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| Forms Approved for the 2022-2023 Grants Cycle  |
| **AlphaNet**Grant ApplicationPlease follow instructions. | **LEAVE BLANK** |
| Type | Grant Cycle | Number |
|  |  |  |
| Review Mtg (Month, Year) | Date Received |
| 1. TITLE OF PROJECT *(Do not exceed 56 characters, including spaces and punctuation.)*      |
| 2. RESPONSE TO THE ALPHANET PRO GRANT OPPORTUNITY[ ]  NO [x]  YES  *(If “Yes,” state title. If “No,” state the grant category)* |
| Category: |       |
| 3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR  | New Investigator [ ]  No [ ]  Yes |
| 3a. NAME *(Last, first, middle)* | 3b. DEGREE(S) |  |
|       |       |       |
| 3c. POSITION TITLE      | 3d. MAILING ADDRESS *(Street, city, state, zip code)*      |
| 3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT      |
| 3f. MAJOR SUBDIVISION      |
| 3g. TELEPHONE AND FAX *(Area code, number and extension)* | E-MAIL ADDRESS: |
| TEL: |       | FAX: |       |       |
| 4. HUMAN SUBJECTS RESEARCH[ ]  No [ ]  Yes | 4a. Research Exempt [ ]  No [ ]  Yes | 5. VERTEBRATE ANIMALS [ ]  No [ ]  Yes |
| If “Yes,” Exemption No. |       |
| 4b. Human Subjects Assurance No.       | 4c. Certification of human subjects training[ ]  No [ ]  Yes | 5a. If “Yes,” IACUC approval Date      | 5b. Animal welfare assurance no. |
|       |
| 6. DATES OF PROPOSED PERIOD OF  SUPPORT *(month, day, year—MM/DD/YY)* | 7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD | 8. COSTS REQUESTED FOR ENTIRE PROPOSED PROJECT PERIOD  |
| From | Through | 7a. Direct Costs ($) | 8a. Direct Costs ($) |
|       |       |       |       |
| 9. APPLICANT ORGANIZATION | 10. ASSOCIATION FOR THE ACCREDITATION OF HUMAN RESEARCH PROTECTION PROGRAMS, INC., (AAHRPP)  |
| Name |       |
| Address |       | Is the Applicant Organization AAHRPP accredited? |
| [ ]  No [ ]  Yes |
|  |  |
|  |  |  |  |
| 11. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE | 12. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION |
| Name |       | Name |       |
| Title |       | Title  |       |
| Address |       | Address |       |
| Tel: |       | Fax: |       | Tel: |       | Fax: |       |
| E-Mail: |       | E-Mail: |       |
| 13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application. | SIGNATURE OF PI/PD NAMED IN 3a.*(In ink. “Per” signature not acceptable.)* | DATE      |
| 14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application.   | SIGNATURE OF OFFICIAL NAMED IN 12.*(In ink. “Per” signature not acceptable.)* | DATE      |

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| DESCRIPTION: State the application’s broad, long-term objectives and specific aims, making reference to the relatedness of the project to Alpha-1 Antitrypsin Deficiency and the Alpha-1 Biomarkers Consortium. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.** |
|  |
|       |
|  |
| PERFORMANCE SITE(S) *(organization, city, state)* |
|       |
| KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below.Start with Principal Investigator. List all other key personnel in alphabetical order, last name first. |
| Name | Organization | Role on Project |
|       |       |       |
|       |       |       |
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**Lay Abstract**

Provide a summary of your proposal in lay terms (the equivalent of grade 8 level English)

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Keywords List**

In order to best assign your Grant Application to the best corresponding reviewers, please select the term(s) that best describe your project from the list below. You may choose more than one item. This regulatory document must be completed and returned as part of the Grant Application.

**SECTION 1**

**GENERAL AREA OF RESEARCH**

Please select one or more of the following that best describes your general area of research.

[ ]  Basic Research

[ ]  Clinical Medicine

[ ]  Clinical Research/(trials)

[ ]  Translational Research

[ ]  Social Science Research

**SECTION 2**

**SPECIFIC AREA OF RESEARCH**

Please select one or more of the following that best describes your area of research. Please feel free to add additional keywords.

