Sponsored Projects: Planning & Organizing a Research Proposal

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Dept. of Medicine
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When Preparing an Application:

- Read instructions
- Never assume that reviewers “will know what you mean”
- Refer to literature thoroughly and thoughtfully
- Explicitly state the rationale of the proposed investigation
- Include well-designed tables and figures
- Present an organized, lucid write-up
Elements of a Good Proposal

- Feasible
- Relevant
- Unique
- Innovative
  - Clear
  - Brief
- Consistent
Anticipate Questions and Answer them before they are asked
Investigator

- Competent
- Enthusiastic
- Thorough
- Professional
Common Proposal Problems

• **Title**
  – Too long
  – Confusing
  – Cute but distracting
  – Not program related

• **Cover Page**
  – Does not follow format precisely
  – Does not include all necessary information
• **Abstract**
  – Not comprehensive
  – Omits significant elements
  – Poor grammar or spelling
  – Too long
  – Cut and paste job

• **Table of Contents**
  – Not included
  – Inaccurate pagination
  – Not informative
• **School Description**
  – Irrelevant information
  – Does not lead reader to proposal objectives
  – Good history: so what?
  – Too long

• **Statement of Need**
  – Deals with wants, not needs
  – No documentation
  – Unrelated to objectives/outcomes desired
  – Problem already solved
  – Not supported by current research
• **Objectives/Outcomes**
  - Not clear
  - Too ambitious
  - Omitted
  - Procedures rather than objectives

• **Innovation**
  - Not new or innovative
  - Attempt to justify new equipment/materials
  - Not clearly described
• **Task/Activity Plan**
  – Insufficient detail
  – Tasks not related to objectives
  – Tasks not justified by needs
  – Time and task charts not included
  – Responsibilities not clear
  – Does not address contingency plans

• **Evaluation of Project Progress**
  – Unrelated to objectives
  – Unrelated to innovation
  – Uses outmoded or inaccurate methods
• **Project Staffing**
  – No identification of responsibilities and roles
  – No documentation of competence (e.g. bio sketches)
  – No indication of time and effort for each individual contributing to project

• **Budget**
  – Unrelated to activities proposed
  – Little or no contribution from institution
  – Amounts not supported by proposal
  – Budget justification missing
  – Categories not those of funding agency
  – Budget cannot be sustained after project ends
• **Collaborative Efforts**
  – Names and responsibilities of all involved in proposal not identified
  – No identification of institutions involved

• **Review of Literature**
  – Unrelated to needs, objectives, innovations
  – Does not lead reader to proposed project
  – Dated material
  – Should not be a review article
NIH's Review Criteria-1

(A) “Significance:

(1) Does this study address an important problem?
(2) If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
(3) What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?”
NIH's Review Criteria-2

(B) “Approach:

(1) Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?

(2) Does the applicant acknowledge potential problem areas and consider alternative tactics?”
NIH's Review Criteria-3

(C) “Innovation:

(1) Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?

(2) Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?”
(D) “**Investigators:**

(1) Are the investigators appropriately trained and well suited to carry out this work?

(2) Is the work proposed appropriate to the experience level of the principal investigator and other researchers?

(3) Does the investigative team bring complementary and integrated expertise to the project (if applicable)?”
NIH's Review Criteria-5

(E) “Environment:

(1) Does the scientific environment in which the work will be done contribute to the probability of success?
(2) Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements?
(3) Is there evidence of institutional support?”
NIH's Review Criteria-6

“Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed."

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated…”
NIH's Review Criteria-7

“Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items [specified in the] research grant application instructions will be assessed.”

“Requests for Applications (RFAs)… may list additional elements, relating to the specific requirement of the RFA…”
“Additional Review Considerations

**Budget:** The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.”
Review of New Investigator R01s: Guidelines for Reviewers

“The five new review criteria must be evaluated in a manner appropriate to the expectations for and problems likely to be faced by a new investigator.”

http://www.csr.nih.gov/guidelines/newinvestigator.htm
• **Approach:** more emphasis should be placed on demonstrating that the techniques/approaches are feasible than on preliminary results

• **Investigator:** more emphasis should be placed on their training and their research potential than on their track record and number of publications.

**Environment:** there should be some evidence of institutional commitment in terms of space and time to perform the research.”

http://www.csr.nih.gov/guidelines/newinvestigator.htm
Why Are Proposals Turned Down?

Research Plan

• The problem is trivial or is unlikely to produce new or useful information.
• The proposed research is based on a hypothesis that rests on doubtful, unsound or insufficient evidence.
• The proposal is more complex than the author realizes.
• The problem is local in significance, production, or control, or otherwise fails to fall clearly in the mainstream of the discipline.
• The problem is intellectually premature - only a pilot study.
• The problem as proposed is overly involved with too many elements required to be investigated simultaneously.
• The description of the research leaves the proposal nebulous, diffuse, and without a clear aim.
Investigator

- Investigator does not have experience or training for the proposed research.
- Investigator appears to be unfamiliar with pertinent literature or methods, or both.
- Investigator's previously published work in the field does not inspire confidence.
- Investigator relies too heavily, or insufficiently, on experienced associates.
- Other responsibilities prevent investigator from devoting sufficient time to this project.
Resources & Environment

• Available equipment is unsuited to the research.
• Institutional setting unfavorable.
Research Design and Methodology

- The proposed methodology, including tests and procedures, are unsuited to the objective. May be beyond the competence of the investigator.
- The over-all design is not carefully thought out.
- Statistical aspects are not given sufficient consideration.
• Approach lacks imagination or originality.
• Controls are either inadequately conceived or described.
• Proposed material for research is unsuited or difficult to obtain.
• The number of observations proposed is unsuitable.
Additional Problems

- Requirements for equipment, personnel or time are unrealistic
- Current research grants are adequate in scope and funding to cover the proposed research.
Common Problems with Grant Applications from New Investigators

- Overly ambitious
- Not independent of previous mentor’s research
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- Unfocussed
- Unrealistic budget
- Methodologies beyond the expertise of investigator or investigative team
NIH Electronic Grant Forms

- [http://grants.nih.gov/grants/forms.htm](http://grants.nih.gov/grants/forms.htm)
- Electronic Applications
- Paper Applications
## Application for Federal Assistance
### SF 424 (R&R)

### 2. Date Submitted
Applicant Identifier

### 3. Date Received by State
State Application Identifier

### 1. Type of Submission
- Pre-application
- Application
- Changed/Corrected Application

### 4. Federal Identifier

### 5. Applicant Information
* Organizational DUNS:

  **Legal Name:**
  - [Department]
  - [Division]

  **First Name:**
  - [Prefix]
  - [Surname]
  - [Suffix]

  **Phone Number:**
  - [Fax Number]

  **Email:**

### 6. Employer Identification (EIN) or (TIN):

### 7. Type of Applicant:

### 8. Type of Application:
- New
- Resubmission
- Renewal
- Continuation
- Revision

### 9. Name of Federal Agency:

### 10. Catalog of Federal Domestic Assistance Number:

### 11. Descriptive Title of Applicant’s Project:

### 12. Areas Affected by Project (cities, counties, states, etc.)

### 13. Proposed Project:
* Start Date
* Ending Date

### 14. Congressional Districts of:
- Applicant
- Project

### 15. Project Director/Principal Investigator Contact Information

- Prefix:
- First Name:
- Middle Name:
- Last Name:
- Suffix:

