simon</td>
<td>PhD</td>
</tr>
</tbody>
</table>

**Position/Title:** Associate Professor  
**Department:** Physical Therapy and Rehab  
**Organization Name:** University of Kansas Medical Center  
**Division:** School of Allied Health  
**Street1:** MSN 202, 3901 Rainbow Boulevard  
**City:** Kansas City  
**County:** Wyandotte  
**State:** KS  
**Province:**  
**Country:** UNITED ST/  
**Zip / Postal Code:** 66160  
**Phone Number:** 913-588-0000  
**Fax Number:** 913-588-0000  
**E-Mail:** psimon@kumc.edu

**Credential, e.g., agency login:**  
**Project Role:** Other (Specify)  
**Other Project Role Category:** Co-Investigator

*Attach Biographical Sketch*  
**Biographical Sketch.pdf**  
**Add Attachment**  
**Delete Attachment**  
**View Attachment**

**Attach Current & Pending Support**

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OMB Number: 4040-0001  
Expiration Date: 04/30/2008
Biographical Sketch

SF 424 Guidelines for this section:

"Include biographical sketches of all Senior/Key Personnel and Other Significant Contributors. The Biographical Sketch may not exceed four pages per person. This 4-page limit includes the table at the top of the first page."

"If the individual is registered in the eRA Commons, include the Commons User Name. This data item is required for the PD/PI but is currently optional for all other Senior/Key Persons. In other federal forms this information is referred to as "Credential, e.g., agency login."

Complete the educational block at the top of the format page, and complete Sections A, B, and C.

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material.

C. Research Support. List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Common errors in this section
- Headers and Footers are included
- The biographical sketch exceeds four pages
- Position and Honors are not listed in chronological order
- PI/PD does not include eRA Commons user name
- Research Support older than three years is included
BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

POSITION TITLE
Professor of Microbiology

eRA COMMONS USER NAME
Carlucci

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>YEAR(s)</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stanford University</td>
<td>Ph.D.</td>
<td>1964</td>
<td>Infectious Diseases</td>
</tr>
<tr>
<td>Harvard Medical School</td>
<td>M.D.</td>
<td>1972</td>
<td>Medicine/Parasitology</td>
</tr>
</tbody>
</table>

A. Positions and Honors.

Positions and Employment
1969-1971 Medical Residency, Internal Medicine, Harvard Medical School
1971-1973 EIS Officer, Hospital Infection Section, Bacterial Diseases Branch, CDC, Atlanta, GA
1973-1974 Instructor and Fellow in Medicine, Hematology, Massachusetts General Hospital, Boston, MA
1974-1975 Instructor in Infectious Diseases, Massachusetts General Hospital, Boston, MA
1978- Senior Associate in Infectious Diseases, Children’s Hospital, Boston, MA
1978-1984 Assistant Professor of Pediatrics, Harvard Medical School
1985-1998 Chief, Hemostasis Laboratory, Children’s Hospital, Boston, MA
1993- Professor of Pediatrics, Harvard Medical School, Boston, MA
1998- Professor, Dept. of Infectious Diseases, Harvard School of Public Health

Other Experience and Professional Memberships
1972-1973 Acting Chief, National Mucosal Infections Study
1975-2000 Director of Infectious Diseases Laboratory
1975-present Hospital Epidemiologist (Medical Director Infection Control 2000-present), Children’s Hospital, Boston
1981-1982 President, Society of Hospital Epidemiologists of America
1988 Member, Society for Pediatric Research
1989-present Medical Director Quality Assurance, Children’s Hospital, Boston, MA
1991-1993 Director, American Society for Microbiology, Division F
1991-1997 Hospital Infection Control Practices Advisory Committee, Centers for Disease Control
1998-present Vice-Chair for Health Outcomes, Dept. of Medicine, Children’s Hospital
1998-2001 Steering Committee, NACHRI/CDC Pediatric Prevention Network

Honors
1982 SERC Advanced Research Scholarship, Infectious Disease Society of America
2001 Anthony Steinway Award for Excellence in Teaching (Children’s Hospital)

B. Selected peer-reviewed publications (in chronological order).

Publications selected from 133 peer-reviewed publications


C. Research Support

**Ongoing Research Support**

R01 HS35793  Carlucci (PI)  9/01/99-8/30/04

AHRQ

Reducing Antimicrobial Resistance in Low-Income Communities: A Randomized Trial.

This study is a randomized trial of interventions to reduce antimicrobial usage and resistance in low-income communities.

Role: PI
Bacteriology and Mycology Study of ICU Patients at Risk for Antimicrobial Resistant Bacterial Infections. The study will perform clinical trials of interventions to reduce antimicrobial resistant infections. Role: PI

Virulence and Immunity to Staphylococci. This study investigates the production of polysaccharide by *Staphylococcus aureus* and its role in virulence as measured in animal models of infection and its ability to function as a target for protective antibody. Role: Paid consultant.

