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| Form Approved Through 02/28/2023 OMB No. 0925-0001**COVER PAGE** |
| Department of Health and Human ServicesPublic Health Services**Grant Application***Do not exceed character length restrictions indicated.* | **LEAVE BLANK—FOR PHS USE ONLY**. |
| Type | Activity | Number |
| Review Group | Formerly |
| Council/Board (Month, Year) | Date Received |
| 1. TITLE OF PROJECT *(Do not exceed 81 characters, including spaces and punctuation.)*      |
| 2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION [ ]  NO [ ]  YES  *(If “Yes,” state number and title)* |
| Number: |       | Title: |       |
| **3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR** |
| 3a. NAME (Last, first, middle) | 3b. DEGREE(S) | 3h. eRA Commons User Name |
|       |       |       |       |       |
| 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 | 4a. Research Exempt  | If “Yes,” Exemption No. |
|  [ ]  No [ ]  Yes | [ ]  No [ ]  Yes |       |
| 4b. Federal-Wide Assurance No.  | 4c. Clinical Trial | 4d. NIH-defined Phase III Clinical Trial |
|       | [ ]  No [ ]  Yes |  [ ]  No [ ]  Yes |
| 5. VERTEBRATE ANIMALS [ ]  No [ ]  Yes | 5a. Animal Welfare Assurance No.  |       |
| 6. DATES OF PROPOSED PERIOD OF  SUPPORT *(month, day, year—MM/DD/YY)* | 7. COSTS REQUESTED FOR BUDGET PERIOD |  |
| From | Through | 7a. Total Direct Costs ($) (all Sites) | 7b. Total Indirect Costs ($)(all sites) | 7c. Total Direct and Indirect Costs ($) |  |
|       |       |       |       |       |  |
| 8. APPLICANT ORGANIZATION | 9. TYPE OF ORGANIZATION |
| Name |       | Public: **→** [ ]  Federal [ ]  State [ ]  Local |
| Address |       | Private: **→** [ ]  Private Nonprofit |
| For-profit: **→** [ ]  General [ ]  Small Business [ ]  Woman-owned [ ]  Socially and Economically Disadvantaged |
| 10. ENTITY IDENTIFICATION NUMBER      |
| DUNS NO. |       | Cong. District |       |
| 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: |       |
| 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. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. | SIGNATURE OF OFFICIAL NAMED IN 13.*(In ink. “Per” signature not acceptable.)* | DATE      |

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| **PROJECT SUMMARY, RELEVANCE, PERFORMANCE SITE AND SENIOR KEY PERSONNEL PAGES** |

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|  |  |
|  |
| PROJECT SUMMARY (See instructions): |
|  |
| RELEVANCE (See instructions): |
|       |
| PROJECT/PERFORMANCE SITE(S) (if additional space is needed, use Project/Performance Site Format Page) |
| **Project/Performance Site Primary Location** |
| Organizational Name: |       |
| DUNS: |       |
| Street 1: |       | Street 2: |       |
| City: |       | County: |       | State: |       |
| Province: |       | Country: |       | Zip/Postal Code: |       |
| Project/Performance Site Congressional Districts: |       |
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| **Additional Project/Performance Site Location** |
| Organizational Name: |       |
| DUNS: |       |
| Street 1: |       | Street 2: |       |
| City: |       | County: |       | State: |       |
| Province: |       | Country: |       | Zip/Postal Code: |       |
| Project/Performance Site Congressional Districts: |       |

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| **Additional Project/Performance Site Location** |
| Organizational Name: |       |
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| Province: |       | Country: |       | Zip/Postal Code: |       |
| Project/Performance Site Congressional Districts: |       |

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| **Additional Project/Performance Site Location** |
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| Province: |       | Country: |       | Zip/Postal Code: |       |
| Project/Performance Site Congressional Districts: |       |