- Position/Title:

- [Department]
  - [Division]

- [Street1]
  - [Street2]

- [City]
  - [County]
  - [State]

- [Province]
  - [Country]
  - [ZIP/Postal Code]

- [Phone Number]
  - [Fax Number]
  - [Email]

CM# Number: 4040-0001
Expiration Date: 04/30/2008
16. ESTIMATED PROJECT FUNDING

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<td>c. * Estimated Program Income</td>
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17. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

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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 18, 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

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* Signature of Authorized Representative

Completed on submission to Grants.gov

* Date Signed

Completed on submission to Grants.gov

20. Pre-application

Add Attachment  Delete Attachment  View Attachment

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

Add Attachment  Delete Attachment  View Attachment
PHS Cover Letter

- Not required, though encouraged
- Internal use only, not seen by peer reviewers
- Application title, PA or RFA title (if appropriate)
- Request for specific Institute and Study Section
- List of individuals who should not review application and reasons
- Agency approval documentation (e.g. budget: $500,000)
PHS 398 Cover Letter

*Mandatory Cover Letter Filename:

Add Cover Letter File  Delete Cover Letter File  View Cover Letter File

OMB Number: 0925-0001
Expiration Date: 9/30/2007
### 1. Project Director / Principal Investigator (PD/PI)

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* New Investigator?  ○ No  ○ Yes

Degrees:

### 2. Human Subjects

Clinical Trial?  ○ No  ○ Yes

* Agency-Defined Phase III Clinical Trial?  ○ No  ○ Yes

### 3. Applicant Organization Contact

Person to be contacted on matters involving this application:

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  * Country:  * Zip / Postal Code: 
1. NIH: New Investigator

- Has not been a Principal Investigator on any PHS research project
  - Except:
    - Small Grant (R03), Exploratory/ Development (R21)
    - Academic Research Enhancement Award (R15)
    - Mentored Research Career Awards directed to investigators at the beginning of their careers (K01, K08, K22, K23, and K25)
  - When Multiple Principal Investigators are proposed, all PIs must meet the definition of New Investigator for this box to be checked.
2. Human Subjects

- NIH defines a **clinical trial** as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).
2. Human Subjects

- An NIH-defined Phase III clinical trial usually involves several hundred or more human subjects, for the purpose of either evaluating an experimental intervention in comparison with a standard or control intervention or of comparing two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.
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/registryindex.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:

Cell Line(s):  □ Specific stem cell line cannot be referenced at this time. One from the registry will be used.
Performance Site(s)

Where the work described in the Research Plan will be conducted

- Applicant organization (CU)
- Collaborating institutions (subcontracts)
  - Domestic (e.g. NYSPI) and foreign institutions
## RESEARCH & RELATED Project/Performance Site Location(s)

### Project/Performance Site Primary Location

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### Project/Performance Site Location 1

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**Additional Location(s)**

- Add Attachment
- Delete Attachment
- View Attachment

**OMB Number:** 4040-0001  
**Expiration Date:** 04/30/2008
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: ____________________________

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: ____________________________

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

7. * Project Narrative

8. Bibliography & References Cited

9. Facilities & Other Resources

10. Equipment

11. Other Attachments
“State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals... understandable to a scientifically or technically literate reader.”
“The second component... is Relevance. Using no more than two or three sentences, describe the relevance of this research to public health... use plain language that can be understood by a general, lay audience.”
8. Bibliography/References Cited

- Full citations of all references cited in the Research Plan
- Relevant and current literature
- No page limitation
9. Facilities & Other Resources

- Facilities to be used for the conduct of the proposed research
  - Laboratory
  - Clinical
  - Animal
  - Computer
  - Office
  - Other: Core facilities (e.g. research pharmacy, biostatistics, machine shop)

- Describe for each performance site

- Discuss how each Facility (unique features, if appropriate) will be utilized in the proposed research plan
R&R Other Project Information:

10. Equipment

- Major items of equipment available for project
- Relevant capabilities
# RESEARCH & RELATED Senior/Key Person Profile (Expanded)

## PROFILE - Project Director/Principal Investigator

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- **Attach Biographical Sketch**
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- **Attach Current & Pending Support**
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**PROFILE - Senior/Key Person**

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

- PD/PI
- Co-PD/PI
- Faculty
- Post Doctoral
- Post Doctoral Associate
- Other Professional
- Graduate Student
- Undergraduate Student
- Technician
- Consultant
- Other (Specify)
Senior/Key Personnel “are defined as individuals who contribute in a substantive, measurable way to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. ”

- Faculty, Professional Co-investigators, Research nurses, Post-docs, Students, Senior technical staff, Interviewers, etc., Consultants - if they meet this definition.
Key Personnel must devote measurable effort to the project whether or not salaries are requested. “Zero calendar months” effort or “as needed” are not acceptable levels of involvement for those designated as Key Personnel.

List alphabetically by last name after principal investigator.
“individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (in person months) to the project. These individuals are typically presented at “effort of zero person months” effort or “as needed”

- Consultants, Mentors on Career Awards (K)
- Include Biosketch
Biographical Sketch (I)

- Key Personnel and Other Significant Contributors and Consultants if they meet the definition of either
- Used by reviewers to assess each investigator’s qualifications for their proposed role in addition to the overall competence of the entire research team
- 4 pages in length total
Biographical Sketch (II)

• Education Block: Education and Training

• A. Positions and Honors (chronological order)
  – Professional experience
  – Previous positions/employment
  – Honors and awards
  – Advisory/review committees
  – Professional memberships
Biographical Sketch (III)

• B. Publications
  – Selected
  – Full citations
  – Peer-Reviewed
  – Published or in press (not in preparation)
  – Chronological order
  – Web addresses (URLs) or PMC identification numbers for publicly available citations may also be included
Biographical Sketch (IV)

C. Research Support

- Selected
- Ongoing and completed
- Last three years
- Irregardless of sponsor (federal and non-federal)
- Describe goals of project
- Indicate responsibilities of key personnel
- Do not include % effort or $ awarded
- This section is not “Other Support”
BIOPGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 1. Follow this format for each person. DO NOT EXCEED FOUR PAGES.

<table>
<thead>
<tr>
<th>NAME</th>
<th>POSITION TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERA COMMONS USER NAME</td>
<td></td>
</tr>
</tbody>
</table>

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>
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</tbody>
</table>

NOTE: The Biographical Sketch may not exceed four pages, items A and B (together) may not exceed two of the four-page limit. Follow the formats and instructions on the attached sample.

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 (in chronological order). Do not include publications submitted or in preparation.

C. Research Support: List selected ongoing or completed (during the last three years) research projects (federal and 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 your role (e.g., PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.
A. Positions and Honors.