Chloride and Sodium Transport in Airway Epithelial Cells The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport. Role: Co-Investigator

Ion Transport in Lungs The major goal of this project is to study chloride and sodium transport in normal and diseased lungs. Role: Co-Investigator

Intermountain Child Health Services Research Consortium This consortium will seek to build pediatric health services research capacity and training in the Intermountain Region. Role: Co-Investigator

Completed Research Support

Evaluating Quality Improvement Strategies (EQUIS) The goal of this study was to evaluate quality improvement and collaborative learning to improve asthma care in office-based pediatrics. Role: Co-Investigator

Epidemiology of Emerging Infections #1 T32 AI07654 The goal of this project was to study emerging infections in high risk populations who are treated in emergency room situations. Role: Co-Investigator
RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? ☑ Yes ☐ No
   1.a. If YES to Human Subjects
       Is the IRB review Pending? ☑ Yes ☐ No

   IRB Approval Date: 

   Exemption Number: [ ] 1  [ ] 2  [ ] 3  [ ] 4  [ ] 5  [ ] 6

   Human Subject Assurance Number: 00003411

2. * Are Vertebrate Animals Used? ☑ Yes ☐ No
   2.a. If YES to Vertebrate Animals

   Is the IACUC review Pending? ☑ Yes ☐ No

   IACUC Approval Date: 

   Animal Welfare Assurance Number: A3237-01

3. * Is proprietary/privileged information included in the application? ☐ Yes ☑ No

4.a. * Does this project have an actual or potential impact on the environment? ☑ Yes ☐ No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☑ No

4.d. If yes, please explain:

5.a. * Does this project involve activities outside the U.S. or partnership with International Collaborators? ☐ Yes ☑ No

5.b. If yes, identify countries:

5.c. Optional Explanation:

6. * Project Summary/Abstract
   Project Summary.pdf Add Attachment Delete Attachment View Attachment

7. * Project Narrative
   Project Narrative.pdf Add Attachment Delete Attachment View Attachment

8. Bibliography & References Cited
   Biographical Sketch.pdf Add Attachment Delete Attachment View Attachment

9. Facilities & Other Resources
   Facilities and Resources.pdf Add Attachment Delete Attachment View Attachment

10. Equipment
    Equipment.pdf Add Attachment Delete Attachment View Attachment

11. Other Attachments Add Attachments Delete Attachments View Attachments

OMB Number: 4040-0001
Expiration Date: 04/30/2008
Project Summary

SF 424 Guidelines for this section:

"The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information."

"This section must be no longer than 30 lines of text. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted."

Font

- Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.

Page Margins

- Use standard paper size (8 ½" x 11).
- Use at least one-half inch margins (top, bottom, left, and right) for all pages.

Uploading the final file document

- "File attachment names longer than approximately 50 characters can cause problems processing packages. Please limit file attachment names. Also, do not use any special characters (example: %, /, #, &) or spacing in the file and for word separation, use underscore (example: my_Attached_File.pdf) in naming the attachments. Please note that if these guidelines are not followed, your application may be rejected." (Grants.gov guidelines)
- Convert all documents to PDF format before uploading

Common errors in this section:

- Project Summary Exceeds the 30 lines of text limit
- Margins are smaller than one-half inch
- Upload the final document as a word document
- Use of special characters in document file names
Example:

Antibiotic resistance is a growing and increasing serious public health problem. Infectious diseases caused by *Escherichia coli* and other bacteria are responsible for millions of deaths each year, and much of the duration of hospital stay, mortality, and morbidity as compared with drug-susceptible infections, economic costs of antibiotic resistance are estimated to be in the billions of dollars. The overall goal of this project is to develop new antinfectives that are highly effective and refractory to antibiotic resistance using a combinatorial Genetic Technology (CGT) that allows the identification of new rRNA target sites and the specific nucleotides that are essential for functionally and viability, and RNA Homology Modeling software that allows accurate prediction of mutant RNA structures.

Phase I of this project was highly successful. A functional mutation library of *E. coli* 16S rRNA was constructed and ~5000 viable clones were sequenced. Using CGT, 67 regions of *E. coli* rRNA that contain nucleotides essential for viability were identified. The 67 functionally important regions included known binding sites for antibiotics, tRNAs, proteins, the large ribosome function, but for which no functional role has been identified to date. Some of the individual regions occur near each other in 30S subunit crystal structures and probably contribute to a single functional role.

The Phase II specific aims are 1) to select one RNA subdomain as a prioritized target from the four potential targets chosen from the RNA “regions of interest” identified in Phase I; 2) to use CGT to identify every mutation of the target that could lead to drug resistance, and use multidimensional NMR spectroscopy and homology modeling to determine the essential structural components of the target; 3) to screen compound libraries against the wild type target and its viable mutants; and 4) to carry out structural studies of target/hit complexes to allow optimization of hit compounds, and validate the target/compound using *in vitro* and *in vivo* assays of antibacterial activity. RiboNovix complete the work necessary to develop drug candidates from the leads, and will move qualified candidates into pre-clinical development.