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| **Additional Project/Performance Site Location** |
| Organizational Name: |       |
| DUNS: |       |
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| City: |       | County: |       | State: |       |
| Province: |       | Country: |       | Zip/Postal Code: |       |
| Project/Performance Site Congressional Districts: |       |

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| SENIOR/KEY PERSONNEL. See instructions. *Use continuation pages as needed* to provide the required information in the format shown below.Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first. |
| Name | eRA Commons User Name | Organization | Role on Project |
|       |       |       |       |
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| OTHER SIGNIFICANT CONTRIBUTORS |
| Name | Organization | Role on Project |
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| **BIOGRAPHICAL SKETCHES** |

*You may remove this page and insert Biosketches of Senior Key Personnel and Other Significant Contributors.*

**BUDGET FORM: SITE ONE**

**(If applicable)**

Primary Institution Budget (SITE I) Institution:

|  |
| --- |
| **PERSONNEL BUDGET EXPENSES** |
| **Name (last, first)** | **Role** | **Annual Salary** | **% Effort** | **Project Period (months)** | **Grant Salary** | **Total Fringe** | **Total** |
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|   **Total Personnel** |  |
| **CONSUMABLES AND OTHER EXPENSES** |
|  |
| **Category** | **Detail/Comments** | **Amount** |
| Travel |  |  |
| Consultants |  |  |
| Equipment |  |  |
| Supplies |  |  |
| Other |  |  |
| Other |  |  |
| Other |  |  |
|  **Total Consumables and Other:** |  |
| **TOTALS** |
|  **Total Direct Costs:** |  |
|  **Total Indirect Costs:** **Indirect Rate: \_\_\_\_\_%**  |  |
|  **Total Direct and Indirect Costs:**  |  |

**BUDGET FORM: SITE TWO**

 ***(If applicable)***

**(If applicable)**

Collaborating Site Budget Institution:

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| --- |
| **PERSONNEL BUDGET EXPENSES** |
| **Name (last, first)** | **Role** | **Annual Salary** | **% Effort** | **Project Period (months)** | **Grant Salary** | **Total Fringe** | **Total** |
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|   **Total Personnel** |  |
| **CONSUMABLES AND OTHER EXPENSES** |
|  |
| **Category** | **Detail/Comments** | **Amount** |
| Travel |  |  |
| Consultants |  |  |
| Equipment |  |  |
| Supplies |  |  |
| Other |  |  |
| Other |  |  |
| Other |  |  |
|  **Total Consumables and Other:** |  |
| **TOTALS** |
|  **Total Direct Costs:** |  |
|  **Total Indirect Costs:**  **Indirect Rate: \_\_\_%**  |  |
|  **Total Direct and Indirect Costs:**  |  |

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| **BUDGET FORM: SITE THREE** ***(If applicable)*** |

Collaborating Site Budget Institution:

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| **PERSONNEL BUDGET EXPENSES** |
| **Name (last, first)** | **Role** | **Annual Salary** | **% Effort** | **Project Period (months)** | **Grant Salary** | **Total Fringe** | **Total** |
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|   **Total Personnel** |  |
| **CONSUMABLES AND OTHER EXPENSES** |
|  |
| **Category** | **Detail/Comments** | **Amount** |
| Travel |  |  |
| Consultants |  |  |
| Equipment |  |  |
| Supplies |  |  |
| Other |  |  |
| Other |  |  |
| Other |  |  |
|  **Total Consumables and Other:** |  |
| **TOTALS** |
|  **Total Direct Costs:** |  |
|  **Total Indirect Costs:**  **Indirect Rate \_\_\_\_\_%**  |  |
|  **Total Direct and Indirect Costs:**  |  |

Collaborating Site Budget Institution:

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| **BUDGET FORM: SITE FOUR** ***(If applicable)*** |