[ ]  Lung-Focused Research

[ ]  Liver-Focused Research

[ ]  Technology Development

[ ]  Epidemiology of AAT deficiency

[ ]  Approaches to promote routine annual pulmonary function testing

[ ]  Role of inflammation in the pathogenesis of AAT lung disease

[ ]  Establishment of effective clinical outcomes measures in AAT deficiency

[ ]  Quantitative CT scanning to assess lung disease progression

[ ]  Biomarkers of early lung or liver disease or of disease exacerbations

[ ]  Quality of life, healthcare utilization, and symptom management

[ ]  Environmental modifiers of lung and liver disease in AAT deficient individuals

[ ]  Clinical manifestations of AAT Deficiency other than in the lungs and liver

[ ]  Alpha-1 antitrypsin replacement therapy

[ ]  Improving outcomes in lung and liver transplant recipients

[ ]  Social dimensions of A1ATD

[ ]  Equitable distribution of medical therapies

[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| GRANT APPLICATION’s |
| TABLE OF CONTENTS |
|  | *Page Numbers* |
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| Keywords List………………………………………………………………………………………………………Table of Contents  |  | 3 |  |
| Table of Contents.................................................................................................................................... |  | 3a |  |
| Detailed Budget for Initial Budget Period  |  | 4 |  |
| Budget Justification……………………………………………………………………………………………… |  | 4a |  |
| Budget for Entire Proposed Project Period  |  |       |  |
| Budgets Pertaining to Consortium/Contractual Arrangements..........................................................  |  |       |  |
| Biographical Sketch – Principal Investigator/Program Director (*Not to exceed four pages*)..  |  |       |  |
| Other Biographical Sketches (Not to exceed four pages for each – *See instructions*)  |  |       |  |
| **Other Support……………………………………………………………………………………………………..** |  |        |  |
| Resources  |  |       |  |
| Research Plan  |  |       |  |
| A. Specific Aims  |  |       |  |
| B. Background and Significance  |  |       |  |
| C. Preliminary Studies (Items A-D: not to exceed 4 pages**\***) Phase I Final Report (SBIR/STTR), or SBIR/STTR Fast Track Product Development Plan  |  |       |  |
| D. Research Design and Methods  |  |       |  |
| E. Human Subjects Research  |  |       |  |
| Protection of Human Subjects (Required if Item 4 on the Face Page is marked “Yes”)  |  |       |  |
| Inclusion of Women (Required if Item 4 on the Face Page is marked “Yes”)  |  |       |  |
| Inclusion of Minorities (Required if Item 4 on the Face Page is marked “Yes”)  |  |       |  |
| Inclusion of Children (Required if Item 4 on the Face Page is marked “Yes”)  |  |       |  |
| Human Subject Protection Certification and/or Training (Optional listing)  |  |       |  |
| F. Vertebrate Animals  |  |       |  |
| G. Literature Cited  |  |       |  |
| H. Consortium/Contractual Arrangements  |  |       |  |
| I. Letters of Support (e.g., Consultants) |  |       |  |
|  |  |
|  |  |  |
| Appendix *(One collated set. No page numbering necessary for Appendix.)*  | Check if Appendix isIncluded[ ]  |
| Number of publications and manuscripts accepted for publication *(not to exceed 10)* |       |  |
| Other items (list):       |   |

|  |  |  |
| --- | --- | --- |
| DETAILED BUDGET FOR INITIAL BUDGET PERIODDIRECT COSTS ONLY | FROM | THROUGH |
|       |       |
| PERSONNEL *(Applicant organization only)* |  | % |  | DOLLAR AMOUNT REQUESTED *(omit cents)* |
| NAME | ROLE ONPROJECT | TYPEAPPT.*(months)* | EFFORTONPROJ. | INST.BASESALARY | SALARY REQUESTED | FRINGE BENFITS | TOTAL |
|       | PrincipalInvestigator |       |       |       |       |       |       |
|       |       |       |       |       |       |       |       |
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|       |       |       |       |       |       |       |       |
| SUBTOTALS |       |       |       |
| CONSULTANT COSTS      |       |
| EQUIPMENT *(Itemize)*      |       |
| SUPPLIES *(Itemize by category)*      |       |
| TRAVEL TO ALPHA-1 FOUNDATION’S INVESTIGTAORS’ MEETING (MANDATORY LINE ITEM)1 PERSON | $1,000      |
| TRAVEL |  |
| PATIENT CARE COSTS | INPATIENT |       |       |
| OUTPATIENT |       |       |
| ALTERATIONS AND RENOVATIONS *(Itemize by category)*      |       |
| OTHER EXPENSES *(Itemize by category)*      |       |
| SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD | $ |       |
| CONSORTIUM/CONTRACTUAL COSTS |  |       |
| TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)* | $ |       |