Anti-infectives developed against the target identified in this study will likely be highly effective against microbial pathogens and resistant to target sites mutation, thus resulting in drugs refractory to antibiotic resistance.
Project Narrative

SF 424 Guidelines for this section:

"Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience."

Font

- Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.)
- Type density, including characters and spaces, must be no more than 15 characters per inch.
- Type may be no more than six lines per inch.

Page Margins

- Use standard paper size (8 ½" x 11).
- Use at least one-half inch margins (top, bottom, left, and right) for all pages.

Uploading the final file document

- "File attachment names longer than approximately 50 characters can cause problems processing packages. Please limit file attachment names. Also, do not use any special characters (example: %, /, #, & ) or spacing in the file and for word separation, use underscore (example: my_Attached_File.pdf) in naming the attachments. Please note that if these guidelines are not followed, your application may be rejected." (Grants.gov guidelines)
- Convert all documents to PDF format before uploading

Common errors in this section:

- Project Narrative exceeds the 2-3 sentence limit
- Margins are smaller than one-half inch
- Upload the final document as a word document
- Use of special characters in document file names

Example:

Antibiotic resistance is a growing and increasingly serious public health problem. Infectious diseases caused by Escherichia coli and other bacteria are responsible for millions of deaths each year, and much of this mortality is due to the rise of antibiotic resistant organisms. The overall goal of this project is to develop new anti-infectives that are highly effective and refractory to antibiotic resistance.
Bibliography & References Cited

SF 424 Guidelines for this section:

"This section (formerly "Literature Cited") should include any references cited in the PHS 398 Research Plan component. The reference should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research. For publicly available citations, URLs or PubMed Central (PMC) submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material."

"Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application."
Facilities & Other Resources

SF 424 Guidelines for this section:

“This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.”

“No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. If there are multiple performance sites, then resources available at each site should be described. In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements. If research involving Select Agent(s) will occur at any performance site(s), the biocontainment resources available at each site should be described.”

Example Template

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:
Equipment

SF Guidelines for this section:

"List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities."

Example:
RiboNovix has use of or owns the following equipment: MJ thermacycler, heat blocks, autoclave, 2 variable temperature incubators (RT- 50C), -80 freezer, cold box, 2 Eppendorf 5415C centrifuges, Perkin-Elmer VictorIII plate reader, under counter refrigerator, UV Camera, New Brunswick shaker incubator, microwave, pH Meter, balance, heat/stir plate, -20 freezer, pipetmen, 2 drummond pipettors, 1 large and 1 small water bath, Beckman low and high speed centrifuges, UV Vis, 2 picofuges, BioRad electrophrator, BioRad Micropulse, 2 power supplies and gel box equipment. Additional equipment necessary for execution of the project is requested in the budget including: a nanodrop spectrophotometer, speedvac, HPLC and columns, water purification equipment, a multidrop, dispenser for 96/384 well plates, and an additional thermal cycler.

Specific Major equipment available at Wayne State University includes: Sorvall RC-5 centrifuge with GSA rotor and SS34 rotors, Molecular Devices multi-well plate spectrophotometer and fluorometer, Licor Global IR automated DNA sequencer, French press, Biocomp gradient formation apparatus, 396-well MJ Research PTC200 thermal cyclers, 4 incubators, 3 New Brunswick shaking water baths, 1 New Brunswick air shaker, Perkin-Elmer Lambda Bio UV-Vis spectrophotometer, and Hitachi UV-Vis detector with flow cell. A Bruker Avance-700 MHz spectrometer equipped with cryoprobe 1H, 13C, 15N triple resonance probe with z-axis PFG coil is located in the Chemistry building.
### Project/Performance Site Location(s)

#### Primary Location

<table>
<thead>
<tr>
<th>Organization Name</th>
<th>Street1</th>
<th>Street2</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Kansas Medical Center</td>
<td>3901 Rainbow Boulevard</td>
<td></td>
</tr>
<tr>
<td>* City: Kansas City</td>
<td>* County: Wyandotte</td>
<td>* State: KS</td>
</tr>
<tr>
<td>* Country: US</td>
<td>* ZIP / Postal Code: 66160</td>
<td></td>
</tr>
</tbody>
</table>

#### Additional Location(s)

<table>
<thead>
<tr>
<th>Street1</th>
<th>Street2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Reset Entry * Next Site

Add Attachment Delete Attachment View Attachment

CMB Number: 4040-0001
Expiration Date: 04/30/2008
4. Human Embryonic Stem Cells

* Does the proposed project involve human embryonic stem cells?  
  ☑ No  ☐ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/registry/index.asp. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

- [ ] Specific stem cell line cannot be referenced at this time. One from the registry will be used.
# PHS 398 Research Plan

## 1. Application Type:
From SF 424 (R&R) Cover Page and PHS398 Checklist. The responses provided on these pages, regarding the type of application being submitted, are repeated for your reference, as you attach the appropriate sections of the research plan.