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| **PERSONNEL BUDGET EXPENSES** |
| **Name (last, first)** | **Role** | **Annual Salary** | **% Effort** | **Project Period (months)** | **Grant Salary** | **Total Fringe** | **Total** |
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|  |  |  |  |  |  |  |  |
|   **Total Personnel** |  |
| **CONSUMABLES AND OTHER EXPENSES** |
|  |
| **Category** | **Detail/Comments** | **Amount** |
| Travel |  |  |
| Consultants |  |  |
| Equipment |  |  |
| Supplies |  |  |
| Other |  |  |
| Other |  |  |
| Other |  |  |
|  **Total Consumables and Other:** |  |
| **TOTALS** |
|  **Total Direct Costs:** |  |
|  **Total Indirect Costs:**  **Indirect Rate: \_\_\_\_%**  |  |
|  **Total Direct and Indirect Costs:**  |  |

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| **BUDGET FORM: CUMULATIVE BUDGET** |

|  |
| --- |
| TOTAL DIRECT COSTS |
| Site One (Primary) | $ |
| Site Two (if applicable) | $ |
| Site Three (if applicable) | $ |
| Site Four (if applicable) | $ |
| **Total Direct Costs:** |  |
| TOTAL INDIRECT COSTS |
| Site One (Primary) | $ |
| Site Two (if applicable) | $ |
| Site Three (if applicable) | $ |
| Site Four (if applicable) | $ |
| **Total Indirect Costs:** |  |
|  |  |
| **TOTAL Direct and Indirect Costs:** |  |

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| **BUDGET JUSTIFICATION: SITE ONE (Primary site)** |

**BUDGET JUSTIFICATION: SITE TWO**

***(If applicable)***

**BUDGET JUSTIFICATION: SITE THREE**

***(If applicable)***

**BUDGET JUSTIFICATION: SITE FOUR**

***(If applicable)***

**INTRODUCTION**

**(Applies only to resubmissions; 1 page limit)**

**SPECIFIC AIMS**

**(1 page limit)**

**RESEARCH PLAN**

**(6 page limit)**

**Letters of Support**

**(List letters below and attach PDF copies to final application)**

**HUMAN SUBJECTS**

**(*If applicable – see below* )**

**Human Subjects and Clinical Trials Information**

**Are Human Subjects Involved? Yes**[ ]  **No**[ ]

**If No to Human Subjects**

Does the proposed research involved human specimens and/or data? **Yes**[ ]  **No**[ ]

If Yes, provide an explanation of why the application does not involved human subjects research:

Click or tap here to enter text.

**If Yes to Human Subjects:**

**Study Record: PHS Human Subjects and Clinical Trials Information**

**Section 1 – Basic Information**

1.1 Study Title (each study title must be unique): Click or tap here to enter text.

 1.2 Is this Study Exempt from Federal Regulations? **Yes**[ ]  **No**[ ]

1.3 Exemption Number: **1**[ ]  **2** [ ]  **3** [ ]  **4** [ ]  **5** [ ]  **6** [ ]  **7** [ ]  **8**[ ]

 **1.4 Clinical Trial Questionnaire**

*If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial*.

1.4.a. Does the study involve human participants? **Yes**[ ]  **No**[ ]

1.4.b. Are the participants prospectively assigned to an intervention? **Yes**[ ]  **No**[ ]

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? **Yes**[ ]  **No**[ ]

1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome? **Yes**[ ]  **No**[ ]

1.5. Provide the ClinicalTrials.gov Identifier for this trial, if applicable:

Click or tap here to enter text.

**Section 2 – Study Population Characteristics**

2.1. Conditions or Focus of Study: Click or tap here to enter text.

2.2. Eligibility Criteria: Click or tap here to enter text.

2.3. Age Limits **Minimum Age:** Click or tap here to enter text.

**Maximum Age: Click or tap here to enter text.**

2.4. Inclusion of Women, Minorities, and Children:

Click or tap here to enter text.

2.5. Recruitment and Retention Plan:

Click or tap here to enter text.