Positions and Employment
1969-1971 Medical Resident, Internal Medicine, Harvard Medical School
1971-1973 EIS Officer, Hospital Infection Section, Bacterial Disease 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
1985-1988 Chief, Hemostasis Laboratory, Children's Hospital, Boston, MA
1983- Professor of Pediatrics, Harvard Medical School, Boston, MA
1986- 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
1969-present Medical Director Quality Assurance, Children's Hospital, Boston, MA
1981-1983 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 Affairs, 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 Stainway 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 HS 37573-3 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

2 R01 AI12345-05 Carlucci (PI) 4/01/01-3/31/06
NIH/NAID
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

R01 AI24560-04 Peterson (PI) 3/01/01-2/28/06
NIH/NAID
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.

2 R01 HL 00000-13 Andersen (PI) 3/01/01-2/28/06
NIH/NHLBI
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

5 R01 HL 00000-07 Baker (PI) 4/1/01 – 3/31/04
NIH/NHLBI
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

1 R01 AI12826-01 Hoffman (PI) 9/28/01-9/27/03
NIH/NAID
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**

5 R01 AI100011-05 Harman (PI) 10/01/99 – 11/30/01
NIH/NAID
Evaluating Quality Improvement Strategies (EQUS)
The goal of this study was to evaluate quality improvement and collaborative learning to improve asthma care in office-based pediatrics.
Role: Co-Investigator

5 R01 A098765 Spielman (PI) 7/01/96 -6/30/01
NIH/NAID
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
Budget Justification

• Complete
• Comprehensive
• Concise
• Calculated correctly
**Budget - overview**

- NIH and other agencies require detailed budgets and justifications.
- Make sure that the requested funding ‘matches’ the scientific project proposed.
  - Peer reviewers will be able to detect if:
    - The budget is ‘padded’.
    - The budget is insufficient to support the project, evoking questions concerning how well investigator understands scope of project.
- Describe additional funding for project, if any.
Budget - overview

- Most categories are usually increased 2%-3% per year
- Equipment is usually purchased in the 1st year
- Plan for unusual changes in future years (e.g. additional personnel, reduction in the number of patient care costs), build that into the budget, and explain in the budget justification
Budget-categories (I)

• A. and B. Senior/Key and Other Personnel
  – Salary and fringe; employees of the University
  – Regardless of whether salary is requested
  – Role on Project
    • Identify role, does not have to be official university title.
    • Justify and describe specific functions in budget justification section
## RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS: 

* Budget Type: [ ] Project  [ ] Subaward/Consortium

Enter name of Organization: ___________________________

Reset Entries  * Start Date: ________  * End Date: ________  Budget Period: 1

(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the form)

### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>* First Name</th>
<th>Middle Name</th>
<th>Last Name</th>
<th>Suffix</th>
<th>* Project Role</th>
<th>Base Salary ($)</th>
<th>Cal. Months</th>
<th>Acad. Months</th>
<th>Sum. Months</th>
<th>* Requested Salary ($)</th>
<th>* Fringe Benefits ($)</th>
<th>* Funds Requested ($)</th>
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</tbody>
</table>

9. Total Funds requested for all Senior/Key Persons in the attached file

Total Senior/Key Person: ___________________________

Additional Senior Key Persons: ___________________________

### B. Other Personnel

<table>
<thead>
<tr>
<th>* Number of Personnel</th>
<th>* Project Role</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Post Doctoral Associates</td>
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<td></td>
<td>Graduate Students</td>
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<tr>
<td></td>
<td>Undergraduate Students</td>
</tr>
<tr>
<td></td>
<td>Secretaries/Clerical</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cal. Months</th>
<th>Acad. Months</th>
<th>Sum. Months</th>
<th>* Requested Salary ($)</th>
<th>* Fringe Benefits ($)</th>
<th>* Funds Requested ($)</th>
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</tbody>
</table>

Total Number Other Personnel: ___________________________

Total Other Personnel: ___________________________

Total Salary, Wages and Fringe Benefits (A+B): ___________________________
Personnel (I)

- Institutional Base Salary
  - Includes base salary + A1 salary
  - Prorate for budget period
  - Take into consideration 7/1 and 1/1 increases for professional and support staff, respectively
  - Special instructions for those w/NYSPI salary
  - Current PHS (NIH) cap of $191,300
Personnel (II)

• Salary Requested
  – Usually institutional base salary x effort on grant
  – May request less - explain in budget justification
  – Special instructions for GRAs

• Fringe Benefits
  – Government-funded sponsored projects
    • Currently 27.1%
  – Non-Govt.-funded sponsored projects
    • Currently 31.1%
    • Rate increases every year
  – 0% for Graduate Research Assistants (GRAs)
RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:  

* Budget Type:  □ Project  □ Subaward/Consortium  

Enter name of Organization:  

Reset Entries  * Start Date:  * End Date:  Budget Period:  1

(If the Reset Entries button is pressed, please navigate to previous year to enable the submission of the)

C. Equipment Description
List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>* Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td>9.</td>
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<td>10.</td>
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</tbody>
</table>

11. Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment:  

Add Attachment  Delete Attachment  View Attachment

D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)  

2. Foreign Travel Costs  

Funds Requested ($)  

Total Travel Cost
C. Equipment

- Items costing $2,500 or more with a lifespan of at least two years
- List each item separately
- Justify each item
- May include price quote
D. Travel

- Itemize in budget justification
- Justify purpose, destination of each trip, no. of individuals traveling
- Special consideration for foreign travel
<table>
<thead>
<tr>
<th></th>
<th>Other Direct Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Publication Costs</td>
<td></td>
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<tr>
<td>3</td>
<td>Consultant Services</td>
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<td>4</td>
<td>ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Subawards/Consortium/Contractual Costs</td>
<td></td>
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<tr>
<td>6</td>
<td>Equipment or Facility Rental/User Fees</td>
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<td>7</td>
<td>Alterations and Renovations</td>
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</tbody>
</table>

Total Other Direct Costs


F. Other Direct Costs

Material and Supplies

- Itemize in separate categories those >$1,000
- Glassware, chemicals and reagents, radioisotopes, animal purchases (species, number of animals), animal care costs, tissue culture/molecular biology supplies
- Animals: number, species
- Animal care: number of days, cost per day
Budget-categories

- **Patient Care Costs**
  - Separate outpatient and inpatient costs
  - Provide names of hospitals and clinics
  - State whether each has a DHHS research patient care rate agreement
  - If not, describe basis for calculating costs
  - Include no. of patient days, cost per day, and cost per test or treatment
Budget-categories

• Publication Costs
• Consultant Costs
• Subcontracts/Consortiums
  – A portion of the work will be conducted at another site, funding will “flow” from NIH to CU (prime) to subcontracted institution (domestic or foreign)
• Service Agreements
• GRA Tuition/Fees
• Core Facilities
Consultants

- Individuals involved in project who are not employees of applicant organization or those involved in subcontracts
- Include names and organizational affiliations
- Describe role and services to be performed (e.g. member of advisory committee, consulting physician)
- Describe no. of days involvement, compensation, travel, per diem, etc.
### H. 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.</td>
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</tbody>
</table>