*Type of Application:
- [x] New
- [ ] Resubmission
- [ ] Renewal
- [ ] Continuation
- [ ] Revision

## 2. Research Plan Attachments:
Please attach applicable sections of the research plan, below.

<table>
<thead>
<tr>
<th>Section</th>
<th>Attachment Name</th>
<th>Action Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction to Application</td>
<td></td>
<td>Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>(for RESUBMISSION or REVISION only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Specific Aims</td>
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</tr>
<tr>
<td>3. Background and Significance</td>
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<tr>
<td>4. Preliminary Studies / Progress Report</td>
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<tr>
<td>5. Research Design and Methods</td>
<td>Research Design and Methods.pdf</td>
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</table>

### Human Subjects Sections
Attachments 8-11 apply only when you have answered "yes" to the question "are human subjects involved" on the R&R Other Project Information Form. In this case, attachments 8-11 may be required, and you are encouraged to consult the Application guide Instructions and/or the specific Funding Opportunity Announcement to determine which sections must be submitted with this application.

<table>
<thead>
<tr>
<th>Section</th>
<th>Attachment Name</th>
<th>Action Options</th>
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<td>10. Targeted/Planned Enrollment</td>
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<td>11. Inclusion of Children</td>
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### Other Research Plan Sections

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<td>13. Select Agent Research</td>
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<td>14. Multiple PI Leadership Plan</td>
<td>Multiple PI Leadership Plan.pdf</td>
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<td>15. Consortium/Contractual Arrangements</td>
<td>Consortium.pdf</td>
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<td>16. Letters of Support</td>
<td>Letter of Support.pdf</td>
<td>Add Attachment Delete Attachment View Attachment</td>
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<td>17. Resource Sharing Plan(s)</td>
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<tr>
<td>18. Appendix</td>
<td>[Add Attachments]</td>
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[View Attachments]
Specific Aims:

SF 424 guidelines for this section:

“List the broad, long-term objectives and the goal of the specific research proposed, for example, to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. **One page is recommended.**”

Common Error:
Numbering Pages (do not number pages on any part of the proposal, grants.gov will automatically number the pages upon submission)
Background and Significance:

SF 424 Guidelines for this section:

"Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field. Two to three pages are recommended."
Preliminary Studies/Progress Report:

SF 424 Guidelines for this section:

*For new applications, use this section to provide an account of the PD/PI’s preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project.

Except for Exploratory/Development Grants (R21/R33), Small Research Grants (R03), and Phase I Small Business Research Grants (R41/R43), peer review committees generally view preliminary data as an essential part of a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project. **Six to eight pages are recommended** for the narrative portion of this section.”
Research Design and Methods

SF 424 Guidelines for this section:

"Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the resource sharing section, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised."

"Although no specific number of pages is recommended for the Research Design and Methods section, be as succinct as possible. There is no requirement that all 25 pages allotted for items 2-5 be used."

Common Error:
Figures are numbered incorrectly
Inclusion Enrollment Report

SF 424 Guidelines for this section:

"If the renewal or revision application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender."
Progress Report Publication List
(NOT TO BE INCLUDED IN NEW APPLICATIONS)

SF 424 Guidelines for this section:

"List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note copies of these publications are no longer accepted as appendix material."

"As part of the Appendix material you may include only up to 3 of the following types of publications:

- Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.
- Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment.
- Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.

(Do not include unpublished theses, or abstracts/manuscripts submitted (but not yet accepted) for publication.)

Note, publications and/or abstracts in press should no longer be included in the appendix material. Include the URL or PMC submission identification numbers along with the full reference in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section."
Protection of Human Subjects
(INCLUDE ONLY IF HUMAN SUBJECTS ARE INVOLVED IN YOUR PROJECT)

SF 424 Guidelines for this section:

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics
   • Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section.
   • Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
   • Identify the criteria for inclusion or exclusion of any subpopulation.
   • Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that ‘prisoners’ includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
   • List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

b. Sources of Materials
   • Describe the research material obtained from living human subjects in the form of specimens, records, or data.
   • Describe any data that will be recorded on the human subjects involved in the project.
   • Describe the linkages to subjects, and indicate who will have access to subject identities.
   • Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

c. Potential Risks
   • Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
   • Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent
   • Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
   • Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. Protection Against Risk
   • Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
   • Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral
intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or IDE covering the proposed use of the test article in the Research Plan.

5. DATA AND SAFETY MONITORING PLAN

- If your research includes a clinical trial, create a subheading entitled “Data and Safety Monitoring Plan.”
- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding IIC, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Be succinct. Contact the FDA (http://www.fda.gov/) and also see the following websites for more information related to IND and IDE requirements:
  - http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html (IND)
  - http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html (IDE)
- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:
  a. PD/PI (required)
  b. Independent individual/Safety Officer
  c. Designated medical monitor
  d. Internal Committee or Board with explicit guidelines
  e. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
  f. Institutional Review Board (IRB - required)
- A detailed Data and Safety Monitoring Plan must be submitted to the applicant’s IRB and subsequently to the funding IC for approval prior to the accrual of human subjects (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html). For additional guidance on creating this Plan, see the above reference.
Inclusion of Women and Minorities

- If human subjects are involved in your project, but not women or minorities, write a brief statement for this section, explaining that women and minorities are not involved in your project.