2.6. Recruitment Status (check one)

Not yet recruiting [ ]

 Recruiting [ ]

 Enrolling by invitation [ ]

Active, not recruiting [ ]

 Completed [ ]

 Suspended [ ]

Terminated (Halted Prematurely) [ ]

 Withdrawn (No Participants Enrolled) [ ]

2.7. Study Timeline:

Click or tap here to enter text.

2.8. Enrollment of First Subject

**Date: (MM/DD/YYYY):** Click or tap here to enter text.

[ ]  **Anticipated or** [ ]  **Actual**

**Inclusion Enrollment Report**

1. Using an Existing Dataset or Resource **Yes** [ ]  **No** [ ]
2. Enrollment Location Type **Domestic** [ ]  **Foreign** [ ]
3. Enrollment Country/ies: Click or tap here to enter text.
4. Enrollment location(s): Click or tap here to enter text.
5. Comments (up to 500 characters): Click or tap here to enter text.

**Planned Enrollment Table**

|  |  |
| --- | --- |
| **Racial Categories** | **Ethnic Categories** |
| # of Not Hispanic or Latino | # of Hispanic or Latino | **Total #** |
| **Female** | **Male** | **Female** | **Male** |  |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White |  |  |  |  |  |
| More than One Race |  |  |  |  |  |
| **Total** |  |  |  |  |  |

**Cumulative (Actual)**

|  |  |
| --- | --- |
| **Racial Categories** | **Ethnic Categories** |
| # Not Hispanic or Latino | # Hispanic or Latino | # Unknown/Not Reported Ethnicity | **Total #** |
| Female | Male | Unknown/Not Reported | Female | Male | Unknown/Not Reported | Female | Male | Unknown/Not Reported |  |
| American Indian/Alaska Native |  |  |  |  |  |  |  |  |  |  |
| Asian |  |  |  |  |  |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |  |  |  |  |  |
| Black or African American |  |  |  |  |  |  |  |  |  |  |
| White |  |  |  |  |  |  |  |  |  |  |
| More than One Race |  |  |  |  |  |  |  |  |  |  |
| Unknown or Not Reported |  |  |  |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |  |  |  |

*NOTE: If you need additional inclusion/enrollment reports, please copy the forms above and add them to your final proposal.*

**Section 3 – Protection and Monitoring Plans**

3.1. Protection of Human Subjects:

Click or tap here to enter text.

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

**Yes**[ ]  **No**[ ]  **N/A**[ ]

If yes, describe the single IRB Plan:

3.3. Data and Safety Monitoring Plan:

Click or tap here to enter text.

3.4. Will and Data and Safety Monitoring Board be appointed for this study?

**Yes** [ ]  **No** [ ]

3.5. Overall Structure of the Study Team:

Click or tap here to enter text.

**Section 4 – Protocol Synopsis** *(Note: this section is only required if you are conducting a clinical trial)*

4.1. Brief Summary:

Click or tap here to enter text.

4.2. Study Design:

4.2.a. Narrative Study Description:

Click or tap here to enter text.

4.2.b Primary Purpose

Treatment [ ]

Prevention [ ]

Diagnostics [ ]

Supportive Care [ ]

Screening [ ]

Health Services Research [ ]

Basic Science [ ]

Device Feasibility [ ]

Other [ ]

4.2.c. Interventions

Intervention Type:

Drug (including placebo) [ ]

Device (including sham) [ ]

Biological/Vaccine [ ]

Procedure/Surgery [ ]

Radiation [ ]

Behavioral (e.g., Psychotherapy, Lifestyle Counseling) [ ]

Genetic (including gene transfer, stem cell and recombinant DNA) [ ]

Dietary Supplement (e.g. vitamins, minerals) [ ]

Combination Product [ ]

Diagnostic Test [ ]

Other [ ]

Name: Click or tap here to enter text.

Description: Click or tap here to enter text.

If additional Interventions need to be added, indicate here and include the above information for each intervention: [ ]

Click or tap here to enter text.