**Total Indirect Costs**: 0.00

Cognizant Federal Agency

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

### I. Total Direct and Indirect Costs

<table>
<thead>
<tr>
<th>Total Direct and Indirect Institutional Costs ( (G + H) )</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.00</td>
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</tbody>
</table>
Indirect Costs

• Also called Facilities and Administration (F&A)
• Percentage of direct costs
• Federally negotiated rate: 61% (on campus)
• MTDC-Modified Total Direct Costs:
  Some items (equipment, patient care costs, tuition, subcontracts > $25K) not included in direct costs base.
Indirect Costs (II)

- Some NIH programs have a lower rate: 8% on training grants (T) and career development awards (K)
- Voluntary health organizations and foundations may have lower rates (e.g. 25%, 10%, 0%)
- Industry-sponsored research contracts and clinical trials have lower rates (25%)
Budget - Future Years

• Some agencies require composite, not detailed, budgets for future years
• Most categories are usually increased 2%-3% per year
• Equipment is usually purchased in the 1st year
• Plan for unusual changes in future years (e.g. additional personnel, reduction in the number of patient care costs), build that into the budget, and explain in the budget justification
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Totals ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Senior/Key Person</td>
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<td>B</td>
<td>Other Personnel</td>
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<td></td>
<td>Total Number Other Personnel</td>
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<td>C</td>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
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<td>D</td>
<td>Equipment</td>
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<td>Travel</td>
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<td>1. Domestic</td>
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<td>2. Foreign</td>
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<td>E</td>
<td>Participant/Trainee Support Costs</td>
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<td></td>
<td>1. Tuition/Fees/Health Insurance</td>
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<td>2. Stipends</td>
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<td>3. Travel</td>
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<td>4. Subsistence</td>
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<td>6. Number of Participants/Trainees</td>
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<td>F</td>
<td>Other Direct Costs</td>
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<td>1. Materials and Supplies</td>
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<td>2. Publication Costs</td>
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<td>6. Equipment or Facility Rental/User Fees</td>
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<td>7. Alterations and Renovations</td>
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<td>10. Other 3</td>
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<tr>
<td>G</td>
<td>Direct Costs (A thru F)</td>
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<tr>
<td>H</td>
<td>Indirect Costs</td>
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<tr>
<td>I</td>
<td>Total Direct and Indirect Costs (G + H)</td>
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<tr>
<td>J</td>
<td>Fee</td>
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</tbody>
</table>
R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a Pure Edge document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1
2) Please attach Attachment 2
3) Please attach Attachment 3
4) Please attach Attachment 4
5) Please attach Attachment 5
6) Please attach Attachment 6
7) Please attach Attachment 7
8) Please attach Attachment 8
9) Please attach Attachment 9
10) Please attach Attachment 10

Add Attachment  | Delete Attachment  | View Attachment
-----------------|-------------------|------------------

OMB Number: 4040-0001
Expiration Date: 04/30/2008
Budget Justification

- Complete
- Comprehensive
- Concise
- Calculated correctly
# 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:

- [ ] 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>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction to Application</td>
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<tr>
<td>(for RESUBMISSION or REVISION only)</td>
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<tr>
<td>2. Specific Aims</td>
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<tr>
<td>3. Background and Significance</td>
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<tr>
<td>4. Preliminary Studies / Progress Report</td>
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<td>5. Research Design and Methods</td>
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<td>6. Inclusion Enrollment Report</td>
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<td>7. Progress Report Publication List</td>
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<tr>
<td><strong>Human Subjects Sections</strong></td>
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<tr>
<td>8. Protection of Human Subjects</td>
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<tr>
<td>9. Inclusion of Women and Minorities</td>
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<tr>
<td>10. Targeted/Planned Enrollment</td>
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<tr>
<td>11. Inclusion of Children</td>
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<tr>
<td><strong>Other Research Plan Sections</strong></td>
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<tr>
<td>12. Vertebrate Animals</td>
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<td>13. Select Agent Research</td>
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<td>14. Multiple PI Leadership Plan</td>
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<td>15. Consortium/Contractual Arrangements</td>
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<tr>
<td>16. Letters of Support</td>
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<td>17. Resource Sharing Plan(s)</td>
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<tr>
<td>18. Appendix</td>
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</tbody>
</table>
25 pages is absolute maximum for Sections 2.2-2.5

“Answer these questions:

1. What do you intend to do?
2. Why is the work important?
3. What has already been done?
4. How are you going to do the work?”
2.2. Specific Aims

- List the broad, long term objectives
- Specifically describe what research is intended to accomplish
- Describe hypotheses to be tested or
- Specific problem to be solved or
- New technology to be developed or
- Testing of existing paradigm or clinical practice

One page is recommended
2.3. Background and Significance

- Briefly describe background of proposal
- Critically evaluate present knowledge
- Identify gaps in knowledge which project is intended to address
- Relate specific aims to broad, long term objectives and health relevance
- State impact on scientific knowledge (e.g. concepts, methodologies, technology) or clinical practice (treatments, services, preventative interventions)

Two-three pages are recommended
2.4. Progress Report/Preliminary Studies
Competing Continuation Applications:
Progress Report

- Summarize previous application's specific aims and progress toward their achievement
- Summarize importance of findings
- Clinical research: subject enrollment
- List publications resulting from this project

Six-eight pages are recommended for narrative portion
2.4 Progress Report/Preliminary Studies

New Applications: Preliminary Studies

- Describe preliminary studies related to application
- Provide information that will establish experience and competence of investigator to pursue this project

“Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.”

Six-eight pages are recommended for narrative portion
2.5. Research Design and Methods

Discuss:

- Research design and procedures as they relate to the specific aims
- Data collection, analysis, and interpretation
- Data sharing plan
- New methodologies to be used
- Novel approaches, tools, etc.
- Potential difficulties and alternative approaches
- Provide a tentative time-table for the investigation
2.6-Inclusion Enrollment Report

- For competing renewal applications
- Report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender
## Inclusion Enrollment Report

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

<table>
<thead>
<tr>
<th>Study Title:</th>
<th>Protocol Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Enrollment:</td>
<td>Grant Number:</td>
</tr>
</tbody>
</table>

### PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Sex/Gender</th>
<th>**</th>
<th>**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>Females</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>Males</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown (individuals not reporting ethnicity)</td>
<td>Unknown or Not Reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic Category: Total of All Subjects*</td>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>**</th>
<th>**</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native</td>
<td></td>
<td></td>
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<tr>
<td>Asian</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td></td>
<td></td>
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<tr>
<td>Black or African American</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
<td></td>
</tr>
<tr>
<td>More Than One Race</td>
<td></td>
<td></td>
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<tr>
<td>Unknown or Not Reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Racial Categories: Total of All Subjects*</td>
<td>**</td>
<td></td>
</tr>
</tbody>
</table>

### PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Females</th>
<th>Males</th>
<th>Unknown or Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
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<td>American Indian or Alaska Native</td>
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<tr>
<td>Asian</td>
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<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
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<td>Black or African American</td>
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<tr>
<td>White</td>
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<tr>
<td>More Than One Race</td>
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<tr>
<td>Unknown or Not Reported</td>
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<tr>
<td>Racial Categories: Total of Hispanics or Latinos**</td>
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</tbody>
</table>