SF 424 Guidelines for this section:

"In the attachment for Item 9, include a heading entitled “Inclusion of Women and Minorities.” Although no specific page limitation applies to this section of the application, be succinct.

Scientific Review Groups will assess each application as being “acceptable” or “unacceptable” with regard to the protection of human subjects.

In this section of the Research Plan, address, at a minimum, the following four points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table. (Instructions for completing this table are provided below.) If you are using existing specimens and/or data that does not meet the criteria for Exemption 4 and you do not have access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion is inappropriate (item 3 below). Alternatively, you may describe the women and minority composition of the population base from whom the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Table in Item 10.

2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

3. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group (see examples below).

4. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Examples of acceptable justifications for exclusion of:

A. **One gender:**

1. One gender is excluded from the study because:
   - inclusion of these individuals would be inappropriate with respect to their health;
   - the research question addressed is relevant to only one gender;
   - evidence from prior research strongly demonstrates no difference between genders;
   - sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.

2. One gender is excluded or severely limited because the purpose of the research constrains the applicant’s selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).

3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.

B. **Minority groups or subgroups:**

1. Some or all minority groups or subgroups are excluded from the study because:
   - Inclusion of these individuals would be inappropriate with respect to their health;
• The research question addressed is relevant to only one racial or ethnic group;
• Evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
• A single minority group study is proposed to fill a research gap;
• Sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.

2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
   • The size of the study;
   • The relevant characteristics of the disease, disorder or condition;
   • The feasibility of making a collaboration or consortium or other arrangements to include representation.

• Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant’s selection of study subjects by race or ethnicity (e.g., uniquely valuable cohorts, stored specimens or existing datasets are of limited minority representation, very small numbers of subjects are involved, or overriding factors dictate selection of subjects, such as matching of transplant recipients or availability of rare surgical specimens).

3. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.”
Targeted/Planned Enrollment

SF 424 Guidelines for this section:

“If this application involves the Inclusion of Women and Minorities, complete the Targeted/Planned Enrollment Table.”

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

<table>
<thead>
<tr>
<th>ETHNIC CATEGORY</th>
<th>SEX/GENDER</th>
<th>FEMALES</th>
<th>MALES</th>
<th>TOTAL</th>
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<tbody>
<tr>
<td>Hispanic or Latino</td>
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<tr>
<td>Not Hispanic or Latino</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic Category: Total of All Subjects *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Racial Categories</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Racial Categories: Total of All Subjects *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."
Inclusion of Children

- If human subjects are involved in your project, but children are not, write a brief statement for this section, explaining that children are not involved in your project.

SF 424 Guidelines for this section:

- “In the attachment for Item 11, include a heading entitled “Inclusion of Children.”

- For the purpose of implementing these guidelines, a child is defined as an individual under the age of 21 years (for additional information see http://grants.nih.gov/grants/funding/children/children.htm and http://grants.nih.gov/grants/guide/notice-files/not98-024.html).

- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, application, or proposal, then you must present an acceptable justification (see below) for the exclusion.

- If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

- Scientific Review Groups will assess each application as being “acceptable” or “unacceptable” with regard to the age-appropriate inclusion or exclusion of children in the research project.

- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research (45 CFR Part 46 Subpart D) apply and must be addressed in the “Human Subjects Research and Protection from Risks” subheading.

Justifications for Exclusion of Children

For the purposes of this policy, all individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section.

It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.

2. There are laws or regulations barring the inclusion of children in the research.

3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.

4. A separate, age-specific study in children is warranted and preferable. Examples include:
   a. The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
   b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
   c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.
5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.

6. Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).

7. Other special cases can be justified by the investigator and found acceptable to the review group and the Institute Director."
Vertebrate Animals
(INCLUDE THIS SECTION ONLY IF YOU HAVE ANIMAL SUBJECTS IN YOUR PROJECT)

SF 424 Guidelines for this section:

"If you indicated that Vertebrate Animals are involved in this project, address the following five key points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations."
Select Agent Research

SF 424 Guidelines for this section:

“Select Agents are hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See http://www.cdc.gov/od/sap/docs/salist.pdf.

If the activities proposed in your application involve only the use of a strain(s) of Select Agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.4(f)(5), the Select Agent requirements do not apply. Use this section to identify the strain(s) of the Select Agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at http://www.cdc.gov/od/sap/sap/exclusion.htm.

If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

If any of the activities proposed in your application involve the use of Select Agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which Select Agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the Select Agent(s) to be used in the proposed research.

2. Provide the registration status of all entities* where Select Agent(s) will be used.
   - If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed.
   
   *An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”

3. Provide a description of all facilities where the Select Agent(s) will be used.
   - Describe the procedures that will be used to monitor possession, use and transfer of Select Agent(s).
   - Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the solicitation.”
Multiple PI Leadership Plan

SF 424 Guidelines for this section:

“For applications designating multiple PDs/PIs, a leadership plan must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.”