4.2.d. Study Phase

Early Phase 1 (or phase 0) [ ]

Phase 1 [ ]

Phase 1-2 [ ]

Phase 2 [ ]

Phase 2-3 [ ]

Phase 3 [ ]

Phase 4 [ ]

Other [ ]

Is this an NIH-defined Phase III clinical trial? **Yes** [ ]  **No** [ ]

4.2.e Intervention Model

Single Group[ ]

Parallel[ ]

Cross-over[ ]

Factorial[ ]

Sequential[ ]

Other[ ]

4.2.f. Masking **Yes** [ ]  **No** [ ]

**Participant** [ ]  **Care Provider** [ ]  **Investigator** [ ]  **Outcomes Assessor** [ ]

4.2.g. Allocation

N/A [ ]

Randomized [ ]

Non-Randomized [ ]

4.3. Outcome Measures

Name: Click or tap here to enter text.

Type **Primary** [ ]  **Secondary** [ ]  **Other** [ ]

Time Frame: Click or tap here to enter text.

Brief Description: Click or tap here to enter text.

If Additional Outcomes: Click or tap here to enter text.

4.4. Statistical Design and Power: Click or tap here to enter text.

4.5. Subject Participation Duration: Click or tap here to enter text.

4.6. Will the study use an FDA-regulated intervention? **Yes** [ ]  **No** [ ]

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Click or tap here to enter text.

4.7. Dissemination Plan: Click or tap here to enter text.

**Section 5 - Other Clinical Trial-related Attachments**

5.1 Other Clinical Trial-related Attachments: Click or tap here to enter text.

**PRINCIPAL INVESTIGATOR ATTESTATION**

**Additional Approvals and Certifications**

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I, (as PI), agree to accept responsibility for scientific conduct of the project and to provide the required progress reports if a pilot grant is awarded as a result of this application and other obligations to comply with the Northern New England Clinical and Translational Research Network terms and conditions outlined in the request for applications.

Any publication, poster or presentation resulting from this research project will cite the NNE-CTR award U54GM115516 and comply with the NIH Public Access Policy.

Principal Investigator Date

**INSTITUTIONAL ASSURANCES FOR COLLABORATING SITES ONLY**

(Note: An institutional official for each collaborating site must sign this form, which should be attached at the end of the proposal – the primary site institutional official has already signed the cover page, thus this is not required for the primary site.) An institutional official may be a Sponsored Programs Officer, Financial Officer, or other official appropriate for the institution. Please copy this page as needed to send to each collaborating institution.

|  |  |
| --- | --- |
| [ ]  | **INSTITUTIONAL ASSURANCE**Faculty status, space/facilities, personnel, efforts, salaries, wages, budgets, cost sharing (if indicated) and assurances have been reviewed and approved. |
|  | **Title:** | **Name:** | **Date:** | **Signature:** |

**Proposal Checklist**

Pilot Project Application for Northern New England Clinical and Translational Research Network

Principal Investigator:

Proposal Title:

[ ]  Signed **Cover Page**

[ ]  Project Summary, Relevance, Performance Sites and Senior/Key Personnel Pages

[ ]  **Biographical Sketches** of all Senior/Key Personnel

[ ]  **Budget** from each site

[ ]  **Budget Justification** from each site

[ ]  **Introduction (if applicable)** (1 page limit)

[ ] If this is a **resubmission**, indicate your responses to the critique and major changes that have been made

[ ]  **Specific Aims** (1 page limit)

[ ]  **Research Plan** (6 page limit)

[ ]  **References/Bibliography** (no page limit)

[ ]  **Letters of Support**, if applicable

[ ]  **Vertebrate Animal section,** if applicable

[ ]  **Human Subjects and Clinical Trials** form, if applicable

[ ]  **PI Signed Attestation** Form

[ ]  **Collaborating Sites Institutional Assurance Signed,** if applicable