*These totals must agree.
** These totals must agree.
2.7-Progress Report Publications

- Titles and complete references for all publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. Web addresses (URLs) or PMC submission identification numbers for publicly available articles may also be included.
2.8-2.11 Human Subjects Research (I)

- Very detailed instructions
- Pertinent even if only a subcontracted institution is involved in human subjects research
- Pertinent even if only receiving specimens
- Peer reviewers will assess protection from research risks as well as inclusion of women, minorities, and children in studies—factored into overall priority score
## Decision Table for Human Subjects Research, Protection and the Inclusion of Women, Minorities, and Children

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>A No Human Subjects</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Requirements for Scenario A:
- Indicate “No Human Subjects Research”

If Human Subjects is “Yes,” see Scenarios B-F below.

| B Human Subjects/E-4            | Yes                       | Yes Exemption: 4                           | No                  | N/A             | N/A                                   |

Requirements for Scenario B:
- Indicate Exemption 4 (E-4) and include justification that E-4 is appropriate.

| C Human Subjects/Other Exemptions| Yes                       | Yes Exemptions: 1, 2, 3, 5, 6             | Yes                 | N/A             | N/A                                   |

Requirements for Scenario C:
- Indicate Exemption number(s) and include justification that the designated exemption(s) is appropriate.
- Address “Inclusion of Women and Minorities”
- Address “Inclusion of Children”
<table>
<thead>
<tr>
<th>D</th>
<th>Clinical Research</th>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Requirements for Scenario D:</td>
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<td></td>
<td>- Address Protection of Human Subjects</td>
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<td></td>
<td>- Address “Inclusion of Women and Minorities”</td>
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<tr>
<td></td>
<td>- Address “Inclusion of Children”</td>
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<td></td>
<td>“Targeted/Planned Enrollment Table(s)” for each new study/protocol (New applications; Competing Renewal applications; Competing Supplements)</td>
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<tr>
<td></td>
<td>“Inclusion Enrollment Report Table(s)” (Competing Renewals; Competing Revisions (Supplements))</td>
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<table>
<thead>
<tr>
<th>E</th>
<th>Clinical Trials</th>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Requirements for Scenario E:</td>
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<tr>
<td></td>
<td>- All requirements in Scenario D</td>
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<td></td>
<td>- Data and Safety Monitoring Plan</td>
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<tr>
<td></td>
<td>- Note: Some trials may require a Data and Safety Monitoring Board, based on risk</td>
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<table>
<thead>
<tr>
<th>F</th>
<th>NIH-Defined Phase III Clinical Trial</th>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
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<td>Requirements for Scenario F:</td>
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<td></td>
<td>- All requirements in Scenario E</td>
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<tr>
<td></td>
<td>Increased requirements for Inclusion of Women and Minorities in Clinical Research</td>
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</table>
Exemption 4: Research involving the collection or study of existing* data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

*Exemption 4 applies to retrospective studies of specimens and/or data that have already been collected. The materials must be “on the shelf” (or in the freezer) at the time the protocol is submitted to the IRB... to determine whether the research is indeed exempt. Research that involves the ongoing collection of specimens and/or data does not meet the criteria for Exemption 4
Human Subjects Research (II)

- **2.8.** Protection of Human Subjects
- **2.9.** Inclusion of Women and Minorities
- **2.10.** Targeted/Planned Enrolment Table
- **2.11.** Inclusion of Children
2.8. Protection of Human Subjects

• 1. Risks To The Subjects
  – A. Human subjects involvement and characteristics
  – B. Sources of materials
  – C. Potential risks

• 2. Adequacy Of Protection Against Risks
  – A. Recruitment and informed consent
  – B. Protection against risk

• 3. Potential Benefits of the Proposed Research to the Subjects and Others

• 4. Importance of the Knowledge to be Gained

• 5. Data And Safety Monitoring Plan
2.9. Inclusion of Women and Minorities

- The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups
- Description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members
- Rationale for proposed exclusion of any sex/gender or racial/ethnic group
- Description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.
2.10. Targeted/Planned Enrolment Table

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

| Study Title: |  |
| Total Planned Enrollment: |  |

**TARGETED/PLANNED ENROLLMENT: Number of Subjects**

<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Sex/Gender</th>
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<tbody>
<tr>
<td></td>
<td>Females</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
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</table>

**Ethnic Category: Total of All Subjects***

<table>
<thead>
<tr>
<th>Racial Categories</th>
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<tbody>
<tr>
<td>American Indian/Alaska Native</td>
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<tr>
<td>Asian</td>
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<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
</tr>
<tr>
<td>Black or African American</td>
</tr>
<tr>
<td>White</td>
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</tbody>
</table>

**Racial Categories: Total of All Subjects***

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

- Description of plans to include children or justification for exclusion
- Rationale for selecting specific age range
- Descriptions of investigators’ expertise for dealing with children at the ages included, appropriateness of available facilities, and statistically meaningful number of children
- Additional Protections for Children Involved as Subjects in Research
2.12. Vertebrate Animals

1. Describe in detail proposed use of animals
   - Identify species, strains, ages, gender and number of animals

2. Justify use of animals, choice of species and numbers

3. Provide information on veterinary care
4. Describe procedures for ensuring that discomfort, distress, pain and injury will be limited

5. Describe any method of euthanasia to be used and the reasons for its selection

IACUC approval is now a “Just in Time” requirement
2.13. Select Agents

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 list of select agents:

http://www.cdc.gov/od/sap/docs/salist.pdf
2.14. Multiple PD/PI Leadership Plan

Leadership plan must be included:

• Rationale for choosing multiple PDs/PIs
• Governance and organizational structure of the leadership team and the research project, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts.
• Roles and administrative, technical, and scientific responsibilities for the PDs/PIs and other collaborators.
• Distribution of budget to specific components of the project or the individual PDs/PIs
2.15. Consortium/Contractual Agreements

- Provide detailed explanation of programmatic, fiscal, and administrative arrangements
- If this agreement constitutes a significant portion of the overall project, explain why applicant organization and not the subcontract should be grantee
2.16. Letters of Support

e.g. Consultants, Individuals providing special reagents, cells, etc., Advisory Board
2.17. Resource Sharing (I)

1. Data Sharing Plan

- For grants requesting >$500,000 in direct costs in any year
- Brief description of how final research data will be shared or, if not possible, why not
- Policy and Resources
2.17. Resource Sharing (II)

– 2. Sharing Model Organisms

• e.g. Genetically modified or mutant organisms; rodents, budding yeast, round worm, fruit fly, zebra fish,
• Not dependent of $ value of grant
• If development of a model organisms is anticipated, describe a plan for sharing and distributing this unique research resource
• If sharing is impossible or restricted, give reasons
• Policy
• Resources
• Investigators should contact Science and Technology ventures, the University’s technology transfer office
• Reviewers will be asked to evaluate sharing plan and describe in an administrative note
2.18. Appendix (I)

• New requirements, effective 1/4/2008
• Publications (up to 3):
  – Manuscripts and/or abstracts accepted for publication but not yet published
  – Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available
  – Patents directly relevant to the project
• Surveys, questionnaires, data collection instruments, clinical protocols, informed consent documents
2.18. Appendix (II)

- Only one copy of material
- Up to 10 PDF attachments
- Summary sheet of items included is encouraged
- Not to be used to circumvent Research Plan’s page limitations
- Only sent to application’s primary reviewers
PHS Checklist
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.