“If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.”
Consortium/Contractual Arrangements

SF 424 Guidelines for this section:

"Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the authorized organizational official on the SF424 (R&R) cover component (Item 18) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

    The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

A separate statement is no longer required."
Letter of Support

SF 424 Guidelines for this section:

“Attach appropriate letters here from all individuals confirming their roles in the project. For consultants, letters should include rate/charge for consulting services.”
Resource Sharing Plan(s)

SF 424 Guidelines for this section:

“NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources.

1) Data Sharing Plan: Investigators seeking $500,000 or more in direct costs in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific Funding Opportunity Announcements may also require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

(2) Sharing Model Organisms: Regardless of the amount requested, in applications where the development of model organisms is anticipated, the applicant must include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See NIH Policy on Sharing of Model Organisms, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html.”
1. Application Type:
From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:

☑ New ☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

Federal Identifier:

2. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

* First Name:

Middle Name:

* Last Name:

Suffix:

☐ Change of Grantee Institution

* Name of former institution:

3. Inventions and Patents  (For renewal applications only)

* Inventions and Patents:  Yes ☐ No ☑

If the answer is "Yes" then please answer the following:

* Previously Reported:  Yes ☐ No ☑
4. * Program Income

Is program income anticipated during the periods for which the grant support is requested?

☐ Yes  ☑ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

<table>
<thead>
<tr>
<th>*Budget Period</th>
<th>*Anticipated Amount ($)</th>
<th>*Source(s)</th>
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</thead>
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</tbody>
</table>

5. Assurances/Certifications (see instructions)

In agreeing to the assurances/certification section 18 on the SF424 (R&R) form, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the agency’s application guide, when applicable. Descriptions of individual assurances/certifications are provided at: http://grants.nih.gov/grants/funding/424

If unable to certify compliance, where applicable, provide an explanation and attach below.

Explanation: ____________________________ [Add Attachment] [Delete Attachment] [View Attachment]
PHS 398 Cover Letter

*Mandatory Cover Letter Filename: Mandatory Cover Letter Filename.pdf

Add Cover Letter File  Delete Cover Letter File  View Cover Letter File
Mandatory Cover Letter Filename

SF 424 Guidelines for this section:

“Applicants are encouraged to include a cover letter with the application. The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH Initiative.
3. Request of an assignment (referral) to a particular awarding component(s) or Scientific Review Group (SRG). The PHS makes the final determination.
4. List of individuals (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. For late applications (see Late Application policy in Section 2.14) include an explanation of the delay as part of the cover letter attachment.
7. When submitting a Changed/Corrected Application after the submission date, a cover letter is required explaining the reason for the Changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment. The system does not retain any previously submitted cover letters until after an application is verified; therefore, you must repeat all information previously submitted in the cover letter as well as any additional information.
8. Explanation of any subaward budget components that are not active for all periods of the proposed grant.
9. Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications $500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc.

Two types of approval documentation are cited as examples in item 6 above: NIH IC approval for an application $500,000 or more and NIH institute approval for a Conference Grant or Cooperative Agreement application (R13 or U13). To attach the approval documents to this submission, please append those referenced documents to your Cover Letter File, and upload as one attachment.

Suggested Cover Letter Format

The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to ICs and to scientific review groups (SRGs). DRR will be utilizing knowledge management approaches as an adjunct to the work of referral experts as part of an overall plan to shorten the time from submission to review. Analysis has shown that requests made by investigators are a valuable source of information in this process. In order to facilitate the use of these requests in conjunction with knowledge management analysis of the content of the application, applicants are requested to use the following format when assignment requests are contained in a cover letter.”

- List one request per line.
- Place institute/center (IC) and SRG review requests (if both are made) on separate lines.
- Place positive and negative requests (if both are made) on separate lines.
- Include name of IC or SRG, followed by a dash and the acronym. Do not use parentheses.
- Provide explanations for each request in a separate paragraph.
Examples:

**Please assign this application to the following Institutes/Centers:**
- National Cancer Institute - NCI
- National Institute for Dental and Craniofacial Research – NIDCR

**Scientific Review Groups**
- Molecular Oncogenesis Study Section – MONC
- Cancer Etiology Study Section – CE

**Please do not assign this application to the following:**
- Scientific Review Groups
- Cancer Genetics Study Section – CG

**The reasons for this request are [provide a narrative explanation for the request(s):**
## PHS 398 Modular Budget, Periods 1 and 2

**Budget Period: 1**

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>End Date:</th>
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</thead>
<tbody>
<tr>
<td>12/01/2008</td>
<td>11/30/2009</td>
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</table>

### A. Direct Costs

<table>
<thead>
<tr>
<th>* Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td><strong>Direct Cost less Consortium F&amp;A</strong></td>
</tr>
<tr>
<td><strong>Consortium F&amp;A</strong></td>
</tr>
<tr>
<td><strong>Total Direct Costs</strong></td>
</tr>
</tbody>
</table>

### B. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Modified Total Direct Costs</td>
<td>47</td>
<td>250,000.00</td>
<td>117,500.00</td>
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</tbody>
</table>