BUDGET JUSTIFICATION

Please provide a description and justification for each line item of your budget (Form Page 4). Use additional continuation pages as needed.

|  |
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| BUDGET FOR ENTIRE PROPOSED PROJECT PERIODDIRECT COSTS ONLY |
| BUDGET CATEGORYTOTALS | INITIAL BUDGETPERIOD*(from Form Page 4)* | ADDITIONAL YEARS OF SUPPORT REQUESTED |
| 2nd | N/A | N/A | N/A |
| PERSONNEL: *Applicant organization only*. |       |       |       |       |       |
| CONSULTANT COSTS |       |       |       |       |       |
| EQUIPMENT |       |       |       |       |       |
| SUPPLIES |       |       |       |       |       |
| TRAVEL TO ALPHA-1 FOUNDATION’S BIENNIAL INVESTIGATORS’ MEETING**(MANDATORY LINE ITEM)** | $1,000 | N/A | N/A | N/A | N/A |
| TRAVEL |       |       |       |       |       |
| PATIENT CARECOSTS | INPATIENT |       |       |       |       |       |
| OUTPATIENT |       |       |       |       |       |
| ALTERATIONS ANDRENOVATIONS (N/A) |       |       |       |       |       |
| OTHER EXPENSES |       |       |       |       |       |
| SUBTOTAL DIRECT COSTS |       |       |       |       |       |
| CONSORTIUM/CONTRACTUALCOSTS | DIRECT |       |       |       |       |       |
| TOTAL DIRECT COSTS |       |       |       |       |       |
| TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD *(Item 8a, Face Page)* | **–––––** | $ |       |
|  |
| BIOGRAPHICAL SKETCHProvide the following information for the key personnel in the order listed on Form Page 2.Follow this format for each person.  **DO NOT EXCEED FOUR PAGES.** |
|  |
| NAME | POSITION TITLE |
| EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)* |
| INSTITUTION AND LOCATION | DEGREE*(if applicable)* | YEAR(s) | FIELD OF STUDY |
|  |  |  |  |
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| **OTHER SUPPORT SAMPLE** |

Provide active support for all key personnel. **Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included. All figures provided must be listed in US Dollars.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. ***Include the principal investigator's name at the top and number consecutively with the rest of the application.*** The sample below is intended to provide guidance regarding the type and extent of information requested. Refer to the specific instructions in Section I.

For information pertaining to the use of and policy for other support, see “Policy and Additional Guidance.”

**Format**

|  |
| --- |
| **NAME OF INDIVIDUAL**ACTIVE/PENDING  |
| Project Number (Principal Investigator) SourceTitle of Project *(or Subproject)*The major goals of this project are… | Dates of Approved/Proposed ProjectAnnual Direct Costs | Percent Effort |
| OVERLAP *(summarized for each individual)* |

**Samples**

**ANDERSON, R.R.**

ACTIVE

2 R01 HL 00000-13 (Anderson) 3/1/1997 – 2/28/2002 30%

NIH/NHLBI $186,529

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.

5 R01 HL 00000-07 (Baker) 4/1/1994 – 3/31/2002 10%

NIH/NHLBI $122,717

Ion Transport in Lungs

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

R000 (Anderson) 9/1/1996 – 8/31/2002 10%

Cystic Fibrosis Foundation $43,123

Gene Transfer of CFTR to the Airway Epithelium

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

PENDING

 DCB 950000 (Anderson) 12/01/2002 – 11/30/2004 20%

 National Science Foundation $82,163

 Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

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| **ALPHANET OTHER SUPPORT *(continued)*** |

OVERLAP

There is scientific overlap between aim 2 of NSF DCB 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 lines.

5 P01 CA 00000-03 (Chen) 7/1/2000 – 6/30/2002 20% academic

NIH/NCI $104,428 (sub only) 100% summer

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 $86,732

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) 9/1/1999 – 8/31/2002 70%

Howard Hughes Medical Institute $581,317

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

|  |
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| RESOURCES |
| FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under “Other,” identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary. |
| Laboratory:      |
| Clinical:      |
| Animal:      |
| Computer:      |
| Office:      |
| Other:

|  |
| --- |
| MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.      |

A1F (2006-2007) Page     **Resources Format Page** |

AlphaNet 2022-2023 **Resources Format Page**

**Continuation Format Page (use as needed)**

AlphaNet 2022-2022 **Continuation Format Page**