*Budget Period  *Anticipated Amount ($)  *Source(s)

☐

☐

☐

☐

☐

5. Assurances/Certifications (see instructions)

In agreeing to the assurances/certifications 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/f424

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

Explanation:  

Add Attachment  Delete Attachment  View Attachment
Modular Grants: The Rationale

- Redefines the “R”-type grants as an assistance mechanism
- Simplifies process and minimizes budget negotiation
- Focuses all parties on science
Modular Grants: The Basics (I)

- Applies to all new/competing R01, R03, R15, and R21 proposals up to $250,000 requested direct costs in any year
- RFAs with budgets of more than $250,000 may be modular at Institute/Center’s discretion
- Direct costs requested in module amounts of $25,000
Modular Grants: Budget (I)

- For most proposals, the same number of modules should be requested in each year; no modules are added for inflationary increases
- Only the direct costs of a consortium/contractual agreement should be included in the direct cost modules
Modular Grants: Budget (II)

- Additional direct costs can be added in $25,000 modules for increases due to large, one-time equipment purchases or major changes in budget due to research needs (for example, varying patient costs or the short term need for interviewers)
- Yearly variations in the number of modules must be justified in narrative form
Modular Grants: The Basics (II)

- Applicant will provide personnel and other budget information in narrative format only
- IRGs may adjust number of modules and Institutes/Centers can adjust to cost management plan
How to Determine the Standard Number of Modules

• Determine the project direct costs. Divide by 25,000 and by number of years. Round to the nearest whole number.

• Example:
  – Year 01: $150,000, Year 02: $156,000, Year 03: $162,240, Year 03: $168,730, Year 04: $175,479, and Year 05: 182,498
  – Total for the five years: $859,947
  – Divided by 25,000: 34.40
  – Divided by 5 years: 6.88
  – Request 7 modules or $175,000 each year
Modular Grants: Budget Justification (I)

• Provide the narrative under the table for the “Modular Budget Format Page”
• Information, in narrative form, will be provided for:
  – All Personnel
  – Significant budget items that result in a change in the number of $25,000 modules
  – Consortium/Contractual arrangements, when applicable
Modular Grants: Budget Justification (II)

• Under Personnel: List all personnel, including:
  – Names
  – Roles on the project
  – Do not provide salary information

• Provide a justification for any variation in the number of modules requested
Modular Grants: Budget Justification (III)

- For Consortium/Contractual costs:
  - Name(s) of participating institution(s) and whether foreign or domestic
  - Estimate of total costs (direct plus indirect) for each year rounded to nearest $1,000
  - List all personnel
  - Role of all personnel on the project
**Budget Period:** 1

**Start Date:**  
**End Date:**  

A. **Direct Costs**

<table>
<thead>
<tr>
<th>* Funds Requested ($)</th>
<th>* Direct Cost less Consortium F&amp;A</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Consortium F&amp;A</td>
</tr>
<tr>
<td></td>
<td>* Total Direct Costs</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.</td>
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<td>2.</td>
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<td>3.</td>
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<td>4.</td>
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</tbody>
</table>

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

**Indirect Cost Rate Agreement Date:**  
**Total Indirect Costs:**  

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

**Funds Requested ($):**
## Cumulative Budget Information

### 1. Total Costs, Entire Project Period

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

<table>
<thead>
<tr>
<th>Justification</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
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</thead>
<tbody>
<tr>
<td>Personnel Justification</td>
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<tr>
<td>Consortium Justification</td>
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<tr>
<td>Additional Narrative Justification</td>
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<tr>
<td></td>
<td>Initial Period</td>
<td>2*</td>
<td>3*</td>
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<tr>
<td>DC 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>

**Personnel**

**Consortium**

**Fee (SBIR/STTR Only)**
<table>
<thead>
<tr>
<th>Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sandy Smith, M.D., Principal Investigator, (effort = 3.8 months calendar) will be responsible for morphological and immunohistochemical characterization of eye, brain, and other tumors arising in transgenic retinoblastomas and uveal melanomas as well as the study of cell death in the HPV E6 and E7 models.</td>
</tr>
<tr>
<td>Alan Jones, Ph.D., Co-investigator, (effort = 1.2 months calendar) will develop the HPV E6 and E7 models of transgenic retinoblastoma mice and will determine the cellular genes responsible for the retinoblastoma in animal models.</td>
</tr>
<tr>
<td>Steven Johnson, Ph.D., Statistician, (effort = .6 months calendar) will assist with experimental design by performing sample size calculations. He will analyze data on new models of transgenic mice as well as data from Vitamin D and virus treatment studies.</td>
</tr>
<tr>
<td>Ms. Rachel Lato, M.S., Research Assistant, (effort = 12 months calendar) is responsible for the Lh-Tag mouse colony under the direction of the PI. She will maintain a breeding program to ensure adequate numbers of transgene-bearing animals. She will perform DNA extractions and PCR.</td>
</tr>
<tr>
<td>Ms. Stephanie Wilson, Technician, (effort = 6 months calendar) is responsible for laboratory animal preparation and some of the biochemical analyses.</td>
</tr>
<tr>
<td>To be Appointed Technician, (effort = 3 months calendar) is responsible for the repair and maintenance of the equipment and will run a variety of assays.</td>
</tr>
<tr>
<td>Ms. Whitney Thomas, Graduate Student, (effort = 6 months calendar) in Dr. Smith's laboratory will participate in all aspects of the proposed experiments.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consortium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approximately $15,000 Total Costs for all years. ($10,000 direct costs; $5,000 F&amp;A costs)</td>
</tr>
<tr>
<td>Consortium with the University of Texas (X) Domestic ( ) Foreign</td>
</tr>
<tr>
<td>Calculations are based on 50% F&amp;A rate for UT.</td>
</tr>
<tr>
<td>George Poole, Ph.D., (effort = .45 month academic) will be responsible for production and molecular biological characterization of transgenic mice expressing N-myc proto-oncogene in photoreceptor cells. He will provide lines of transgenic mice developing melanoma due to targeted expression of SV40-T antigen.</td>
</tr>
</tbody>
</table>
Personnel

John Smith, M.D., Ph.D., Principal Investigator (effort = 3 academic months, 1 summer month) will be responsible for the overall administration and direction of the project. He will analyze reaction of soluble IV9-HLA-A*0201 complex with TCR on 88A62 anti-IV9CTL.

Helen Thomas, M.D., (effort = 2 academic months) will focus on investigating the ability of various SL9-specific CD8 CTL clones from various HIV infected individuals whose T-cell receptors bind with different strength to the cognate pepMHC complex (SL9-HLA-A*0201) to suppress viral replication in HIV infected cells in vitro. In addition, Dr. Thomas will maintain initial preparation of the CTL clones and will characterize them on a regular basis to ensure maintenance of their initial quality.