**Cognizant Agency (Agency Name, POC Name and Phone Number)**

Department of Health and Human Services
Peter Nwagu
214-767-5362

**Indirect Cost Rate Agreement Date**: 12/21/2005

**Total Indirect Costs**: 117,500.00

### C. Total Direct and Indirect Costs (A + B)

**Funds Requested ($)**: 367,500.00

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**Budget Period: 2**

<table>
<thead>
<tr>
<th>Start Date:</th>
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<td>11/30/2010</td>
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### A. Direct Costs

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<tr>
<th>* Funds Requested ($)</th>
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<td><strong>Direct Cost less Consortium F&amp;A</strong></td>
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<td><strong>Total Direct Costs</strong></td>
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</table>

### B. Indirect Costs

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<tr>
<th>Indirect Cost Type</th>
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</tbody>
</table>

**Cognizant Agency (Agency Name, POC Name and Phone Number)**

Department of Health and Human Services
Peter Nwagu
214-767-5362

**Indirect Cost Rate Agreement Date**: 12/21/2005

**Total Indirect Costs**: 117,500.00

### C. Total Direct and Indirect Costs (A + B)

**Funds Requested ($)**: 367,500.00
# PHS 398 Modular Budget, Periods 3 and 4

**Budget Period: 3**

| Start Date: 12/01/2010 | End Date: 11/30/2011 |

## A. Direct Costs

<table>
<thead>
<tr>
<th>* Funds Requested ($)</th>
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<tbody>
<tr>
<td>Direct Cost less Consortium F&amp;A</td>
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<td>* Total Direct Costs</td>
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## B. Indirect Costs

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<tr>
<th>Indirect Cost Type</th>
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<th>* Funds Requested ($)</th>
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</table>

Cognizant Agency (Agency Name, POC Name and Phone Number): Department of Health and Human Services

| Peter Nwaogu |
| 214-767-5962 |

Indirect Cost Rate Agreement Date: 12/21/2005

Total Indirect Costs: 117,500.00

## C. Total Direct and Indirect Costs (A + B)

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>367,500.00</td>
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</tbody>
</table>

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# Budget Period: 4

| Start Date: 12/01/2011 | End Date: 11/30/2012 |

## A. Direct Costs

<table>
<thead>
<tr>
<th>* Funds Requested ($)</th>
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<tbody>
<tr>
<td>Direct Cost less Consortium F&amp;A</td>
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<tr>
<td>Consortium F&amp;A</td>
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<tr>
<td>* Total Direct Costs</td>
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</tbody>
</table>

## B. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

Cognizant Agency (Agency Name, POC Name and Phone Number): Department of Health and Human Services

| Peter Nwaogu |
| 214-767-5962 |

Indirect Cost Rate Agreement Date: 12/21/2005

Total Indirect Costs: 117,500.00

## C. Total Direct and Indirect Costs (A + B)

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
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<tbody>
<tr>
<td>367,500.00</td>
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</table>
## PHS 398 Modular Budget, Period 5 and Cumulative

### Budget Period: 5

**Start Date:** 12/01/2012  
**End Date:** 11/30/2013

### A. Direct Costs

* Funds Requested ($)

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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<tbody>
<tr>
<td>Direct Cost less Consortium F&amp;A</td>
<td>250,000.00</td>
</tr>
<tr>
<td>Consortium F&amp;A</td>
<td></td>
</tr>
<tr>
<td>* Total Direct Costs</td>
<td>250,000.00</td>
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</table>

### B. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>* Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>Modified Total Direct Costs</td>
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<td>250,000.00</td>
<td>117,500.00</td>
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| 2. | | | |
| 3. | | | |
| 4. | | | |

**Cognizant Agency** (Agency Name, POC Name and Phone Number)

Department of Health and Human Services  
Peter Nwaogu  
214-787-5362

**Indirect Cost Rate Agreement Date:** 12/21/2005  
**Total Indirect Costs:** 117,500.00

### C. Total Direct and Indirect Costs (A + B)

**Funds Requested ($):** 367,500.00

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## Cumulative Budget Information

### 1. Total Costs, Entire Project Period

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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<tbody>
<tr>
<td>* Section A, Total Direct Cost less Consortium F&amp;A for Entire Project Period</td>
<td>$1,250,000.00</td>
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<tr>
<td>Section A, Total Consortium F&amp;A for Entire Project Period</td>
<td>$</td>
</tr>
<tr>
<td>* Section A, Total Direct Costs for Entire Project Period</td>
<td>$1,250,000.00</td>
</tr>
<tr>
<td>* Section B, Total Indirect Costs for Entire Project Period</td>
<td>$587,500.00</td>
</tr>
<tr>
<td>* Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period</td>
<td>$1,837,500.00</td>
</tr>
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### 2. Budget Justifications

- **Personnel Justification**: Personnel Justification.pdf  
  Add Attachment | Delete Attachment | View Attachment
- **Consortium Justification**: Consortium.pdf  
  Add Attachment | Delete Attachment | View Attachment
- **Additional Narrative Justification**: Additional Narrative.pdf  
  Add Attachment | Delete Attachment | View Attachment
Budget Period: 5
Start Date: 12/01/2012
End Date: 11/30/2013

A. Direct Costs
* Funds Requested ($)
* Direct Cost less Consortium F&A 250,000.00
Consortium F&A
* Total Direct Costs 250,000.00

B. Indirect Costs
Indirect Cost Type  Indirect Cost Rate (%)  Indirect Cost Base ($)  * Funds Requested ($)
1. Modified Total Direct Costs 47 250,000.00 117,500.00
2. 
3. 
4. 

Cognizant Agency (Agency Name, POC Name and Phone Number)
Department of Health and Human Services
Peter Nwaogu
214-767-5362

Indirect Cost Rate Agreement Date 12/21/2005
Total Indirect Costs 117,500.00

C. Total Direct and Indirect Costs (A + B)
Funds Requested ($) 397,500.00

Cumulative Budget Information

1. Total Costs, Entire Project Period
* Section A, Total Direct Cost less Consortium F&A for Entire Project Period $1,250,000.00
Section A, Total Consortium F&A for Entire Project Period $
* Section A, Total Direct Costs for Entire Project Period $
* Section B, Total Indirect Costs for Entire Project Period $587,500.00
* Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period $1,837,500.00

2. Budget Justifications
Personnel Justification Personnel Justification.pdf Add Attachment Delete Attachment View Attachment
Consortium Justification Consortium Justification.pdf Add Attachment Delete Attachment View Attachment
Additional Narrative Justification Additional Narrative.pdf Add Attachment Delete Attachment View Attachment
Personnel Justification:

SF 424 Guidelines for this section:

“List all personnel, including names, number of person months devoted to the project (indicate academic, calendar, and/or summer) and roles on the project. Do not provide individual salary information. Since the modules should be a reasonable estimate of costs allowable, allocable, and appropriate for the proposed project, you must use the current legislatively imposed salary limitation when estimating the number of modules. For guidance on current salary limitations contact your office of sponsored programs.”

“NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits, and tuition remission. This limit should also be used when estimating the number of modules”

Common Errors:
- Effort measured in percentage rather than Calendar Year Months (CYM)
- Graduate Student’s effort exceeds 6 CYM (50%)

Example:

Wen Liu, Ph.D., Principle Investigator, (3 CY Mo effort) will oversee development, recruitment, testing, data processing and analysis. He will be responsible for the development of treatment and testing protocol, computer programs for data acquisition and processing, database management, data analysis, and preparation of progress reports, final report and manuscripts. Dr. Liu has a primary appointment as an associate professor in the Department of Physical Therapy and Rehabilitation Science at the University of Kansas Medical Center (KUMC).

Chao Sun, M.D., MPH, consultant, (1 CY Mo effort) will provide advice on the clinical aspects of the project design and acupuncture treatment, and help on the interpretation of results and preparation of final report and manuscripts. Dr. Sun is a physician in Occupational Medicine and a licensed acupuncturist.

Byron Gajewski, Ph.D., co-investigator, (1 CY Mo effort) will help on project design and subject random assignment. Dr. Gajewski will also responsible for statistical analysis of results, and help on the preparation of final report and manuscripts. His expertise in clinical trail studies and statistical analysis is a great resource for the proposed study.

Eric Vidoni, Ph.D., P.T., post-doctoral fellow (6 CY Mo effort) will work as a project manager. He will be responsible for the day-to-day progress of the project, coordinating data collection and database management, helping on data analysis, helping on preparation of progress reports, final report and manuscripts.

TBA, B.S. or M.S. database manager, (6 CY Mo effort) will be responsible for the subject recruitment, stroke registry, database management, and helping on the preparation of clean data set for statistical analysis. This individual will be blind to the subjects’ group membership during data collection and analysis period.

Minzhao Huang, M.D. (Chinese medicine), licensed acupuncturist, (5 CY Mo effort) will conduct the acupuncture treatment following the standard procedure. Dr. Huang received her MD degree in Chinese medicine previously in China. She is a licensed acupuncturist and has practiced acupuncture and herb medicine for more than 10 years in the USA.
Consortium Justification
(INCLUDE ONLY IF YOU HAVE CONSORTIUM AGREEMENT IN YOUR PROJECT)

SF 4245 Guidelines for this section:

"Provide an estimate of total costs (direct plus facilities and administrative) for each year, rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, along with all personnel, including percent of effort (in person months) and roles on the project. Do not provide individual salary information. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the total consortium/contractual costs must be included in the overall requested modular direct cost amount. "
Additional Narrative

SF 424 Guidelines for this section:

“For all modular budgets, request total direct costs (in modules of $25,000), reflecting appropriate support for the project. There will be no future year escalations. A typical modular grant application will request the same number of modules in each year. Provide an additional narrative budget justification for any variation in the number of modules requested.”

Example:

Additional Narrative
Variation between the proposed budgets for Budget Years 1 and 2 is due to a greater amount of experimental work, which requires more research reagents and supplies, and a greater percentage of personnel effort during year one of the project.