Thomas Club, Ph.D., PostDoctoral Fellow (effort = 12 calendar months) will be involved in all the measurement of SD50 and SD25 for RT-and gag-derived peptides required to induce various responses of anti-HIV CTL. Most of her effort will be directed towards measurement of the intervals of epitope densities on target cells required for various responses of anti-HIV CTL.

Jane Jones, Ph.D., PostDoctoral Fellow (effort = 12 calendar months) will be responsible for the isolation and characterization of recombinant MHC class I molecules using Drosophila Melanogaster and E. coli expression systems and measurement of kinetics and affinity of reactions between soluble complex of immunodominant peptide SL9 with HLA-A*0201 soluble protein and TCR on various clones of live anti-SL9 CTL. Dr. Jones will also measure level of a.b-TCR and CD8 molecules on anti-SL9 CTL.

--See following continuation page.--

Consortium

Approximately $25,000 Total Costs per year (50% F&A; $16,667 direct costs)

Consortium with the University of Virginia  {X} Domestic   { } Foreign

James Livingston, Ph.D., will devote .9 month academic. Dr. Livingston will be responsible for establishing CTL clones from HIV-infected subjects, and propagating previously isolated CTL clones. Dr. Livingston will also be responsible for planning and overseeing all functional cell assays.

--See following continuation page.--
Continued from Personnel, Modular Budget Format Page:

Ms. Stephanie Wilson, Technician, (effort = 6 calendar months) is responsible for laboratory animal preparation and some of the biochemical analyses.

To be Appointed Technician, (effort = 3 calendar months) is responsible for the repair and maintenance of the equipment and will run a variety of assays.

Ms. Whitney Johnson, Graduate Student, (effort = 6 calendar months) in Dr. Smith’s laboratory will participate in all aspects of the proposed experiments.

Equipment (This additional narrative budget justification is provided because there is a variation in the number of modules requested.)

Purchase of a Thermocycler ($10,000) and HPLC Fraction Collector ($15,000) is requested during the first year. This will increase the requested budget for the first year by one module ($25,000). The requested equipment is necessary for this project and will be used extensively to analyze IV9-HLA-A*0201 complex.

Continued from Consortium, Modular Budget Format Page:

Norman Cross, (6 calendar months) Research Technologist will perform all CTL assays, proliferation assays, ELISA assays and assays designed to measure inhibition of HIV-1 replication by virus-specific CTL clones.
Other Support (I)

- Do **not** include with application-**will be requested** after peer review before an award is to made
- Key personnel (excluding consultants)
- “All financial resources …available in direct support of an individual’s research endeavors”
- Active and pending support
  - Includes Federal, non-Federal, commercial, and institutional funding
  - Excludes training awards, gifts, and prizes
Other Support (II)

• Information requested:
  – Project I.D. number
  – Funding agency
  – Major goals
  – Inclusive dates of project
  – Annual direct costs
  – Percent effort
  – Overlap
Other Support (III)

• “Overlap, whether scientific, budgetary, or commitment of an individual’s effort greater than 100 percent, is not permitted.”
Other Support (IV)

• **Overlap**: Summarize potential overlap between the listed active/pending support and current application
  - **Scientific**: two or more applications for the same research
  - **Budgetary**: duplicate or equivalent requested budgetary items are provided by another source
  - **Committed effort**: Personnel has time commitments exceeding 100%

• **Resolution of overlap at the time of the award**
**NAME OF INDIVIDUAL**

<table>
<thead>
<tr>
<th>Project Number (Principal Investigator)</th>
<th>Dates of Approved/Proposed Project</th>
<th>Percent Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 R01 HL 00000-13 (Anderson)</td>
<td>3/1/1997 - 2/28/2002</td>
<td>30%</td>
</tr>
<tr>
<td>NIH/NHLBI</td>
<td>$186,529</td>
<td></td>
</tr>
<tr>
<td>Chloride and Sodium Transport in Airway Epithelial Cells</td>
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</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Project Number (Principal Investigator)</th>
<th>Dates of Approved/Proposed Project</th>
<th>Percent Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 R01 HL 00000-07 (Baker)</td>
<td>4/1/1994 - 3/31/2002</td>
<td>10%</td>
</tr>
<tr>
<td>NIH/NHLBI</td>
<td>$122,717</td>
<td></td>
</tr>
<tr>
<td>Ion Transport in Lungs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

<table>
<thead>
<tr>
<th>Project Number (Principal Investigator)</th>
<th>Dates of Approved/Proposed Project</th>
<th>Percent Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>R000 (Anderson)</td>
<td>9/1/1996 - 8/31/2002</td>
<td>10%</td>
</tr>
<tr>
<td>Cystic Fibrosis Foundation</td>
<td>$43,123</td>
<td></td>
</tr>
<tr>
<td>Gene Transfer of CFTR to the Airway Epithelium</td>
<td></td>
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</tr>
</tbody>
</table>

The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

**PENDING**

<table>
<thead>
<tr>
<th>Project Number</th>
<th>Dates of Approved/Proposed Project</th>
<th>Percent Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCG 950000</td>
<td>12/01/2002 - 11/30/2004</td>
<td>20%</td>
</tr>
<tr>
<td>National Science Foundation $82,163</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liposome Membrane Composition and Function</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.
OVERLAP
There is scientific overlap between aim 2 of NSF DGB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

RICHARDS, L.
NONE

HERNANDEZ, M.
ACTIVE
5 R01 CA 00000-07 (Hernandez) 4/1/1995 – 3/31/2002 40% academic
NIH/NCI
Gene Therapy for Small Cell Lung Carcinoma

The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC cell lines and to study the effect on growth and invasiveness of the lungs.

5 P01 CA 00000-03 (Chen) 7/1/2000 – 6/30/2002 20% academic
NIH/NCI
Mutations in p53 in Progression of Small Cell Lung Carcinoma

The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez) 9/1/1996 – 8/31/2002 20% academic
American Cancer Society
p53 Mutations in Breast Cancer

The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

OVERLAP
Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 30 percent effort, Dr. Hernandez will request approval to reduce her effort on the NCI grant.

BENNETT, P.
ACTIVE
Investigator Award (Bennett) 9/1/1990 – 8/31/2002 70%
Howard Hughes Medical Institute SS81.317
Gene Cloning and Targeting for Neurological Disease Genes
This award supports the PI’s program to map and clone the gene(s) implicated in the development of Alzheimer’s disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP: None
Resources for Grant Writing

• Writing a Grant Proposal
  (Application Forms and Writing Tips)
  http://www.cumc.columbia.edu/dept/gsas/ac_programs/fund-crs.htm
K Awards

• Helpful Hints for Mentored Clinical Scientist Development Award (K08)
  – http://www.nhlbi.nih.gov/funding/training/redbook/hints.htm
  – Model application
    • http://www.nhlbi.nih.gov/funding/training/redbook/k08model.htm

• Helpful Hints for Mentored Patient-Oriented Research Career Development Award (K23)
  – http://www.nhlbi.nih.gov/funding/training/redbook/hints4k23.htm
  – Model applications
    • http://www.nhlbi.nih.gov/funding/training/redbook/k23models.htm
25 Pages Combined

- **The Candidate**
  - All sections

- **Research Plan**
  - 2. Specific Aims  ➞  5. Research Design
The Candidate

- Candidate’s Background
- Career Goals and Objectives: Scientific Biography
- Career Development/Training Activities During Award Period
Candidate’s Background

- Personal, other training experiences
  - Masters degree
- Other research experiences
  - MD/PhD, Medical school, Fellowship
- Reasons for basic, clinical, translational, behavioral, multidisciplinary research, relevant publications
Career Goals and Objectives:

Scientific Biography

• Unique expertise/Scientific history
  – Previous work
    • Consistent themes, or
    • Why research interests have changed direction
  – e.g. joint appointments, multidisciplinary

• Skills that are lacking
  – Identification of specific modules to address problem areas, provides justification of award
  – Role of specific mentor(s) or Advisory Committee member(s)
• **Short-term Career Goals**
  – Timeline for funded period

  **Year 1**: Preliminary data

  **Year 2-4**: Submit publications (possible journals),
  Presentations at national meetings (examples),
  Formulation of R01 application

  **Year 5**: By the end of the funded period, applicant will be an independent investigator with R01 funding
• Long-term Career Goals
  – Scientific goals
    • Basic science, translational, clinical, epidemiologic, behavioral
  – Mentoring goals
    • How mentoring has been important to you
    • Previous/current mentoring responsibilities
  – Networking goals
    • Multidisciplinary activities, grants, etc
Career Development/Training Activities During Award Period

• Review of didactic courses, clinical training, and research experiences to date
• Identification of training modules required to fill gaps in knowledge in order to reach long term goals
  – Rational for each of the modules
• **New Section on each Modules**
  – Reason for module
  – Specific Description of each “Mode of Learning” and role of mentor(s)
  • Expectation for the number of abstracts to be submitted each year; which scientific areas, which meetings
  • Expectation for the number of papers to be submitted each year; number of papers in which scientific areas
  • Role of mentors
  – Module: Career skills
    – Grantsmanship
    – Becoming a mentor
    – Laboratory management
<table>
<thead>
<tr>
<th>Module</th>
<th>Mentor(s)</th>
<th>Mode of learning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Area</td>
<td>Specific names</td>
<td>Coursework&lt;br&gt;1-on-1 meetings (schedule? e.g. weekly)&lt;br&gt;Guided readings&lt;br&gt;Research meetings (schedule? e.g. weekly)&lt;br&gt;Applied training&lt;br&gt;Clinical experience</td>
</tr>
<tr>
<td>Career skills</td>
<td>All mentors</td>
<td>Improving communication skills&lt;br&gt;Grant writing course&lt;br&gt;Professional workshops/seminars&lt;br&gt;Collaborations&lt;br&gt;Abstracts and manuscripts&lt;br&gt;R01 grant application submission</td>
</tr>
<tr>
<td>Dissemination of Research Results</td>
<td></td>
<td>Supervising technical support personnel, organizing lab meetings, journal clubs</td>
</tr>
<tr>
<td>Research management</td>
<td></td>
<td>e.g. training new lab members, undergraduate, summer students</td>
</tr>
<tr>
<td>Mentorship</td>
<td></td>
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</tbody>
</table>
• **Mentors/Advisory Committee**
  – Scientific area per mentor/committee member
  – Schedule of meetings

• **Summary of coursework**
  – List previous relevant coursework
  – Proposed coursework
    • Course number and description
    • Include courses on grant writing and responsible conduct of research
  – Additional didactic activities
    • e.g. those offered by professional societies, workshops, symposiums
• Clinical activities
  – Be specific, mention hrs. per week, restate % of time dedicated to research
• Timetable
<table>
<thead>
<tr>
<th>Objectives and Tasks</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Training Activities per Individual Modules</td>
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<tr>
<td>Coursework (hrs/wk)</td>
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<tr>
<td>Didactic Meetings (hrs/wk)</td>
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<tr>
<td>Research meetings</td>
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<tr>
<td>Applied training</td>
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<tr>
<td>2. Research Activities Plan</td>
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<tr>
<td>IRB preparation</td>
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<tr>
<td>Subject recruitment</td>
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<tr>
<td>Study experiments/protocol</td>
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<tr>
<td>Data collection</td>
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<tr>
<td>Data analysis</td>
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<tr>
<td>3. Last Module: Career skills</td>
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<tr>
<td>Prepare and present abstracts (#/yr)</td>
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<tr>
<td>Conceptualize and prepare manuscripts (#/yr)</td>
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<tr>
<td>R01 development and submission</td>
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<tr>
<td>Module assessment with mentor (hrs/wk) and co-mentor (hrs/month)</td>
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</tbody>
</table>
Statements by Sponsor, Co-Sponsors, Consultants and Contributors

- Sponsor’s Assessment of the Candidate
- Sponsor’s Concept of the Research and Career Development Plans of the Candidate
  - Research
  - Developmental activities
    - Seminars, scientific meetings, presentations, publications
• **Sponsor’s Plans for Providing Guidance and Counseling**
  – How this will promote candidate’s development
  – Candidate’s transition from mentored to independent investigator

• **Candidate’s Additional Responsibilities**
  – Courses, seminars, lab meetings
  – Teaching
  – Clinical
  – Administrative
• **Source of Support for Candidate’s Research Project**
  - Grants
  - Core/shared facilities
  - Technical support

• **Sponsor’s Past and Current Trainees**
  - Name, position and date when mentored by sponsor, current position (title and institution), awards/ grants made to trainees
- **Advisory Committee**
  - **Purpose**
    - Reviews research progress, publications, R01 submission, career development activities, didactic program
    - Provides scientific guidance
    - Documents meetings with an annual report
    - Name, title, and short paragraph on each member
    - Each should provide a letter
- **Collaborators and Consultants**
  - Name, title, and short paragraph on each individual
  - Each should provide a letter
Environment and Institutional Commitment to the Candidate

- Description of Institutional Environment
- Institutional Commitment to the Candidate’s Research Career Development
• **Description of Institutional Environment**
  - Paragraph on CU/CUMC
  - Paragraph on Dept/Division
  - Paragraph’s on other involved schools, centers, shared resources, CTSA, etc.
  - Paragraph on any mentoring program for junior faculty
• Institutional Commitment to the Candidate’s Research Career Development
  – Letter from Dept. Chair
    • Specifics on protected time (most K awards: 75%)
    • Specifics on faculty appointment (full-time)
    • Statement that appointment and salary are not contingent on award
    • Statement on availability of research resources, personnel, office space, etc. required for project
    • Statement that sponsors will be able to provide time and support for mentoring responsibilities
    • Signed and dated
  – Letter from Division Chief
  – Letter from Chiefs for any joint appointments
Letters of Reference - 3

- From individuals not directly involved in the application or proposed research project, not mentor
- Familiar with your qualifications, training, and interests
- Should address candidate's competence, professional training and qualifications and potential to develop into an independent investigator
- Where possible, not from the candidate's current department or organization